May 13, 2015

Dennis McLerran
Administrator
U.S. Environmental Protection Agency (EPA) Region 10
1200 Sixth Avenue; Mail Code: RA-210
Seattle, WA 98101
Via Electronic Mail: mclerran.dennis@epa.gov

Dear Administrator McLerran,

The National Association of Clean Water Agencies (NACWA) is writing to express its concerns with recent actions by the U.S. Environmental Protection Agency's (EPA) Region 10 office to influence the outcome of the Washington Department of Ecology's proposed human health criteria and implementation provisions, issued on January 12, 2015. NACWA represents the interests of more than 280 public wastewater treatment agencies across the country, including 10 in Washington.

The outcome of Washington's rulemaking process will have significant and long-term impacts for the clean water community and other dischargers across Washington and throughout Region 10. In addition, the Region's actions reflect a broader, nationally relevant concern for NACWA and its members over the increasingly coercive approach EPA uses during the state water quality standards development process.

At issue in Washington is the state's ability, as authorized under the Clean Water Act (CWA), to develop what it believes is a sound and balanced approach, which has been carefully evaluated and vetted with the state's stakeholders, to dealing with toxic pollutants. In response to Washington's January proposed rule, your office issued a strongly worded letter, dated March 23, 2015, outlining how the state's package does not "fully reflect" EPA policies, guidance and legal requirements. While we understand that it is standard practice for EPA to comment on proposed state water quality standards rules, the tone of this letter suggests that Washington has no other choice but to make their rule consistent not only with existing federal criteria and guidance, but also with EPA's policy preferences, as well as draft documents still undergoing revision at the federal level. EPA also does not indicate where the state failed to use the best scientific data to defend its proposal, choosing instead to roundly condemn the entire approach.

Section 303 of the Clean Water Act (CWA) outlines the authority and responsibility of the states to develop and regularly review and revise water quality standards. The responsibility of EPA is to review those standards once they are submitted to the Agency. EPA's regulations at 40 CFR 131.4 set forth the state requirements for standards development and 40 CFR 131.5 outlines EPA's authority to review those standards to determine whether the state has adopted uses "consistent with the requirements" of the CWA and criteria that "protect the designated water uses". However, the language in the CWA and the implementing regulations was not intended to give EPA authority to disapprove standards because the state's science and policy decisions are not identical to the Agency's preference, policies and guidance. Furthermore, the regulations provide no direction on how the Agency engages with the state during draft rule development prior to state final rule submittal. Instead, 40 CFR 131.21 outlines the process for EPA review once the state makes its formal submittal to the Agency and 131.22 lays out the process for EPA to develop standards for the state if the state fails to do so.

In practice, however, EPA routinely engages with the states before the formal submittal and significantly influences the content of state proposals, seeking to ensure full approval and obviate the need for formal EPA disapproval or promulgation of federal standards. Whether due to a lack of resources or political will, states often succumb to this "informal" pressure from EPA and make revisions to their rules to address EPA's preferences to ensure approval even if these changes may be counter to the state's policy, science, and risk choice position.

Even more concerning to NACWA is that, by coercing the state to promulgate standards that conform to EPA's approach, EPA is essentially eliminating judicial review. NACWA is concerned that this behavior by EPA violates the spirit and letter of the Administrative Procedures Act, and is contrary to the Agency's stated commitment to work more cooperatively and transparently with states and the regulated community.

This process of influence by EPA has reached concerning new levels with the development, review, and approval of Oregon's human health criteria and EPA's March 23, 2015 comments on the Washington proposal. In both cases EPA Region 10 has employed coercive pressure to ensure that the states only submit approvable programs that are effectively identical to federal preferences, guidelines, and policies. In the case of Washington's proposed rule, which in fact was consistent with the range of values and approaches included in existing federal guidance, EPA appears to ignore the flexibility afforded to states in its own guidance by insisting that the state's program conform to EPA's preferred approach. These tactics are inconsistent with the CWA's cooperative federalism foundation and history that provides the states the responsibility for developing and approving water quality standards. EPA has long used these strategies at the permitting stage – issuing 'interim objections' to signal to the state that changes must be made – to avoid EPA overfilling on permits and facing direct legal challenge to its policies. EPA's decision to use such tactics in its role in helping states develop state water quality standards is cause for great concern among NACWA's members.

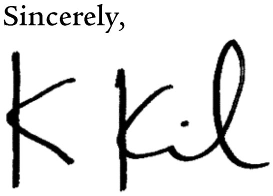
It is reasonable to expect EPA to engage with the state during its standards development process and to provide input and guidance to assist the state in developing robust science, policy and risk decisions at the state level that satisfy the requirements of the CWA. But your office's March 23 letter to Washington is framed as a formal objection, rather than a discussion of the policy and science options and choices available to the state. State standards must, by law and regulation, reflect the best available science, but the standards development process also incorporates numerous state policy, science, and risk decisions including determining the level of acceptable risk. In performing its CWA-required review function – whether during the rule development process or during its official standards review – EPA must not overstep its authority and substitute its policy preferences over legitimate state policy, science, and risk decisions that are "consistent with the applicable requirements" of the CWA. The structure established by the CWA – where EPA provides criteria recommendations and guidance and the states develop water quality standards based on that information as well as state policy and risk decisions (where a range of acceptable CWA options exist) – must be preserved to ensure that federal preference and the criteria recommendations do not become de facto regulations.

In developing water quality criteria recommendations at the federal level EPA consistently points to its duty to develop scientifically-sound criteria that, by CWA mandate, are based solely on scientific and risk policy factors and do not account for cost impacts on the regulated community or other state-specific factors. In its interactions with the regulated community EPA asserts that its criteria recommendations are not directly enforceable and therefore have no cost impact. EPA's actions in Region 10 and elsewhere across the country – essentially requiring that state standards be identical to federal preference, criteria, and guidance – have the effect of applying those federal criteria recommendations, preference, and guidance as the law of the land.

In the case of Washington, the state must be allowed to exercise its CWA-delegated responsibilities in standards development without undue influence from EPA. If the state chooses to submit a package that EPA believes it cannot approve it must be allowed to do so. If EPA dislikes the standards submitted by the state the Agency can follow the appropriate procedures to disapprove the state standards and/or promulgate federal standards and then be prepared to defend either of those actions in federal court if any party chooses to challenge them.

Thank you for considering NACWA's concerns.

Sincerely,



Ken Kirk
Executive Director

cc:
Gina McCarthy, EPA
Ken Kopocis, EPA
Maia Bellon, Washington Department of Ecology
Robert Duff, Senior Policy Advisor, Governor Inslee's Office
Daniel Opalski, Director, Office of Water and Watersheds, EPA Region 10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
WATER AND WATERSHEDS

May 29, 2015

Don Essig
Idaho Department of Environmental Quality
1410 N. Hilton
Boise, Idaho 83706

RE: EPA comments on Idaho's Proposed Policy Decisions Related to Human Health Criteria for Toxics

Dear Don:

The EPA appreciates the opportunity to provide comments to the Idaho Department of Environmental Quality (DEQ) on the policy recommendations that DEQ will use to inform revisions to Idaho's human health ambient water quality criteria. In particular, the EPA appreciated DEQ's presentation at the April 21, 2015 negotiated rulemaking meeting, where you discussed these proposed policy decisions as well as several options DEQ is still contemplating. The EPA supports DEQ's ongoing efforts and recognizes the challenging work that DEQ has undertaken thus far in consideration of revisions to Idaho's human health criteria.

The enclosed detailed comments reflect many of the issues the EPA identified in our previous letters on each of the policy discussion papers developed by DEQ over the past year. Given that DEQ has further considered these important policy decisions and is now providing a recommended position, or in some cases consideration of several options, the EPA is providing more specific comments for your consideration. Please note that, in some instances, the EPA is providing more general comments at this time and is requesting additional information to better understand DEQ's proposal before providing more detailed comments.

In general, the EPA is encouraged that several of DEQ's proposed policy decisions reflect recommendations consistent with EPA's 2000 Human Health Methodology and more recent EPA policy documents. At the same time, the EPA is concerned about some of DEQ's proposed policy decisions and we have described those concerns and provide suggestions for addressing them in the enclosed comments. In addition, it is important to note some overarching themes that the EPA will consider when evaluating protective human health criteria:

- Tribal Reserved Rights: In addition to complying with the CWA and EPA's regulations, when setting criteria to adequately protect Idaho's designated uses, it is necessary to consider tribal reserved rights, including tribal treaty-reserved fishing rights (executive orders and federal statutes could also apply).

- Best available science: The EPA commends DEQ for its collaborative work to develop state-specific fish consumption survey data and tribal fish consumption survey data for

Idaho. The EPA is encouraged that Idaho is considering the tribal survey data along with the state-wide survey data, and appreciates Idaho's efforts to coordinate and collaborate with EPA and the tribes. Along with using local and regional FCR data, DEQ should use the best available science to select all the input parameters needed to derive its human health criteria. In many instances, the EPA's 2014 draft 304(a) recommended criteria represents the best available science. If the EPA's criteria recommendations become final before Idaho adopts a final human health criteria rule, the EPA recommends that the state use that information instead of the 2014 draft criteria information.

- Protection of Downstream Waters: It is important for Idaho to demonstrate how its revised human health water quality criteria will provide for the attainment and maintenance of the water quality of downstream waters, consistent with EPA's regulations at 40 CFR 131.10(b).

The EPA appreciates DEQ's efforts to revise Idaho's human health criteria for toxic pollutants and looks forward to continued conversations regarding these important decisions. In addition, EPA remains committed to supporting DEQ's work and is available to provide technical assistance as you develop a proposed rule. If you have any questions or would like to discuss these comments further, please contact me at (206) 553-1834 or Lon Kissinger at (206) 553-2115.

Sincerely,

Lisa Macchio
Water Quality Standards Coordinator

Enclosure

04747

EPA's Comments on Idaho Department of Environmental Quality's (DEQ) Policy Recommendations Related to Revisions to Idaho's Human Health Criteria for Toxics
May 29, 2015

Derivation of FCR using consumers only

EPA supports DEQ's proposed policy decision to base its fish consumption rate (FCR) on consumers only and to exclude non-consumers in the derivation of a FCR for Idaho. This is consistent with EPA's recommendation to use consumer only data when available. In particular, EPA supports DEQ deriving FCRs from 24-hour recall survey results using a statistical modeling approach developed by the National Cancer Institute, the NCI method, to develop defensible consumer only FCRs for Idaho. This is consistent with EPA's approach to develop the FCR used to compute national human health ambient water quality criteria. If such modeling approaches are not used to derive FCRs from short term dietary recall data, biased FCRs would result.

Evaluate range of exposure/risk in both general and higher consuming subpopulations

EPA supports DEQ's proposed policy decision to evaluate the range of exposure/risk in both the general population and higher consuming populations. Human health criteria are designed to minimize the risk of adverse cancer and non-cancer effects occurring from lifetime exposure to pollutants through the ingestion of drinking water and consumption of fish/shellfish. When choosing exposure factor values to include in the derivation of a criterion for a given pollutant, EPA recommends considering values that are relevant to populations that are most susceptible to that pollutant. For example, highly exposed populations should be considered when setting criteria. To that end, EPA's methodology notes a preference for the use of local data to calculate human health criteria (e.g., locally derived FCRs, drinking water intake rates and body weights, and waterbody-specific bioaccumulation rates), over national default values, to better represent local conditions.[1]

Deterministic or Probabilistic

EPA needs additional detailed information to evaluate whether DEQ's proposal to employ probabilistic risk assessment (PRA) to develop human health criteria is scientifically defensible and protective. EPA recommends that DEQ present a draft proposal at the next rulemaking meeting that clearly defines desired outcomes for the PRA approach and how they will be met. For example, the EPA generally recommends that variables describing toxicity should not be distributed, as insufficient data generally exist to develop distributions for toxicity variables, and toxicity metrics are developed by consensus at the national level. Therefore, it is important for DEQ to clearly explain why it is choosing the PRA approach and how it will address the

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[1] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf.

following types of issues, as these would be considerations in EPA's assessment of a PRA approach. EPA is available to provide more detailed comments once DEQ provides additional information on its proposal.

(1) The purpose and scope of the analysis should be clearly articulated. This should include derivation of human health criteria that are protective of higher fish consuming populations. The risk management decisions related to interpretation of output exposure or risk distributions should be specified (e.g., human health criteria shall be derived such that the 95^{th} percentile of the risk distribution will equal 1 in 1,000,000).

(2) The methods used for the analysis (including all models and/or software used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results, for example correlation of variables) should be well documented, easily located, and reproducible. This documentation should include a discussion of the degree to which the data used are representative of the population under study, and possible sources of bias and uncertainty in both the input and output distributions. In particular, variability (the range of values a variable might assume) should be distinguished from uncertainty (lack of knowledge about a variable).

(3) DEQ also should calculate human health criteria using deterministic (e.g., point estimate) methods. Providing these values will allow comparisons between the probabilistic and deterministic approaches for developing human health criteria. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models as well as the strengths and weaknesses of differing assumptions.

Exclusion of market fish

EPA is concerned with DEQ's proposed policy decision to exclude market fish from the FCR that it will use to derive revised human health criteria. As EPA stated in our June 2014 comment letter on this topic, a FCR that reflects the amount of fish Idahoans consume should not just include fish consumed from local waters. Therefore, EPA recommends that DEQ include market fish in the FCR used to derive human health criteria. This approach is consistent with a national water quality program principle that every state does its share to protect people who consume fish and shellfish that originate from multiple jurisdictions. In addition, the goal of water quality criteria for human health is to protect people from exposure to pollutants through fish and water over a lifetime, and the goal of a state's designated use should be that the waters are safe to fish in the context of the total consumption pattern of its residents.

Exclusion of anadromous fish

EPA is concerned with DEQ's proposed policy decision to exclude anadromous fish from the FCR, and recommends that DEQ include anadromous fish in the FCR used to derive HHC.

While EPA's 304(a) recommended criteria account for exposures to non-carcinogens and nonlinear carcinogens in anadromous fish using the RSC, EPA supports and recommends that states include anadromous fish in the FCR when there are available, scientifically sound regional and/or local data that suggest high consumption of anadromous fish. For example, because of the uncertainties in the sources of salmon contaminant body burdens (discussed in more detail below), the large amounts of salmon consumed by Native Americans, and the fact that market basket preferences of individuals may vary,[2] Oregon and Washington chose to include salmon in the FCR used to derive human health criteria. EPA approved Oregon's human health criteria in 2011. Similarly, EPA supported Washington's decision to derive human health criteria using a FCR that included anadromous fish consumption.[3] In light of this and the fact that Washington and Oregon are downstream from Idaho, implementation of human health water quality criteria throughout the Pacific Northwest would be facilitated by uniformly including salmon in the FCR for Idaho.

EPA also is concerned with DEQ's proposed policy decision to account for anadromous fish exposures using the RSC instead of the FCR because adjusting the RSC to reflect exposures to contaminants in anadromous fish is difficult to accomplish in a data driven way.

Because of uncertainty regarding where and how marine species acquire the bulk of their contaminant body burden, EPA also recommends that DEQ consider scientific studies in addition to the Hope 2012 study. For example, EPA believes that further characterization of salmon ocean habitat is warranted and some adult salmon may feed in, and acquire contaminants from, near coastal waters that are under the jurisdiction of the CWA. Also, the Hope paper's conclusions are limited by its focus on PCBs and not other toxics. Central to the modeling, is the assumption that contaminant uptake occurs largely through diet. While this is true for PCBs, depending on a chemical's lipophilicity, direct uptake from water may be a significant contributor to an organism's contaminant body burden (Qiao et al. 2001). In the case of adult salmon, direct uptake of chemicals from water is a possibility during their return migration through inland waters. The Hope paper also does not discuss different patterns of contaminant uptake associated with the complex life histories of other salmonids. In addition, the Hope paper

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[2]For example, a study on fish consumption habits of Asian Pacific Islanders demonstrated FCRs similar to Puget Sound Tribes but indicated that certain ethnic groups preferred to consume non-anadromous species.
Sechena R, Nakano C, Shiquan L, Polissar N, Lorenzana R, Truong S, Fenske R. 1999. Asian and Pacific Islander Seafood Consumption Study (EPA 910/R-99-003)
http://www.epa.gov/r10earth/pdf/asian_pacific_islander_seafood_consumption_1999.pdf

[3] Washington proposed draft HHC in January 2015 for public comment. The comment period closed on March 23, 2015, and Washington has not yet adopted final HHC and submitted them to EPA for CWA action. Therefore, EPA has not yet reviewed or acted upon Washington's HHC.

references EPA's policy of excluding salmon from the FCR used to assess site-specific health risks at Superfund sites in Puget Sound. However, it is important to note that EPA's Superfund policy generally applies to risk assessments for bioaccumulative pollutants in discrete geographic areas where cleanup is to occur, which does not raise the same scope of considerations or potential impacts as the development of state-wide water quality criteria. In summary, EPA recommends that DEQ consider that returning adult salmon may acquire contaminants directly from fresh water (Qiao et al. 2001).[4] DEQ may wish to consult with established experts (such as Weitkamp)[5] who have documented that certain adult salmon species from Idaho waters may reside in coastal waters of the U.S. (i.e., fall run chinook and coho salmon).

Risk Level

EPA supports DEQ's proposed policy decision to retain its 10^{-6} risk level to protect the populations in Idaho. However, EPA is concerned with DEQ's decision to protect high consuming populations, including tribes, at a 10^{-6} cancer risk level using the mean consumption rate of consumer only data. Instead, EPA recommends that DEQ consider the approach used by Oregon to protect high consuming populations at a 10^{-6} cancer risk level using the 95th percentile of consumer only data. This approach is more consistent with EPA's general recommendation that states and authorized tribes select a FCR that reflects consumption that is not suppressed when sufficient data are available.[6] Deriving criteria using an unsuppressed FCR furthers the restoration goals of the CWA, and ensures protection of human health as pollutant levels decrease, fish habitats are restored, and fish availability increases. Further, in cases where tribal treaty or other reserved fishing rights apply, selecting a FCR that reflects unsuppressed fish consumption may be necessary in order to satisfy such rights. Government-to-government consultation with affected tribes is important in deciding which fish consumption data should be used.

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[4]Qiao P, Gobas FAPC, Farrell AP. Relative Contributions of Aqueous and Dietary Uptake of Hydrophobic Chemicals to the Body Burden in Juvenile Rainbow Trout http://www.researchgate.net/profile/Frank_Gobas2/publication/12373146_Relative_contributions_of_aqueous_and_dietary_uptake_of_hydrophobic_chemicals_to_the_body_burden_in_juvenile_rainbow_trout/links/0fcfd5112a3b20b012000000.pdf

[5] http://www.nwfsc.noaa.gov/contact/display_staffprofile.cfm?staffid=189

[6] EPA. January 2013. *Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions*. http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/hhfaqs.pdf.

Relative Source Contribution (RSC)

EPA recommends that DEQ provide additional detailed information regarding its proposal to adjust the RSC based on changes in FCR, bioaccumulation, and water-plus-organism vs. organism only human health criteria. As previously noted, EPA is concerned because adjusting the RSC is difficult to accomplish in a data driven way. It is true that the relative dose fractions contributed by fish and water exposures relative to all other routes of exposure would be affected by consideration of the above factors. However, exposures not associated with fish and water ingestion are also chemical-specific and have not been presented in such a way as to support data driven modification of the RSC. To support this approach, DEQ would need to provide chemical-specific alternate route exposure to modify the RSC in a data driven way that is scientifically sound. DEQ also should consider the recommended adjusted RSCs that will be described in EPA's final updated 304(a) human health water quality criteria recommendations.

Bioaccumulation Factors (BAFs)

The EPA supports DEQ's proposed policy decision to use BAFs. This approach is consistent with the EPA's 2000 Human Health Methodology, which recommends use of BAFs when available, and reflects the latest scientific information on bioaccumulation. Unlike bioconcentration factors that only account for uptake from the water column, BAF's account for other exposure pathways. As DEQ is aware, the EPA is in the process of updating its national 304(a) recommended water quality criteria for the protection of human health and the proposed criteria updates include the use of BAFs specific to different trophic levels. During DEQ's presentation on April 21, 2015, DEQ recommended consideration of trophic level BAFs; more specifically, a trophic weighted BAF value based on information from DEQ's fish consumption survey. There are a number of issues DEQ may need to consider when weighting trophic level BAFs. For example, the data from a general population survey should be sufficiently robust to determine fish consumption by trophic level, and also representative of higher consumers, who may be consuming greater amounts of higher trophic level fish. For example, Columbia River Intertribal Fish Commission (CRITFC) survey respondents consume a much higher fraction of trophic level 4 fish than the general U.S. population (CRITFC 1994).[7] EPA is encouraged by DEQ's recommendation to derive criteria using BAFs and looks forward to reviewing additional details in order to evaluate DEQ's selected approach.

Body Weight and Drinking Water Intake Assumptions

EPA supports DEQ's proposed policy decision to apply a three step preference to estimate body weight assumptions consistent with EPA's guidance [i.e., 1) data from Idaho's fish consumption surveys, 2) data from the Idaho Department of Health and Welfare BRF State Survey, 3) EPA's 2011 Exposure Factors Handbook/NHANES]. If the approach to use local or regional data is not

[7] Columbia River Intertribal Fish Commission. 1994. A Fish Consumption Survey Of The Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin. Technical Report 94-3 https://www.deq.idaho.gov/media/895853-fish-consumption-survey-1994.pdf

sufficiently reliable, EPA encourages DEQ to consider the new information used to update EPA's national criteria recommendations including EPA's 2011 Exposure Factors Handbook. For example, EPA derived its 2014 draft 304(a) recommendations using an updated body weight assumption of 80 kg, the national mean based on a survey of the U.S. population and described in EPA's 2011 Exposure Factors Handbook.

EPA supports DEQ's proposed policy decision to use a drinking water intake assumption of 2.4 L/day. EPA derived its 2014 draft 304(a) recommendations using a drinking water intake rate of 3 L/day. This rate represented a consumer-only estimate of combined direct and indirect water ingestion for all sources of water at the 90th percentile for adults ages 21 and older. In response to public comments that focused on the most current national drinking water data, EPA intends to finalize the updated 304(a) criteria using a drinking water intake rate of 2.4 L/day, which represents the per capita estimate of combined direct and indirect community water ingestion at the 90th percentile for adults ages 21 and older.

80	Plain Text 6	**State Primacy for Adoption of WQ Standards**	08	0054	0054.12	08	0054	As you are aware, the EPA has initiated a federal rulemaking process to amend Washington's existing human health criteria in the National Toxics Rule, which were last updated in 1992. The EPA is encouraged that Ecology proposed its own rule and we hope that Ecology will finalize a scientifically defensible rule that protects the health of Washington's citizens. As stated in Regional Administrator Dennis McLerran's December 18, 2014 letter to Director Maia Bellon, despite our having initiated a federal rulemaking, if Washington submits a final rule to the EPA for Clean Water Act review and action prior to our completion of a federal proposal, the EPA will fulfill its Clean Water Act duty to review and act on the state's submittal.	Comment noted.
81	0024-3	**State Primacy for Adoption of WQ Standards**	08	0024-3	0024.23	08	0024	In some instances where Ecology rejects EPA’s EFH recommendations, Ecology asserts that states make the first effort at developing water quality standards. See, e.g., Overview at 15-17, 23, 31 (“risk management decision made by states”). While this is true, it does not give a state a free hand to disregard the requirements of the Clean Water Act and best science nor disregard the needs of the community. Further, Ecology’s explanations in its Overview document are often garbled and unclear regarding what precisely Ecology is doing and why. See, e.g., Overview at 30-32 (presenting legally and scientifically flawed analysis of bioaccumulation vs. bioconcentration).	Ecology disagrees with the contention that the discussion of BCF and BAF are flawed.
82	0029c	**State Primacy for Adoption of WQ Standards**	08	0029c	0029c.16	08	0029	Comment No. 10: There is no scientific or public health policy basis for criteria based on a FCR of 175 g/day and risk policy of one in one million. Ecology is required to develop criteria that are scientifically defensible and based on the agency determinations for risk management – decisions under the Clean Water Act that are the prerogative of the state, not EPA. There has been a persistent misunderstanding or misrepresentation that a one in one million risk policy is a threshold or baseline for the protection of human health. This is exemplified by the statements from the EPA Region 10 Administrator that “everyone should be protected to the same level.”[101] This statement ignores the fact there is no reasonable basis to protect everyone to same level – across any population there will always be a range of exposures and therefore a range of risk. There is also no basis in the long history of the regulatory management of cancer risk by EPA and the FDA that supports the contention that all fish consumers in Washington must be protected to a risk level of one in one million. The real question posed by demands to regulate the highest Tribal consumption rates at one in one million is whether Ecology should adopt a more stringent risk policy than required under the Clean Water Act and EPA guidance. If Ecology considered this demand, the effective risk policy would be in the range from one in one hundred million or one in ten million to one in one million. On this critical issue – whether Washington needs to adopt a more conservative range for its risk policy than EPA guidance – the Northwest Tribes and EPA Region 10 have been silent. Ecology presented the risk policy issue to EPA Region 10 on numerous occasions over the past two years. The origins and basis for the one in one million risk policy were the	Ecology has stated on numerous occasions that the FCR and the RL are risk management decisions. This is clear in EPA 2000. Ecology has not found a specific public health or scientific basis for the mandatory use of a risk level of one in one million or for a FCR of 175 g/day, although the state’s decision to use 175 for the final criteria was based on consideration of many factors, with a main goal of protection of the public health of all people who consume fish and/or shellfish from Washington waters.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
WATER AND WATERSHEDS

November 6, 2015

Don Essig
Idaho Department of Environmental Quality
1410 N. Hilton
Boise, Idaho 83706

RE: EPA Comments on Idaho's Revised Human Health Toxic Criteria, Proposed Rule, Docket No. 58-0102-1201

Dear Don:

The EPA appreciates the opportunity to provide comments to the Idaho Department of Environmental Quality (DEQ) on its proposed updated human health ambient water quality criteria, which were published for public comment on October 7, 2015. The enclosed comments reflect many of the issues the EPA identified in our previous comment letters to DEQ and, in some instances, provide additional clarification. The EPA continues to recognize the challenging work undertaken thus far in revising Idaho's human health criteria.

The EPA commends Idaho for using state of the art survey methodology to characterize current fish consumption rates for the general population and anglers in Idaho. Given the regulatory importance of these survey results, EPA strongly recommended that DEQ have the results peer reviewed by individuals with the necessary expertise, and address peer review concerns prior to fully incorporating this work into a regulatory context. EPA understands that DEQ has decided to conduct a peer review and is supportive of that effort.

The EPA also supports DEQ's decision to incorporate many of the EPA's latest scientific and policy recommendations consistent with the EPA's 2015 updates to its 304(a) national human health criteria recommendations. At the same time, the EPA remains concerned about some of DEQ's proposed decisions in deriving human health criteria. In particular, the EPA is concerned with DEQ's approach to calculating its fish consumption rate because DEQ has not adequately demonstrated how criteria derived using the proposed fish consumption rate would be scientifically defensible, would be protective of designated uses in Idaho (as informed by reserved rights of tribal consumers), and would ensure the attainment and maintenance of water quality standards in downstream waters in Oregon and Washington.

The EPA is available to further discuss our comments and we remain committed to providing assistance as DEQ develops the final rule. If you have any questions, please feel free to contact me or Lisa Macchio at (206) 553-1834.

Sincerely,

Angela Chung, Manager
Water Quality Standards Unit

Enclosures

04760

EPA Comments on Idaho Department of Environmental Quality's (DEQ) October 7, 2015 Proposed Rule Revisions to Idaho's Human Health Criteria for Toxics Docket No. 58-0102-1201 November 6, 2015

The Idaho Department of Environmental Quality (DEQ) provided proposed new and revised surface water quality standards (WQS) found at IDAPA 58-0102-1201 to the public for review and comment on October 7, 2015.[1] The EPA reviewed the state's proposed rule and associated documents and provides the following comments for DEQ's consideration. The comments are organized as follows:

A. Fish Consumption Rate (FCR)
    1. DEQ's Fish Consumption Survey Analysis and Results
    2. Exclusion of Market Fish (Other than Rainbow Trout)
    3. Exclusion of Anadromous Fish
    4. Tribal Reserved Fishing Rights
B. Other Input Variables
    1. Cancer Risk Level
    2. Relative Source Contribution (RSC)
    3. Bioaccumulation Factor (BAF)
    4. Body Weight and Drinking Water Intake
    5. Toxicity Factors: Reference Doses (RfDs) and Cancer Slope Factors (CSFs)
C. Pollutant Scope
D. Use of Probabilistic Risk Assessment
E. Downstream Waters Protection
F. Specific Comments on DEQ's Proposed Rule Language

Please note that the EPA's positions described in the comments below, regarding the state's proposed WQS, are preliminary in nature and do not constitute an approval or disapproval by the EPA under the Clean Water Act (CWA) Section 303(c). Approval and/or disapproval decisions will be made by the EPA following adoption of the new and revised standards by the state of Idaho and submittal of revisions to the EPA. In addition, the EPA's comments do not constitute, and are not intended to be, an Administrator determination under CWA Section 303(c)(4)(B).

A. Fish Consumption Rate (FCR)

As the EPA has long acknowledged, it remains our practice to encourage states and authorized tribes to make appropriate adjustments to reflect local conditions affecting fish consumption.[2] Thus far, Idaho has not yet presented the EPA with a rationale that is adequate to establish that Idaho's proposed FCR is appropriate and will lead to criteria sufficient to protect Idaho's CWA Section 101(a)(2) uses (e.g., Primary and Secondary Contact Recreation, IDAPA 58.01.02.100.02(a)&(b)), as required under 40 CFR 131.11. While reserving final judgment on

[1] DEQ, *Water Quality Docket No. 58-0102-1201 - Proposed Rule*, http://www.deq.idaho.gov/58-0102-1201.
[2] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf.

this issue until we receive Idaho's final submission and supporting rationale, we emphasize that Idaho's approach currently appears to be inconsistent with the CWA and its implementing regulations. We outline our concerns in more detail below, and recommend that Idaho modify its approach consistent with the comments below.

1. DEQ's Fish Consumption Survey Analysis and Results

The EPA contracted with Westat, a well-known statistical consulting firm, to review DEQ's fish consumption survey results as reported in the Fish Consumption Survey report prepared by Northwest Research Group.[3] Westat identified a number of issues that DEQ should review (see attached memoranda from Westat), and EPA is available to discuss this information further. For example, Westat determined that the frequency of fish consumption declined over the seven day recall period. DEQ did not account for this trend, which could result in an underestimation of fish consumption. As previously noted, it is important for DEQ's fish consumption survey results to be peer reviewed by individuals with the necessary expertise. The Westat review provides information that DEQ should consider along with the results of its peer review. In particular, it is important that the National Cancer Institute (NCI) analysis, which involves many assumptions and employs statistical methodology not generally accessible to the lay person, be adequately reviewed. In addition, it is important that DEQ's final peer review findings be readily available and distributed to support the credibility of DEQ's survey results.

2. Market Fish (Other than Rainbow Trout)

CWA Section 303(c)(2)(A) requires that WQS protect "public health or welfare, enhance the quality of water and serve the purposes of [the Act]." CWA Section 101(a)(2) establishes as a national goal "water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water [wherever attainable]." The EPA has previously interpreted the "fishable" language in Section 101(a)(2) to refer not only to protecting water quality so the fish and shellfish thrive, but also so that when caught they can be safely eaten by humans. Thus, in order to be consistent with Section 101(a)(2), the applicable criteria for such "fishable" designated uses must not only protect the aquatic organisms themselves but also protect human health through consumption of fish and shellfish.[4]

The EPA's recommended 304(a) water quality criteria to protect human health (and the EPA's accompanying risk assessment methodologies) reflect this longstanding conclusion about the CWA: consumers of fish and shellfish are to be assured that if criteria are met in a waterbody designated with the uses specified in Section 101(a) of the CWA, then that means they can safely eat fish and shellfish drawn from that waterbody.[5] Thus, the EPA has consistently implemented the CWA to ensure that the total rate of consumption of fish and shellfish from inland, estuarine, and near-coastal waters reflects the consumption rates that are characteristic of the population of concern. In other words, the EPA expects that the standards will be set such that residents can safely consume from local waters the amount of fish they would normally consume from all

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[3] Northwest Research Group, Idaho Fish Consumption Survey. August 25, 2015.

[4] EPA's interpretation of the CWA is consistent with years of past practice. As evidence, see memorandum from Geoffrey H. Grubbs and Robert H. Wayland (October 2000) posted at http://water.epa.gov/scitech/swguidance/standards/upload/2000_10_31_standards_shellfish.pdf

[5] See discussion in *Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, 65 Fed. Reg. 66465 (2000).

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inland and near shore waters. The EPA recognizes that consumers of fish and shellfish might not be limiting their consumption of fish and shellfish to those that were sourced from their own state's fishable waters. However, the relevant objective is to assure that they can do so without concern for their health.

Idaho's approach is to exclude from the FCR the fraction of the consumption of freshwater and estuarine fish and shellfish that is currently associated with fish originating from waters outside of Idaho.[6] Idaho justifies its approach on the grounds that Idaho lacks regulatory authority over fish caught outside of its borders. Based on the information and rationale EPA has received from Idaho to date, we note the following reasons why Idaho's justification for this approach is not scientifically sound:

- The purpose of including consumption from waters outside of Idaho's borders in the FCR is not to support any purported regulation of such waters by Idaho. Rather, the purpose of including this fish consumption in the FCR is so that a determination that a particular Idaho water body is "fishable" will result in adequate health protection for Idahoans should they consume, from local waters, the amount of fish they would normally consume from all inland and near shore waters.
- The approach of excluding "market fish" appears to assume that there is no exposure to pollutants from fish that were sourced outside of Idaho. This is because the full allowance for acceptable pollutant levels is given exclusively to local state waters. Consider if every state took this approach. For a non-carcinogenic pollutant with a specified Reference Dose, the criteria development equation would allocate this full dose to fish originating from the individual state. If a person then consumes overall 25 grams/day (g/day) of fish, comprised of 5 g/day each from 5 different states (and each state set a state-specific consumption rate of 5 g/day), then the consumer could potentially receive five times the acceptable pollutant dose.

3. Anadromous Fish

The EPA recognizes that Idaho has included steelhead, an anadromous species, in the calculation of its FCR. However, the EPA continues to have concerns with DEQ's proposed policy decision to exclude all other anadromous fish from the FCR, and recommends that DEQ either include all other anadromous fish in the FCR or provide additional demonstration of how criteria derived using a lower FCR that excludes anadromous fish will protect downstream shared waters in the Columbia River basin and protect the tribal populations exercising their treaty-reserved rights (see comments below regarding consideration of tribal reserved fishing rights).[7]

While the EPA's 304(a) recommended criteria account for exposures to non-carcinogens and nonlinear carcinogens in anadromous fish using the relative source contribution (RSC), the EPA supports and recommends that states include anadromous fish in the FCR when there is credible and compelling evidence of significant consumption of anadromous fish. For example, Oregon and Washington chose to include salmon in the FCR used to derive human health criteria due to,

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[6] Idaho makes one exception to this rule, with rainbow trout, on the grounds that the majority of the rainbow trout in the market comes from Idaho aquaculture facilities.
[7] EPA reference to anadromous fish in this letter refers to all other anadromous fish except steelhead.

amongst other reasons, the large amounts of salmon consumed by tribes, the variation in individual market basket preferences (i.e., the types of fish that people purchase and consume), and uncertainties in the sources of salmon contaminant body burdens from inland and near shore waters (e.g., salmon residing in Puget Sound). The EPA approved Oregon's human health criteria in 2011. Similarly, the EPA supports Washington's decision to develop human health criteria using a FCR that includes anadromous fish consumption.

The EPA also has reviewed recent work related to salmon contaminant acquisition from near coastal waters of the Pacific Northwest and recommends that DEQ also consider this available information. For example, the research conducted by Sandra O'Neill, James West, David Herman, and Gina Yitalo provides evidence that certain Pacific Northwest salmon species, most notably chinook and coho, acquire organic pollutants from near coastal marine waters. [8] O'Neill et al. assayed salmon and herring for several classes of persistent organic pollutants (POPs). The POPs of interest included polybrominated diphenyl ethers (PBDEs), polychlorinated biphenyls (PCBs), hexachlorobenzene (HCB), and the insecticide DDT. An analysis of these POPs in herring populations identified unique regionally-specific patterns of these chemicals or "fingerprints," thus showing herring are acquiring contaminants from waters under CWA jurisdiction. Chinook salmon harvested from specific locations were found to have the same contaminant "fingerprints" as those exhibited by co-located herring samples, suggesting that they are feeding on herring in near coastal waters. This work provides evidence that certain chinook salmon species are acquiring contaminants from near coastal waters of Washington and Oregon, as well as California and British Columbia. Similar but more limited data by O'Neill et al. indicate that coho salmon, which reside in coastal waters and have feeding preferences similar to chinook salmon, are also acquiring contaminants from waters under CWA jurisdiction.

In addition, EPA has communicated with Laurie Weitkamp and Peter Lawson from NOAA,[9] who have stated that chinook (and likely coho) salmon from Idaho reside in near coastal waters off the Oregon coast. Myers at al. 1998, analyzing coated wire tag recovery, has concluded that Snake River Chinook salmon have a coastal residence pattern.[10] O'Neill et al.'s work shows that resident chinook salmon from these waters have regional contaminant fingerprints specific to this area. Given the contaminant fingerprint correlation between herring and coastal resident salmon at all locations where both species were analyzed, it is very likely that coastal salmon originating in Idaho waters are acquiring contaminants from coastal waters under CWA jurisdiction.

EPA recognizes that salmon acquire most of their body weight and, therefore, most of their body burden of highly bioaccumulative contaminants during open-ocean feeding. However, it is

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[8] Ms. O'Neill and Mr. West are both with the Washington Department of Fish and Wildlife.

[9] L. Weitkamp,personal communication 5/19/2015. P. Lawson personal communication via phone, May, 2015.Dr. Laurie Weitkamp has extensively examined recovery of coated wire tags (CWTs) from adult salmon harvested in marine waters. CWTs, inserted into juvenile salmon in hatcheries, allow researchers to determine the relationship between spawning locations and ocean ranges of various salmon species. Dr. Peter Lawson has done genetic testing of adult salmon in marine waters. By matching unique DNA patterns of juvenile and adult salmonids, researchers can determine where adult salmon came from.

[10] Myers K.W., K.Y. Aydin, R.V. Walker, S. Fowler, M.L. Dahlberg. 1996. Known Ocean Ranges of Stocks of Pacific Salmon and Steelhead, as Shown by Tagging Experiments, 1956-1995. Submitted to the North Pacific Anadromous Fish Commission. Fisheries Research Institute. University of Washington School of Fisheries.

possible that salmon may acquire less bioaccumulative contaminants directly from water during their return spawning migration as adults.[11] EPA consulted with Frank Gobas, a well-known expert in bioaccumulation and bioconcentration in aquatic food webs, to evaluate this issue and prepare an analysis.[12] The analysis first involved the development of contaminant concentrations in salmon tissue that were associated with either a cancer risk of 1 in 1,000,000 or a non-cancer hazard quotient of 1. These risk-based concentrations assumed a fish consumption rate of 175 grams per day by an 80 kilogram person. Next, bioconcentration modeling was performed to determine the water concentration that results in a salmon tissue concentration associated with the aforementioned risk-levels.[13] The model includes quantitative structure activity relationship biotransformation of chemicals and the impacts of changing lipid content associated with migration energy expenditure.[14,15] The model also accounts for the time dependent nature of chemical uptake. This modeling utilized a range of migration times for spawning Idaho chinook and sockeye salmon associated with several harvest locations within Idaho. The longer the migration time, the greater the opportunity for contaminants to bioconcentrate. Finally, ratios of Idaho's proposed water quality criteria to modeled water concentrations were computed. The results showed, for example, toxicity ratios of 10 or greater for 13 chemicals with non-carcinogenic toxicity. In other words, for 13 non-carcinogenic chemicals, Idaho's proposed criteria could result in hazard quotients of 10 or more for populations consuming Idaho returning salmon at a rate of 175 grams per day or more. This far exceeds EPA's recommendation of limiting risks to non-carcinogens to a hazard quotient of 1 or less. Therefore, DEQ should consider these results. EPA has enclosed the analysis for your review and consideration (see attached spreadsheets).

Idaho cites work by Hope 2012, suggesting that salmon do not acquire contaminants from waters under CWA jurisdiction, to justify excluding anadromous species from the FCR used to develop DEQ's proposed criteria.[16] The Hope study's conclusions are limited by its focus on PCBs and not on other toxics, and the study does not consider salmon acquisition of contaminants from near coastal waters as demonstrated by O'Neill et al. Central to the modeling is the assumption that contaminant uptake occurs largely through diet. While this is true for PCBs, depending on a chemical's lipophilicity, direct uptake from water may be a significant contributor to an organism's contaminant body burden.[17] The Gobas work on contaminant bioconcentration in migrating adult Idaho salmon, described above, provides evidence that adult Idaho salmon may acquire contaminants directly from the water column through their gills, in addition to dietary

[11] Less bioaccumulative contaminants refer to contaminants with log octanol-water partition coefficients (log Kow) between two and four.
[12] Dr. Gobas is with Simon Fraser University in Vancouver BC.
[13] Lo et a. 2015, Environ Toxicol Chem. 2015 Oct;34(10):2282-94
[14] US EPA EPI SUITE v. 4.11
[15] Debruyn et al. 2004, Environ Sci Technol. 2004 Dec 1;38(23):6217-24
[16] Hope, B.K. 2012. "Acquisition of Polychlorinated Biphenyls (PCBs) by Pacific Chinook Salmon: An Exploration of Various Exposure Scenarios." Integrated Environmental Assessment and Management 8:553–562. Cited by DEQ in: Considerations in Deciding Which Fish to Include in Idaho's Fish Consumption Rate Policy Summary, State of Idaho Department of Environmental Quality.
[17] Qiao, P., A.P.C. Gobas, and A.P. Farell. 2000. "Relative Contributions of Aqueous and Dietary Uptake of Hydrophobic Chemicals to the Body Burden in Juvenile Rainbow Trout." Archives of Environmental Contamination and Toxicology 39:369–377.

uptake. Finally, the Hope study also does not discuss different patterns of contaminant uptake associated with the complex life histories of other salmonids, such as steelhead.

In conclusion, DEQ should consider the above-referenced scientific information when making its final decision on whether to include anadromous salmonids, other than steelhead, in calculating the FCR. The EPA remains concerned that Idaho's decision to exclude most anadromous salmonids results in human health criteria that are not adequate to protect Idaho's primary and secondary contact recreation uses.[18]

4. Tribal Reserved Fishing Rights

Per EPA's regulations at § 131.11(a), water quality criteria must contain sufficient parameters or constituents to protect the designated use, and for waters with multiple use designations, the criteria must support the most sensitive use. In determining whether WQS comply with the CWA and EPA's regulations, when setting criteria to support the most sensitive fishing designated use in Idaho, it is necessary to consider other applicable laws, including federal treaties. In Idaho, certain tribes hold reserved rights to take fish for subsistence purposes, including treaty-reserved rights to fish at all usual and accustomed fishing grounds and stations and in unoccupied lands of the United States, which in combination appear to cover the majority of waters under state jurisdiction.

Many areas where reserved rights are exercised cannot be directly protected or regulated by the tribal governments and, therefore, the responsibility falls to the state and federal governments to ensure their protection.[19] In order to effectuate and harmonize these reserved rights with the CWA, such rights appropriately must be considered when determining which criteria are necessary to adequately protect Idaho's waters used for consumption of fish (designated as Primary or Secondary Contact Recreation, IDAPA 58.01.02.100.02(a)&(b)).

Protecting Idaho's fishing designated uses necessitates protecting the population exercising those uses. Where a population exercising such uses has a legally protected right to do so under federal law such as a treaty, the criteria protecting such uses must be consistent with such right. Thus, in order to protect the applicable fishing designated uses in areas where such rights apply, as informed by the treaty-reserved right to continue legally protected culturally important subsistence fishing practices, the state must consider the tribal population exercising their reserved fishing rights in Idaho as the target general population for the purposes of deriving criteria that will protect the subsistence fishing use and allow the tribes to harvest and consume fish consistent with their reserved rights.

The data used to determine the FCR are critical to deriving criteria that will protect the subsistence fishing use. The data used to determine a FCR must reasonably represent tribal subsistence consumers' practices that reflect consumption unsuppressed by fish availability or

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[18]As DEQ has acknowledged, "if anadromous species data are omitted from the data set, it is possible that the resulting criteria may not be adequately protective of Idahoans who eat salmon, steelhead, or other anadromous fish." *Idaho Fish Consumption Rate and Human Health Water Quality Criteria; Discussion Paper #5: Anadromous Fish*, pg. 4, available at http://www.deq.idaho.gov/media/1117748/58-0102-1201-discussion-paper5.pdf.

[19] Note that for formal and informal reservation lands, eligible tribes can obtain treatment in a similar manner as a state (TAS) status and set their own WQS under the CWA, including human health criteria.

concerns about the safety of available fish. Deriving criteria using an unsuppressed FCR furthers the restoration goals of the CWA, and ensures protection of human health as pollutant levels decrease, fish habitats are restored, and fish availability increases. If sufficient data regarding unsuppressed fish consumption levels are unavailable, consultation with tribes is important in deciding which fish consumption data should be used.

With these principles in mind, the EPA has concerns with whether DEQ's decision to calculate the FCR based only on current consumption of Idaho fish, and to use a mean FCR for high consuming populations, will adequately protect the treaty-reserved subsistence fishing use. First, in calculating the FCR, DEQ has not considered suppression, specifically suppressed consumption amongst tribal populations in Idaho with reserved rights to fish for their subsistence. Current average FCRs for the Nez Perce and Shoshone Bannock tribes are below heritage rates documented for both of these tribes, as well as heritage rates for the Kootenai and Coeur d'Alene tribes, suggesting that current tribal consumption rates could be suppressed.[20] Second, given that tribal consumption rates are likely suppressed, DEQ has not provided adequate justification for how a rate based on the mean FCR for the tribal target general population will adequately protect tribal fish consumers exercising their treaty-reserved rights, including those whose consumption is not suppressed. Finally, as discussed in greater detail above, the omission of anadromous species from the FCR may result in criteria that are not adequately protective of Idaho's designated uses as informed by the reserved fishing rights of tribal consumers.[21] Based on local conditions in Idaho, it is particularly appropriate to include anadromous species in the FCR, because it is well documented that a large proportion of fish consumption for the tribal target population to be protected consists of anadromous species, such as salmon.[22]

Accordingly, EPA recommends that DEQ select a FCR that reflects the tribal subsistence consumers' unsuppressed fish consumption, including consumption of anadromous fish. If such data are unavailable at this time, the EPA recommends using an upper percentile of consumer-only data to account for uncertainty in the unsuppressed consumption rates of tribal consumers within the state and to help ensure that the resulting criteria protect the tribal target general

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[20] Polissar, N.L, Al Salisbury, C. Ridolfi, K. Callahan, M. Neradilek, D.S. Hippe, *A Fish Consumption Survey of the Nez Perce Tribe Volumes I-III.* Seattle, WA: The Mountain-Whisper-Light Statistics (2015); Polissar, N.L, Al Salisbury, C. Ridolfi, K. Callahan, M. Neradilek, D.S. Hippe, *A Fish Consumption Survey of the Shoshone-Bannock Tribes Volumes I-III.* Seattle, WA: The Mountain-Whisper-Light Statistics (2015); Ridolfi Inc., *Heritage Fish Consumption Rates of the Kootenai Tribe* (November 17, 2014); Ridolfi Inc., *Heritage Fish Consumption Rates of the Coeur d'Alene Tribe* (July 19, 2015).

[21] As DEQ has acknowledged, "if anadromous species data are omitted from the data set, it is possible that the resulting criteria may not be adequately protective of Idahoans who eat salmon, steelhead, or other anadromous fish" and "the complexity of Pacific Northwest fish consumption and its high inclusion of these fish species in the diets of all means that ignoring anadromous fish would be less protective of those within Idaho who enjoy consuming these types of fish." *Idaho Fish Consumption Rate and Human Health Water Quality Criteria; Discussion Paper #5: Anadromous Fish*, pg. 4 & 5, available at http://www.deq.idaho.gov/media/1117748/58-0102-1201-discussion-paper5.pdf.

[22] "Including marine fish in the fish consumption rate may be particularly appropriate if a large proportion of fish consumption for the population to be protected consists of marine fish (such as salmon) and this exposure is clearly documented." USEPA, *Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions*, pg 5, *available at* http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/hhfaqs.pdf.

population exercising their treaty-reserved rights. Additionally, government-to-government communications with affected tribes could inform, among other things, which fish consumption data should be used by DEQ.

B. <u>Idaho's Other Proposed Human Health Criteria Inputs</u>

1. Cancer Risk Level

The EPA supports DEQ's proposed policy decision to retain its 10^{-6} cancer risk level to derive human health criteria.

2. Relative Source Contribution (RSC)

In June 2015, the EPA published final updated ambient water quality criteria recommendations for the protection of human health for 94 chemical pollutants.[23] These updated recommendations reflect the latest scientific information and EPA policies, including updated body weight, drinking water consumption rate, FCR, bioaccumulation factors, health toxicity values, and relative source contributions (RSCs). The EPA supports DEQ's proposed approach to use RSC values specified in EPA's 2015 final 304(a) human health criteria recommendations.

3. Bioaccumulation Factors (BAFs)

As stated in DEQ's Technical Support Document (TSD) for the human health criteria, DEQ created an Idaho-specific BAF weighting equation using Idaho fish consumption survey data and stated that the approach they used was similar to the framework that EPA used to derive the BAF weighting in the EPA's 2015 final human health criteria recommendations.[24] According to the TSD, DEQ used food frequency data collected for the Idaho general population and dietary recall data for the tribal population. From these data, DEQ developed a trophic level weighted BAF using the following equation: $(FCR_{TL2} \times BAF_{TL2} + FCR_{TL3} \times BAF_{TL3} + FCR_{TL4} \times BAF_{TL4}) / (FCR_{TL2} + FCR_{TL3} + FCR_{TL4})$. This approach is appropriate and addresses the EPA's previous concern that Idaho tribal populations consume larger amounts of high trophic level fish relative to the U.S. general population. However, the EPA recommends that DEQ provide more information on the derivation of the trophic level specific FCRs used to compute weighted BAFs.

4. Body Weight and Drinking Water Intake

As discussed in the TSD, body weight estimates used in the calculation of Idaho's proposed human health criteria are based on use of a body weight distribution DEQ developed from the general population data from DEQ's fish consumption survey. Using this data, a logarithmic distribution was developed for body weight for calculation of Probabilistic Risk Assessment (PRA)-based proposed human health criteria.[25] EPA is supportive of DEQ's approach to using

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[23] Final Updated Ambient Water Quality Criteria for the Protection of Human Health, (80 FR 36986, June 29, 2015). See also: USEPA, 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhfinal.cfm.

[24] Idaho Department of Environmental Quality. *Idaho Human Health Criteria, Technical Support Document.* October 2015.

[25] Ibid

the Idaho local data for estimating body weight and concurs that the body weight distribution was appropriately derived.

As discussed in the TSD, DEQ developed drinking water intake estimates for the PRA-based calculation of the proposed human health criteria based on the National Health and Nutrition Examination Survey (NHANES) 2003-2006 data as presented in the EPA's Exposure Factors Handbook. A distribution was fit to the body-weight normalized drinking water intake values to ensure an appropriate correlation with body weight. This distribution was then used in the PRA approach and applied to both Idaho general and tribal populations.[26] The EPA selected the 90th percentile of this distribution (2.4 liters/day) to derive the EPA's 2015 final 304(a) human health criteria recommendations. Although DEQ's approach to estimating drinking water intake differs from the EPA's, DEQ's drinking water rate distribution has been appropriately derived.

In addition, the correlation between drinking water ingestion rate and body weight was adequately addressed in DEQ's PRA analysis. However, DEQ should re-evaluate the correlation between body weight and fish consumption rate using regression on log transformed fish consumption and body weight distributions (See enclosed Westat memoranda).

5. Toxicity Factors (Reference Doses (RfDs) and Cancer Slope Factors (CSFs))

The EPA supports DEQ's proposal to use RfDs and CSFs consistent with the EPA's 2015 final 304(a) human health criteria recommendations or, in some cases, toxicity factors based on the latest science.

C. Idaho's Proposed Pollutant Scope

The EPA is supportive of DEQ taking this opportunity to revise most of its currently applicable human health criteria and to include additional human health criteria for pollutants with EPA 304(a) criteria recommendations that Idaho had not previously adopted. DEQ is proposing to update or add criteria for 104 chemicals. As previously noted, the EPA published updated final 304(a) recommended human health criteria for 94 pollutants in June 2015.

D. Idaho's Use of Probabilistic Risk Assessment (PRA) to Derive Human Health Criteria

The EPA continues to question the fish consumption distribution that DEQ used in its PRA analysis (see the EPA's comments above regarding inclusion of market and anadromous fish in developing a FCR). Use of a FCR distribution that does not include consumption of market and anadromous fish will result in PRA-based criteria that will produce fish- and water-based contaminant exposures that exceed acceptable levels.

Additionally, DEQ's PRA for high fish consuming populations are derived using the assumption that, at the selected criteria, the mean of the hazard quotient distribution will equal one, and the mean of the risk distribution will equal 1×10^{-6}. EPA remains concerned with this approach. This approach will allow for a large fraction of high fish consumers, including tribes with reserved fishing rights (see above discussion on tribal reserved fishing rights), to have exposures

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[26] Ibid

that either exceed an acceptable dose (i.e., the reference dose) for noncarcinogens or exceed a dose associated with a risk of 1×10^{-6} for carcinogens.

Another concern is development of an appropriate tribal fish consumption distribution for PRA. The National Cancer Institute (NCI) method cannot be used to characterize consumption of a particular grouping of fish (e.g., fish caught in Idaho waters) if the data necessary for the method are not available. Idaho has used tribal Food Frequency Questionnaire (FFQ) and NCI data in an attempt to develop "NCI-like" estimates of average tribal consumption of fish caught in Idaho waters. As previously noted, DEQ should include market fish, including anadromous species, in the FCR used to set Idaho's AWQC. The EPA also has methodological concerns about using FFQ and NCI data to derive "NCI-like" FCR statistics based on Westat's review of the PRA approach (see attached Westat memoranda). Thus, the EPA recommends that the NCI group 2 (i.e., anadromous, near coastal and inland fish and shellfish) FCR data for the Nez Perce Tribe be used to develop statistics representing current fish consumption.

E. Idaho's Proposed Approach to Downstream Protection

The EPA is encouraged by DEQ's inclusion of a downstream protection narrative criterion in the proposed rule, following the language in EPA's "*Templates for Narrative Downstream Protection Criteria in State Water Quality Standards*" (EPA publication No. 820-F-14-002). However, the EPA's *Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions* suggests that states consider a more tailored and specific narrative criterion and/or a numeric criterion in certain situations, such as when more stringent numeric criteria are in place downstream and/or environmental justice issues are relevant.[27] As mentioned above, most of Idaho's waters are in the Columbia River basin and are, therefore, upstream of Washington's and Oregon's portion of the Columbia River. The EPA strongly encourages DEQ to adopt numeric human health criteria (either in addition to or instead of a narrative criterion) that ensure the attainment and maintenance of downstream human health water quality criteria, or to provide additional rationale detailing how use of a narrative downstream protection criterion in combination with Idaho's numeric human health criteria will ensure the attainment and maintenance of downstream human health criteria, consistent with the EPA's regulations at 40 CFR 131.10(b).

F. Other Specific Comments on Idaho's Preliminary Rule Language

Section 010. Definitions.

46. Harmonic Mean. EPA supports DEQ's proposed revisions to this definition. However, EPA continues to suggest DEQ consider including the following equation in the definition for harmonic mean, as it provides additional clarity:

$$Q(harmonic) = n / \sum_{i=1}^{n} \frac{1}{Qi}$$

[27] EPA. June 2014. *Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions.* http://water.epa.gov/scitech/swguidance/standards/library/upload/downstream-faqs.pdf

Section 210. Numeric Criteria for Toxic Substances for Waters Designated for Aquatic Life, Recreation, or Domestic Water Supply Use.

210.01.a. Criteria for Toxic Substances. EPA supports DEQ's proposed revisions to the application of the human health criteria for toxics for the protection of consumption of water and organisms such that these criteria apply only to primary and secondary contact recreation uses and no longer apply to aquatic life uses. Given that the provision in Idaho's water quality standards at Section 100.02 a. and b. states in part that secondary contact recreation may include activities such as fishing, the application of the water and organisms human health toxic criteria to only recreation uses and not aquatic life is appropriate.

With respect to DEQ's proposed revision to the headings in the toxics criteria table, specifically for the human health criteria, EPA recommends DEQ retain the word "organisms" and not replace it with the word "fish." "Organisms" more closely represents the concept that consumption is meant to encompass more than just fish but rather fish, shellfish, and other aquatic life.

210.03. Applicability. DEQ has proposed clarifying language regarding mixing zones as well as revising the low flow design conditions applicable to human health criteria. Consistent with the 2000 Human Health Methodology, DEQ has proposed to revise its regulations to require the harmonic mean flow be used to implement both carcinogen and noncarcinogen human health criteria.[28] EPA supports this proposed revision.

210.03.d.ii. This provision provides a frequency and duration for human health criteria that are not to be exceeded based on an annual harmonic mean. EPA understands DEQ is attempting to clarify the frequency and duration for the state's human health criteria and is supportive of that effort. EPA's 304(a) recommendations for human health criteria are based on long-term average exposure over a lifetime (70 years). Idaho's proposed duration of one year is protective because it represents long-term or chronic exposure but within a reasonable timescale for the purposes of regularly assessing attainment of the criteria. However, the harmonic mean is an inappropriate measure of central tendency in this context, because it is likely to under-represent the presence of pollutants in ambient water. Harmonic means are an appropriate measure of central tendency when evaluating rates with varying denominators, such as flows or speeds. However, for measures of varying mass per volume, such as concentrations of contaminants in ambient water, the arithmetic (for skewed datasets) or the geometric mean is the more appropriate measure of central tendency. EPA recommends that DEQ delete reference to the harmonic mean and, instead, insert arithmetic mean.

210.05.a.iii. The proposed revisions update the reference from EPA's ACQUIRE database to ECOTOX database. EPA supports this revision.

210.05.b.ii. The EPA is concerned that this provision lacks specificity with regard to a fish consumption rate and the target population to be protected that will be used to derive numeric human health criteria in the future, when numeric criteria are not identified in the toxics table. It

[28] FR Vol 65 No. 214. Pg. 66450. Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000).

would seem reasonable to specify an appropriate fish consumption rate as well as the target population and percentile of the target population that would be used to estimate a fish consumption rate consistent with how Idaho's numeric criteria in the table at Section 210 were derived. For example, the language in b.ii. refers to using a fish consumption rate that is representative of the population to be protected. The EPA suggests DEQ include specific language identifying the population to be protected consistent with EPA's previous comments.

284.04.b and c. DEQ combined the wording in 04.b. and c. and deleted any redundant language. These revisions are not substantive as they do not change where the criteria apply. The EPA supports the proposed revisions regarding the application of the site-specific criteria for the South Fork Coeur d'Alene River subbasin.

400.06 Intake Credits for Water Quality Based Effluent Limitations. This provision refers to the Idaho Pollutant Discharge Elimination System Program (IPDES) rules and is not a water quality standard. However, in EPA's October 2, 2015 letter from Michael Lidgard to Paula Wilson, EPA provided comments on IDAPA 58.01.25 regarding the proposed intake credit rule language as proposed in the IPDES rules. The EPA is continuing to coordinate with DEQ's IPDES program and has recommended that, if DEQ intends to adopt an intake credit provision into the IPDES rules, it be consistent with the Great Lakes Initiative (GLI). Another option is for DEQ to consider Oregon's intake credit provision rule language, as that language is most similar to the GLI and was approved by EPA.

Westat | An Employee-Owned Research Corporation

Memo

Date: October 19, 2015

To: Greg Frey, SRA

From: John Rogers, Rebecca Birch, and David Marker

Subject: Review of Idaho Fish Survey

Westat was requested by SRA and EPA to review three documents and a translation procedure, all related to the findings from the Idaho Fish Survey. Our comments are as follows.

1. Overall comments:

In our comments, "fish" refers to fish and shellfish.

It is not very unclear how many days of dietary recall data were collected. First, the daily dietary recall questions were only answered if question FFQ3 [did you eat fish in the last 7 days] is Yes. So someone who ate fish only on day 8 would be excluded from the dietary recall questions. It appears that 8 days of daily recall were reported for those who ate fish yesterday but only 7 days for those who did not eat fish yesterday. If FCR24_1 [did you eat fish yesterday] is Yes, the questionnaire collects data about yesterday's fish consumption. Then the instructions for questions FCR7D_1_A through FCR7D_3_B distinguish between "excluding yesterday how many meals did you eat … that included fish or seafood in the past 7 days" [looks like 8 days total] if fish was eaten yesterday versus "… in the past 7 days how many meals did you eat …" and "Not including today, what was the most recent day of the week when you consumed …" if fish was not eaten yesterday [looks like 7 days total].

Given that the dietary recall data were collected only if the respondent said they ate fish in the past seven days, we think the fish consumption in the seven days prior to the call should be used when aggregating dietary recall data across multiple days, not 8 days.

The definition of consumption events is unclear. If two different types of fish are consumed at a meal, the FFQ seems to count this as one consumption event. Is this one or two consumption events in the dietary recall? Is every snack a consumption event regardless of size or how many types of fish were consumed?

Frequency of fish consumption was assessed using the FFQ and the multiple days of dietary recall data. The report says "the total number of consumption events estimated using the dietary recall questions is significantly lower than the total number of consumption events estimated using the food frequency questions" (page 81) but provides no data for comparison to quantify what "significantly lower" means. At the same time the report notes that the reported frequency of fish consumption drops as the days between the consumption event and the survey contact increases (page 75). Might this indication of recall bias explain some of the difference?

The report notes that there are differences between the portion size estimates from the FFQ and the average portion size estimates from the dietary recall. Interpretation of that difference is complicated by: 1) the skewed distribution of the amounts from the daily recalls; 2) how the respondent estimates long-term portion size; and 3) differences in what a portion means between the FFQ and dietary recall. If the respondent provides an estimate of the median portion size (as opposed to the mean), the difference between the log-transformed portion sizes may be less significant, and more normally distributed.

It is not clear how a "complete" survey was defined. Also the survey report gives weighted sample sizes (is this weighted population estimate scaled down to the sample size?). We would like to see unweighted sample sizes. Table 1 (page 10) in the IMS analysis report provides unweighted sample sizes. However, it is still unclear concerning the number of subjects that were consumers versus non-consumers.

In theory, usual fish intake can be estimated from 24-hour recalls or multiple-day recalls (in this case 7 or 8 day recalls). However, if the best estimate of usual fish intake is based on 24-hour recalls, then the decrease in the reported frequency of fish consumption with increasing length of the recall period (days between the consumption event and the survey contact) indicates that the estimate based on multiple-day recalls will be biased low. Correcting this bias requires making some assumptions (such as logit(probability of fish consumption) and log(amount consumed per day) changes linearly with the length of the recall period). With a reasonable assumption, this bias can be corrected by

1) fitting a more complicated version of the NCI model that includes an adjustment;
2) scaling the estimated usual fish consumption from the NCI model up to adjust for the bias (applying a multiplicative factor, perhaps (probability of fish consumption on Day 1)/(Probability of fish consumption on any day in the recall period)); or,
3) using only the first (yesterday) day of dietary recall to estimate usual fish consumption.

Using just the 24-hour recall, if separate models are fit for anglers and non-anglers, the NCI model may not converge due to few respondents with two recalls, both with fish consumption. Scaling the output when predicting data from several days may be the easiest option.

The NCI macro uses the NLMIXED procedure. The weights in the NLMIXED procedure are defined using the REPLICATE statement. The documentation for the REPLICATE statement states that "Only the last observation of the REPLICATE variable for each subject is used". Thus, the same weight is used for each recall within a person. The best weight to use is the weight for the respondent (used for the first recall). As a result, 1) the analysis file for the NI method should have the weight for the first recall on both the records for the first and second recall; and 2) the weight for the second recall defined by NRG is not used in the analysis.

In the IMS report, Table 1 (page 10) shows the sample sizes for anglers and non-anglers and the number of respondents used in the NCI model. It is not completely clear why some cases were not included in the NCI model. Does the line labeled "Annual Fish Consumption Unavailable" correspond to those that did not eat fish in the last year (non-consumers)? There are 243 cases labeled "Recall Data Unavailable (i.e. Missing)". What does this mean? There were 660 respondents that were dropped because various covariates were missing. Without knowing specifics about the missing values, perhaps imputed values could be used or missing values can be treated as a separate category of the categorical variables? How does the distribution of the demographic variables for those in the NCI model compare to the distribution for all fish consumers?

2. Idaho Fish Consumption Survey

SUBMITTED TO: Idaho Department of Environmental Quality
SUBMITTED BY: Northwest Research Group, LLC www.nwresearchgroup.com
DATE SUBMITTED: Final: August 25, 2015

We are interested in identifying any survey design factors that might introduce any uncertainty or bias/loss of accuracy in results of the fish consumption survey. In addition to whatever the reviewers identify as a potential issue, we would specifically like comments on the topics listed below.

2.1 Representativeness of sample using a telephone interview.

The methodology to collect data using a telephone interview using two frames (cell and landline) seems appropriate. According to the 2012 National Health Interview Survey only 2.7 percent of adults in Idaho are without a cell or land line phone. Those people will not be represented. While there may be some reason to think they have different fish consumption levels than others with otherwise similar demographics (since they are by definition living somewhat removed from society lives), there impact on overall estimates are likely to be small.

2.2 Methodology used to select land line and cell phone numbers and representativeness of sample

The methodology to select land line and cell numbers appears to be appropriate. The resulting samples of telephone numbers should be representative of the cell phone or landline populations. See item 2.11.

2.3 Stratification of sample based on Idaho health districts.

The stratification approach looks appropriate, trying to enforce geographic and gender representativeness in the sample minimizes variation in the weights.

2.4 Representation of anglers and non-anglers and weighting

They decided to use only the telephone landline and cell lists for sampling and classifying the anglers based on reported possession of a fishing license. This approach appears to be reasonable. The number of anglers estimated from the survey (33%) differs somewhat from the number estimated by IDFW (26%). It is possible that anglers were more likely to respond to a survey on fish consumption then non-anglers. At the same time, the list from IDFW has some uncertainty in that two lists of different sizes were provided.

2.5 Quotas for age, gender, and income and relation to representativeness of the sample

In general, enforcing the quotas helps to reduce the required effects of weighting. However, quota sampling has been discouraged for decades in government surveys because it can introduce biases that are not necessarily accounted for through the weighting process. In particular, it results in over-representing those who are easier to reach by telephone. Of particular interest in a fish consumption survey, those who spend a greater amount of time away from home (including fishing) are harder to reach, and thus are underrepresented in a quota sample. If they are reachable by cell phone this form of bias may be reduced, but it is hard to know for sure.

2.6 Consideration of race and representativeness of the survey sample

The racial breakdown of the population is only reported as White Alone versus Non-White (roughly 5%). Race was not used for weighting. Since quotas were not used for race, the sample may not be representative of the population racial distribution. A weighting adjustment based on race would improve the representativeness of the weighted sample with respect to race. See item 2.11.

The proportion of whites in the sample is higher than in the State of Idaho. Nationally, whites consume less fish than non-whites (EPA, 2014). If the weighting were to include race it might improve the accuracy of the estimates.

2.7 Impact of not being able to interview 5% of contacted households because of language issues.

Obviously, this subpopulation will not be represented in the survey results. To the extent that this subpopulation is similar to others with similar demographics, a weighting adjustment based on demographics might make the weighted sample more representative.

They report that early analysis indicated no significant differences in consumption rates between English speaking Hispanic and non-Hispanic respondents. However, this does not mean that there will be no difference between English speaking and non-English speaking respondents. They are assuming that English speaking Hispanics are more similar to non-English speaking Hispanics than they are to non-Hispanics in dietary behavior, which may or may not be true.

In particular, if the non-English speakers are Native Americans, their lack of English could be hypothesized to be correlated with following more traditional lifestyles, ones that involve consumption of much greater amounts of fish. In such a case their exclusion will underestimate the true fish consumption in Idaho.

2.8 Quantifying portion size:

2.8.1 Use of common objects to describe portion size

If the common object is familiar to the study population, it is likely easier for respondents to report their portion size in relation to the object than to estimate weight (grams or ounces) or volume (cups or tablespoons), unless they cooked it themselves. They did qualitative research among the population of interest to assist them in selecting common objects to be used as portion size references.

2.8.2 Asking respondents to quantify portion size in ounces

It is likely difficult for respondents to provide the amount of fish they consumed in ounces, unless they prepared the fish. However, they tested the use of portion size estimation aids (PSEA) to assess if using PSEAs would improve reporting of fish consumed in ounces. They report that the results showed saying the PSEA was equivalent to a specific number of ounces and asking respondents to then provide their consumption in ounces provided accurate estimates. This is the methodology they used. It seems reasonable and best available without pre-mailing (or directing to a website) portion size pictures like what are used in the ASA24.

2.8.3 Use of a deck of cards as the portion size estimation model

According to their research, most people thought about a deck of cards or palm of hand when estimating portion sizes and there was no difference in accuracy between these two PSEAs. They chose to go with a deck of cards. This choice seems reasonable given the research findings and that hand sizes vary by age and gender and other factors.

2.9 Use of an 8 day recall period, (SEE: p 24, item 6 describing recall issues for longer periods from qualitative research).

The use of a single versus multiple-day dietary recall for assessing usual fish consumption depends on a combination of bias and precision. The decrease in the reported frequency of fish consumption with increasing length of the recall period (page 75) will contribute to increased bias as the number of recall days increases. The bias can be corrected in various ways (an adjustment factor, modifying the NCI model, or using only the first day of dietary recall). The increasing imprecision of the respondent recall as the length of the recall period increases affects the precision of the estimates; but the NCI method can still be used to calculate those estimates if proper adjustments are made. As a result, increasing the recall period has diminishing benefit. We recommend either adjusting the estimates for bias associated with the longer recall period or calculating the usual fish consumption from only the first recall day. Disregarding this length bias, as was apparently done, can produce inaccurate estimates.

Assuming that respondents had a difficult time recalling fish consumption events beyond a few days (like they report), an 8 day recall period probably underestimates usual fish consumption due to the likely lowered estimated probability of consumption (for those that were reported no consumption and may have forgotten a fish consumption event).

2.10 Impact of response rate on survey results

Non-response contributes to possible bias and decreased precision of the survey estimates. NRG appeared to make reasonable efforts to increase or maintain response rates while collecting the data. Without independent estimates of fish consumption for the non-respondents it is not possible to truly assess the bias. A non-response adjustment to the weights can help to minimize the bias. An analysis of frequency and amount of fish consumption as a function of the effort used to collect the data (such as number of contacts to get a completed survey response) can be used to approximate the possible bias due to non-response. The non-response adjustment (post stratification) provides minimal adjustment for non-response. We recommend additional adjustments of the weights to account for different non-response rates for different demographic groups. NRG provided some adjustment of the weights for health region and gender; however did not provide more extensive adjustments for non-response (particularly with respect to an apparent imbalance in income) citing concerns for possible large weights in some health districts. While it is true that such adjustments may increase the variance, they will reduce the bias. In general this trade-off is worthwhile when the response rates are not high. We recommend additional non-response weight adjustments.

2.11 Weighting of results based on land vs. cell phones

The general approach to weighting the combined cell and landline samples, as represented by BW_1, is reasonable. However some details of the implementation are unclear or appear incorrect, in particular:

1) On page 35 they define CP as the number of cell phones but it appears to really be whether or not they have a cell phone used for making or receiving phone calls (this is ok, but should be corrected in the documentation)
2) On page 35, the numbers for the universe counts (ULL and UCP) seem very implausible....they must be larger. If these are in error, then obviously the weights are wrong.
3) On page 35, the formula for BW_1 is wrong (we assume it is just a typo, since the -1 should be an exponent)
4) They did not collect the number of adults in the household and therefore made a "fix" based on the number in the household; that is a potential source of bias
5) The question they used to determine phone service (TEL on page 104) is not a standard one and might lead to some errors. For example, the cell phone is based on personal use and the landline is household availability and the two are confused in this question.
6) The purpose and implementation of the adjustment in BW_2 on page 36 is unclear. Is the adjustment (BW_2) applied to all respondents in a health district or only the cell-phone-only respondents? It is not clear what some of the numbers in Table 12 are or where they came from. They appear to be household numbers; however the adjustment should be for adults; this may be a potential source of bias. Based on the numbers in the last three columns of Table 12, it looks like the purpose of BW_2 is to get the percentage of cell-only households in the sample to equal the corresponding percentage in the population; however, it is not clear how the equations for BW_2 and BWFinal achieve that for the "Non Wire-less Only" respondents.

2.12 Implementation of post stratification weighting

The post stratification provides some adjustment for non-response. However, it excluded adjustments by income level, household composition, and education.

2.13 Weighting for re-contact interviews

The weighting for the re-contact interviews provides a simple adjustment for non-response. If these weights were important, we would recommend a more complicated adjustment. However, since the NCI model only uses one weight per respondent (preferably the weight for the first recall, not a separate weight for each recall), the calculation of an adjusted weight for each recall is not required when using the NCI method for analysis.

2.14 Imputation used to populate missing values

The imputation used to populate missing values is not explained in detail. The discussion on page 42 says the values were imputed based on characteristics of their neighbors but provides no description of how "neighbors" are defined. It is not clear what values were or were not imputed. It is also not clear how the imputed values were used. Were they used to create Table 15? Were they used for weighting? The second bullet on page 42 seems to imply the imputed values were not used in the analysis file.

2.15 Data processing and calculations

We found no problems with what was presented. However, the description does not say how the 7 or 8 day fish consumption (average or sum?) was calculated from the daily values (only the calculation for daily values for yesterday is presented, we assume the other days consumption was calculated in a similar manner). We recommend the fish consumption be calculated for 7 and not 8 days, as noted in the overall comments.

2.16 Bootstrapping approach used to develop confidence limits

The Bootstrapping approach apparently does not incorporate the weights. As a result, for evaluating population differences, the confidence intervals may be smaller than appropriate. It is not clear how the confidence intervals were used. The word "significant" is used in several places. It is not clear if it refers to statistical significance.

2.17 Discussion Section

2.17.1 Addressing non-response bias

They say 25 percent is "significantly higher than the average response rate." Twenty-five percent is not unreasonable for a telephone survey these days, but it still leaves room for significant nonresponse bias if the respondents are not like the nonrespondents. It is difficult to know if the 75 percent that did not respond are systematically different in their fish consumption behaviors. This is of particular concern given that they used a quota sample rather than a traditional random sample. This might contribute to the over-representation of higher income individuals and anglers

– these groups may be more interested in the survey topic thus more likely to respond. Could non-response be adjusted for with weighting factors?

2.17.2 Impact of over-representation of higher income individuals and anglers

They mention that more complicated weights could be applied to adjust for these differences, but that could result in large weights within individual health districts. They could assess the impact of the over-representation by applying the weights, running the analysis, and comparing the results.

In general it is always true that weighting adjustments will reduce precision (larger standard errors for sampling), but the trade-off is that it will hopefully reduce bias. This is important because the confidence intervals, or tests of hypotheses, will only have the claimed level of accuracy (e.g. 95 percent) if the bias is trivial. If there are large biases all of these intervals will be incorrect. That is why we do typically adjust for known under-represented groups. In some cases it may be worthwhile to trim a few excessively large weights. This process is expected to produce smaller overall mean squared errors, and more appropriately-sized confidence intervals.

2.18 Review of the questionnaire and identification of any issues in accurately recording fish consumption. Of particular interest is review of the methodology for inquiry into consumption over the past 7 days.

As noted in the general comments above, clarification of when there is data for 7 days versus 8 days is needed. Also, given the decrease in the proportion of respondents reporting fish consumption with increasing length of the recall period, estimates based on multiple-day recalls are likely to be biased low without an appropriate adjustment.

3. NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho

This report was prepared under DEQ Contract K079 with Information Management Services, Inc.: Dennis W. Buckman, PhD, Ruth Parsons, BA, Lisa Kahle, BA, September 9, 2015.

We are interested in any NCI data analysis factors that might introduce uncertainty or bias/loss of accuracy in NCI results. We are particularly interested in whether or not the data analysis approach is sufficiently described. In addition to whatever the reviewers identify as potential issues, we would like comments on the topics listed below:

3.1 How well are the selection and impact of covariate choices documented?

The covariates used in the NCI model are listed in the report (page 11). No justification for using these covariates is provided. In addition to these covariates, three other variables that are apparently available are: gender, household composition (single versus multi-person, see page 40 of the survey report), and amount consumed from the FFQ. An easy approach to selecting covariates is to include all available covariates. Alternatively a combination of a weighted logistic regression (using the SAS SURVEYLOGISTIC procedure with the BRR weights created for calculating confidence intervals for usual fish consumption) predicting the probability of fish consumption in a recall, and a weighted linear regression predicting log-transformed (or Box-Cox transformed) amount of fish consumed (using the SAS SURVEYREG procedure), can be used to assess which predictors or interactions of predictors are statistically significant when predicting the outcome. For the NCI model, we recommend including the same predictors for both the probability and amount models, including predictors that are significant when predicting either probability of consumption or transformed amount. In general it is important to include predictors that are clearly significant ($p<.01$). Predictors that are believed to be related to fish consumption but not significant should also be included. We believe the amount consumed from the FFQ should be an important predictor of amount consumed in the NCI model. For continuous predictors (body weight, age, and amount consumed from the FFQ) the weighted regression models can be used to assess how the variables might be transformed and whether the relationships are linear.

3.2 Are there any issues associated with use of 8 days of dietary recall information rather than the last 24 hours?

Yes. At a minimum, compared to using only the last 24 hours, the estimates are biased without an adjustment for the decreasing frequency of reported fish consumption as the length of the recall period increases. See the general comments above.

3.3 Is the combination and weighting of general and angler populations done appropriately?

The details of how the NCI macros were applied to the data files are not completely clear. For each type of fish consumption, we suspect the NCI method was applied to the data from the angler and non-angler subpopulations in separate runs, that all runs used the survey weights, and the summary statistics calculated from the simulated usual intake values for each respondent (from the DISTRIB macro) were calculated using the survey weight associated with the first recall for each respondent. The summary statistics can be calculated after combining the output files from the runs of the DISTRIB macro. If these procedures were used, we believe the calculations were done appropriately.

3.4 How, and how well, is it documented that the results meet assumptions of the NCI model (e.g. transformed positive fish consumption rates are normally distributed)?

The report provides no information on the values of Box-Cox transformation parameter (lambda), whether the transformed consumption amounts are normally distributed (a normal quantile plot of the transformed consumption amounts (not the plot from the NCI Box-Cox macro that was used) would help), whether there are any outliers, and the estimates of the variance components from the NCI model fit (between person for the probability model and the within and between person components for the amount model). This information would help assess the model fit and why the NCI macro had problems estimating lambda and the correlation parameter. In our experience, setting lambda instead of fitting lambda in the model and ignoring the correlation parameter has little effect on the results when calculating usual intake of fish. Given the relatively large number of respondents with two recalls with reported fish consumption we are surprised that lambda and the correlation parameter could not be fit using the MIXTRAN macro; at the same time, we have no reason to question this result.

4. Development of Human Health Water Quality Criteria for the State of Idaho (Draft), Windward Environmental, September 15, 2015

We are interested in whether or not the probabilistic analysis is adequately described. Further, we are interested in any methodological issues that were inappropriately or incompletely addressed in the PRA. In addition to anything that the reviewers might provide, we are interested in the following topics:

4.1 Selection of input distributions, in particular development of a Nez Perce fish consumption rate distribution.

The distribution fit to the percentiles of body weight appears to provide a good fit to the data. The distribution fit to the percentiles of drinking water intake per body weight appears to provide a reasonable fit to the data. Given the limited data for fish consumption for the Nez Pierce tribe, interpolating while setting the lower 5 percent to the 5th percentile and setting a maximum value and interpolation for percentiles above the 95th percentile appears reasonable.

One might question how the maximum value was obtained. Based on the footnote on page 12 of the Windward report, the maximum was based on what might be the maximum simulated value from the NCI DRISTRIB macro for the Idaho general population (1,261 g/day) multiplied by 0.242. If we have understood the calculations, this approach appears somewhat arbitrary because 1) the maximum value depends on how many simulated values DISTRIB creates, and 2) the adjustment factor of 0.242 seems to be based on calculations that are unrelated to the relationship between the maximum of the two distributions. A possible alternative is to calculate the 95th and 99.9th percentile for the general Idaho population and assume the ratio of those percentiles is the same for the general Idaho populations and the Nez Pierce population.

4.2 Correlation

4.2.1 Between body weight and drinking water ingestion rate

Assuming the drinking water ingestion rate per body weight is independent of the body weight appears to be a reasonable assumption. If needed, analysis of NHANES data could be used to test the assumptions. Thus simulating body weight and independently simulating drinking ingestion rate per body weight appears to be reasonable.

4.2.2 Between body weight and fish consumption rate

We expect the fish consumption rate to increase with increasing body weight. The assumed distribution for the body weight appears to be a lognormal distribution. The distribution of fish consumption rate can often be reasonably approximated by a lognormal distribution. Thus, when assessing correlation, we strongly recommend plotting and calculating the correlation between the log-transformed body weight and the log-transformed FCR. The statistical assessment of correlation (here using regression) assumes the prediction errors are normally distributed with roughly constant variance. That assumption is clearly not true for the data plotted in Figure 2-3 of the Windward report. We expect a plot using the log-transformed values will have an approximate bivariate normal distribution.

5. Translation of NPT consumption of 'Group 2' fish to equivalent consumption of 'Idaho Fish'

We are interested in whether or not the approach is adequately documented and whether or not there are any issues with this analytical approach. In particular, we are interested in how IDEQ has processed weighting factors in deriving consumption rates of fish caught in Idaho.

In general the re-grouping of fish seems appropriate given the available data. We have three concerns:

1. The explanation of how the prorating was done is hard to follow. The prorating of event salmon (salmon + steelhead): If a participant reported 10 oz. of salmon at events and 6 oz. of chinook and 4 oz. of steelhead at nonevents, then they were assigned 4 oz. for event steelhead. Is this how it was done?

2. Why was Coho left out of the prorating? Is it sometimes confused with steelhead?

3. The fraction of salmon + steelhead that is chinook is apparently calculated separately for each respondent. Where does the 81.3% come from? This is apparently the weighted mean percent of chinook (out of salmon+chinook+ coho+steelhead) across all participants that reported nonevent salmon, chinook, coho, and steelhead, is that correct? Although the fraction you are interested in can be calculated for each respondent, the resulting fractions can be imprecise, resulting in biased overall estimates. As an alternative, we recommend calculating the ratio of the weighted mean chinook non-event consumption to the weighted mean salmon+chinook+ coho+steelhead non-event consumption and using one ratio for all respondents. If there is concern that the ratio may differ among respondents, the ratio can be calculated separately for different demographic groups.

The application of the weights seems appropriate. The resulting fraction of the Group 2 that was assigned as Idaho fish (0.242) was then multiplied by the results that were obtained from the NCI Method for the original Group 2.

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Memo

Date: October 26, 2015

To: Greg Frey, SRA, and Lon Kissinger, EPA

From: John Rogers

Subject: To-do list for improving the estimates of Idaho fish consumption

At the request of SRA, Westat provides the following recommended to-do list for predicting fish consumption from the ID survey. Note that these recommendations are based on our understanding of the data and the calculations used previously. The recommendations may need to be adjusted for unanticipated characteristics of the data. The to-do list refers to comments in our October 19, 2015 memo.

The to-do list:

Revise the survey weights:

- Recalculate the base weights, noting the comments in item 2.11.
- Review the imputation of the missing demographic variables. This needs to be described better.
- Adjust the base weights for non-response using raking. The variables used for raking would include those in Table 15 in the NRG report. This will create respondent weights adjusted for imbalance due to the sampling process and non-response, W_i. If a few weights are particularly large relative to most weights, those weights might be trimmed. The weights for other cases would be increased so that the sum of the weights is unchanged.
- Set the weight for the second recall to equal the weight for the first recall.

Revise the calculations to calculate fish consumption over 7 days.

- For each respondent and recall, calculate the quantity of fish consumed in each day of the recall ("yesterday" and the prior 7 days) as documented on page 116 of the NRG report, call this A_{ird}, i references the respondent (1 to N), r references the recall (1 or 2), and d references the day (1 to 8). Then calculate the average daily consumption over the first 7 days for each respondent and recall: $A_{ir(7)} = \frac{\sum_{d=1}^{7} A_{ird}}{7}$.

- Using only the first recall for each subject ($r = 1$), calculate the weighted mean of the fish consumption on the first day and the fish consumption across the first 7 days (the sums are over all completed recalls):

$$\bar{A}_1 = \frac{\sum_{i=1}^{N} A_{i11} W_i}{\sum_{i=1}^{N} W_i}$$

$$\bar{A}_{(7)} = \frac{\sum_{i=1}^{N} A_{i1(7)} W_i}{\sum_{i=1}^{N} W_i}$$

Note: this is a slightly different formula than outlined in the comments.

- Calculate the ratio for adjusting the NCI estimate of usual fish consumption to estimate usual fish consumption adjusted for decreased recall over time.

$$R = \frac{\bar{A}_1}{\bar{A}_{(7)}}$$

Fitting the NCI model

- Decide what cases to include in the NCI model. Is there a reasonable way to include cases with missing demographic variables, such as treating the missing values as a separate category or using imputed demographic variables?

- Create BRR replicate weights for calculating variances.

- Decide what predictors to use:

  - Use the SAS SURVEYLOGISTIC procedure to identify significant predictors of reported fish consumption (Yes versus No) using the BRR weights. First identify significant main effects. Second identify significant two-way interactions of the significant main effects. Candidate predictors would be demographic variables (including body weight) and FFQ variables (frequency of fist consumption, amount consumed). It is worth considering transforming or categorizing the FFQ variables to handle non-linear relationships. Although it can be done different ways, we suggest 1) including main effects that are significant at the 5% level; 2) including interactions of the main effects that are significant at the 1% level; and 3) including any other main effects believed to be associated with fish consumption.

  - Use the SAS SURVEYREG procedure to identify significant predictors of log-transformed (or Box-Cox transformed) reported amount of fish consumed using the BRR weights, using the steps above.

- In the NCI model, we suggest using the same covariates for the probability and amount models.

- Fit the NCI model to $A_{ir(7)}$. If necessary, determine the Box-Cox transformation parameter (Lambda) before fitting the NCI model. If the correlated model cannot be fit, using the uncorrelated model is OK. Report the Lambda and the magnitude of the variance components from the NCI model when using the full sample weight.

- Multiply the usual fish consumption from the NCI DISTRIB macro by the ratio R from above to provide an unbiased estimate of usual fish consumption.

Do the calculations for the PRA:

- Revise the adjustment for estimating the top 5% of the Nez Pierce distribution, see comment 4.1.
- Consider a correlation between log-transformed body weight and log-transformed usual fish consumption. Alternatively, if the body weight is a significant predictor of usual fish consumption (in the probability and particularly the amount model), the distribution of fish consumption should be a function of body weight.
- Calculate the weighted fraction of chinook across all respondents when adjusting for different fish species categories (Group 2 versus ID fish). See comment 5, item 3.

Clarify various items, see comments, in particular:

- The process for developing imputed values when data were missing
- Weighting of angler and general populations in developing overall results
- Discussion in the NCI analysis report as to how well model assumptions are met

Review of DEQ Approach for Developing an NCI-Like Distribution of Idaho Caught Fish, 11/5/15

EPA requested Westat review DEQ's approach for developing an "NCI-like" fish consumption rate (FCR) distribution for fish from Idaho waters. This memo summarizes conversations between Lon Kissinger EPA Region 10 and Westat statistician Dr. John Rogers.

DEQ developed a Nez Perce distribution of consumption of Idaho caught fish by scaling the NCI-derived distribution for consumption of Category 2 fish, multiplying the percentiles by 0.242 to calculate the percentiles of the distribution of Nez Perce Idaho fish consumption. The scaling factor, 0.242, was the ratio of the average consumption of Idaho caught fish to the average consumption of Category 2 fish. Both of these averages were obtained from the Nez Perce FFQ survey. The resulting scaled or transformed NCI-distribution is referred to here as the "NCI-like" distribution.

After discussions with Westat regarding the relationship between the NCI-derived distributions for different types of fish, we suggest that further analysis be done on the approach used to develop a Nez Perce "NCI-like" distribution of Idaho caught fish. It appears that the current procedure is likely to underestimate the upper percentiles of the Idaho fish consumption distribution.

Given that FCR distributions are reasonably log normally distributed, there is likely a linear relationship between log transformed percentiles of the distribution of Idaho caught fish consumption and the distribution of Group 2 fish consumption (for which we have the NCI estimate of the distribution).

Let P_I represent percentiles of the distribution of Idaho caught fish consumption that are to be estimated. Let $P_{G2,NCI}$ represent percentiles of the distribution of Group 2 fish consumption estimated using the NCI method. Then assume:

$$Ln(P_i) = ln(S) + F*Ln(P_{G2,NCI}), \text{ or equivalently } P_i = S * (P_{G2,NCI})^F.$$

The problem is how to estimate S, a scaling factor, and F, a slope roughly equal to the ratio of the standard deviation of $Ln(P_i)$ to the standard deviation of $(lnP_{G2,NCI})$.

Using results from NHANES data previously analyzed for EPA Headquarters, Westat did a quick analysis comparing the NCI-derived distributions of fish consumption for different types of fish. Let R equal the ratio of the mean fish consumption for the fish type used as the dependent distribution to the mean fish consumption for the fish type used as an independent distribution. When predicting the distribution of a less consumed fish type from the distribution of a more consumed fish type (i.e., $R < 1$), it appears the F should be greater than 1.0 with higher slopes as R decreases.

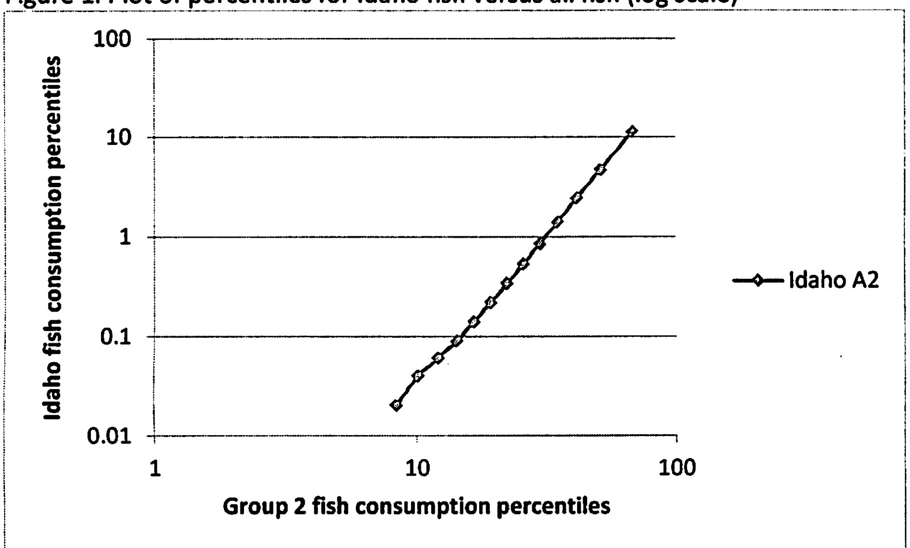
As an example of the calculations, Table 1 has the 35th through 95th percentiles of the consumption distributions for all fish and for Idaho caught fish from the Idaho state survey (see: NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho, Tables A1 and A2, using All Subjects). Lower percentiles were not included because the estimates were reported as "<.01" or were particularly imprecise.

Table 1 Percentiles of fish consumption for all subjects

Percentile	All Fish Table A1	Idaho fish Table A2
35	8.31	0.02
40	10.09	0.04
45	12.06	0.06
50	14.25	0.09
55	16.61	0.14
60	19.27	0.22
65	22.29	0.34
70	25.71	0.53
75	29.74	0.84
80	34.85	1.38
85	41.44	2.42
90	51.11	4.66
95	67.66	11.24

Figure 1 shows a plot of the percentiles of Idaho fish consumption as a function of the percentiles of all fish consumption, using log scales. As can be seen, the log-transformed percentiles fall on a roughly straight line.

Figure 1. Plot of percentiles for Idaho fish versus all fish (log scale)



Fitting a linear regression to predict the log-transformed percentiles for Idaho fish consumption from the log-transformed percentiles of all fish consumption gives a slope of F = 3.00. Although this analysis used selected percentiles, using all percentiles between the 1st and 99th percentiles and using more precision is recommended.

Different slopes will be obtained using different data or different subsets of the data (such as anglers only). For all subjects in the Idaho state survey the ratio of the means (R) is .106, smaller than the ratio of 0.242 estimated for the Nez Perce from the FFQ. Although one could use F = 3.00 for the Nez Perce, since F appears to increase as R decreases and R for the Idaho state data is less than for the Nez Perce, an appropriate slope for predicting Nez Perce Idaho fish consumption from Group 2 fish consumption may be less than 3.00. Some judgment is required to set the value of F. Considerations might include:

- calculations using Idaho data (as above),
- calculations using NHANES data, or possibly
- calculations using FFQ data (note that the precision and bias of FFQ data are uncertain and lower percentiles of FFQ estimated Idaho fish consumption are zero; it is not possible to calculate the log of zero).

Once F is set, calculate R, in the case of the Nez Perce based on the FFQ data. R is the ratio of the reported means of Idaho fish consumption and Group 2 fish consumption:

$$R = Mean(I_{FFQ}) / Mean(G2_{FFQ}) = 0.242$$

Also calculate the mean of $P_{G2,NCI}$ and $(P_{G2,NCI})^F$ across all percentiles (excluding the 0th and 100th percentile). These means are calculated using the percentiles from the DISTRIB macro because those are the data that are available.

The calculations assume the ratio of the mean Idaho fish consumption to the mean Group 2 fish consumption is the same for the FFQ data as for the NCI or "NCI-like" data, i.e.,:

$$Mean(I_{FFQ})/Mean(G2_{FFQ})=Mean(P_i)/Mean(P_{G2,NCI})$$

Since $Mean(P_i) = S^* Mean((P_{G2,NCI})^F)$, solving for S gives:

$$S = R * Mean(P_{G2,NCI}) / Mean((P_{G2,NCI})^F)$$

Finally, calculate the "NCI-like" distribution:

$$P_i = S * (P_{G2,NCI})^F$$

The mean of P_i across all percentiles (excluding the 0th and 100th percentile) should be equal to $Mean(I_{FFQ})$. Note that if F = 1.0, then S = R and the scaled NCI distribution is the same as calculated previously by Idaho DEQ. Using a slope (F) greater than 1.0 spreads out the distribution, particularly the upper tail, compared to using F = 1.

We expect the approach outlined above, using an estimated value of the slope F, will provide a better estimate of Nez Perce Idaho caught fish consumption distribution than assuming F equals 1.0.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
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OFFICE OF THE
REGIONAL
ADMINISTRATOR

DEC 18 2014

Maia Bellon, Director
Department of Ecology
P.O. Box 47600
Olympia, Washington 98504-7600

Dear Director Bellon:

I am writing in follow up to my letter dated April 8, 2014, in which I described the U.S. Environmental Protection Agency's intention to amend the National Toxics Rule for the State of Washington's human health water quality criteria should the Washington Department of Ecology not finalize its human health water quality criteria by the end of 2014. Consistent with that letter, I am informing you that the EPA has initiated its internal federal rulemaking process to amend the NTR for Washington's human health water quality criteria and plans to publicly announce the initiation of the process on the EPA's Website in mid-January 2015 via a monthly notice that summarizes upcoming EPA regulatory actions (known as the Action Initiation List).

At the same time, as you know, the EPA remains interested and committed to supporting the State's process to complete a water quality standards submission for the EPA to review. I am encouraged by Ecology's timeline to issue a draft rule for public comment in January 2015, and appreciate the Governor's personal investment in moving the State's efforts forward. I continue to strongly encourage the State to fully consider the issues that the EPA has raised during the State's rulemaking process, particularly regarding the need for the State to base its decision on sound science and the best available data, which provide evidence of fish consumption rates well above 6.5 grams per day in Washington, and to explain why a change in the State's long-standing cancer risk protection level is necessary and how it is consistent with its strategy for protecting higher fish consumers in Washington. I am hopeful that Washington's submission to the EPA fully addresses these issues, protects human health and the environment, and is consistent with the Clean Water Act.

The EPA recognizes that its federal rulemaking activities, specifically the timeframe for developing draft federal water quality criteria for Washington, would overlap with Washington's potential timeline for finalizing its rule. Therefore, it is important to note that, if Washington were to submit a final rule to the EPA for Clean Water Act review and action, the EPA would likely pause its federal rulemaking activities to fulfill its required duty to review and act on the submittal under the Clean Water Act (to either approve the submittal within 60 days or disapprove within 90 days). However, initiating the EPA's internal rulemaking process now, preserves the EPA's ability to propose a rule in a timely manner should action on our part become necessary.

Consistent with the input we have provided the State, the EPA will ensure that its federal rulemaking process fully considers the best available science, including local and regional information, and applicable EPA policies, guidance, and legal requirements. These policy and legal considerations would include an assessment of downstream waters protection, environmental justice, federal trust responsibility, and tribal treaty rights and how those issues should inform the EPA's analysis of the protectiveness of the water quality criteria. At this time, the EPA believes it would be able to complete a proposed federal rule within approximately 9-12 months unless, as previously noted, it pauses its process to review a final State submittal. The EPA acknowledges that this would mean the earliest timeline for a federal proposal would likely be August 2015, which is later than the May 2015 timeframe I noted in my April 2014 letter. I believe the August timeframe strikes a balance by providing time for Washington to potentially complete its rulemaking process and submit a final rule to the EPA for Clean Water Act review while at the same time allowing the EPA to prepare to move forward with updating the federal rule should that action become necessary.

Finally, the EPA recognizes that industry and local governments have raised concerns about implementation flexibility and being provided time to meet new, more stringent water quality standards. The EPA supports Ecology's efforts to regularly engage a broad range of stakeholders about these concerns during its rulemaking process, and several of those concerns have been addressed in the State's analysis on the potential economic costs and benefits of the preliminary draft rule. The EPA intends to continue working with the State on its development and use of appropriate implementation mechanisms that are consistent with the Clean Water Act, including variances and compliance schedules.

We are keenly aware of the need to implement water quality standards in ways that make reasonable progress in improving water quality while protecting the economic viability of state industries and communities. To that end, the EPA is available to meet jointly with Ecology and key stakeholders to discuss how implementation mechanisms can and should work to make progress toward improved water quality while accounting for the needs of the regulated community. We look forward to continuing to work with the State on a successful path forward.

The EPA remains very appreciative of the challenging work that Ecology has undertaken thus far to adopt human health water quality criteria and we look forward to reviewing a rule proposal in January. Developing water quality standards that protect public health remains a high priority issue for the EPA, especially in Region 10. Please note that, as with my April 8, 2014 letter, this letter does not constitute and is not intended as an Administrator determination under CWA section 303(c)(4(B). If you would like to discuss these topics further, please contact me directly or have your staff contact Dan Opalski, our Director for the Office of Water and Watersheds, at (206) 553-1855.

Sincerely,

Dennis J. McLerran
Regional Administrator

cc: Michael Grayum, Executive Director
Northwest Indian Fisheries Commission

Brian Cladoosby, Tribal Chairman
Swinomish Tribe

Matt Steuerwalt, Policy Advisor
Washington State Governor's Office

Considerations in Deciding Which Fish to Include in Idaho's Fish Consumption Rate

Policy Summary

State of Idaho
Department of Environmental Quality

August 2015

04792

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Introduction

Water quality criteria are established, in part, to protect human health. For strongly bioaccumulative environmental contaminants, the major route of exposure is through consuming contaminated fish tissue. Therefore, water quality criteria for toxic chemicals are derived based on the usual fish consumption rate (FCR) for a targeted population. This paper summarizes the factors considered in recommending which fish to include in Idaho's regulatory FCR.

Idaho Regulatory Jurisdiction

Idaho does not have regulatory authority over discharges to either estuarine or marine waters. As such, Idaho water quality criteria have very little effect on the contaminant body burden (i.e., total amount of contaminant) of estuarine or marine fishes. Similarly, Idahoans' exposure to estuarine or marine fishes is mostly limited to what they purchase in the market.

In addition, the Clean Water Act only applies to US waters. The US Environmental Protection Agency (EPA) acknowledges this regulatory reality by excluding marine fish from its estimated national FCR. Furthermore, EPA suggests that "an inland state may only be interested in freshwater fish UFCRs [usual fish consumption rates]," acknowledging the lack of regulatory authority inland states have over the quality of both marine and estuarine fishes (EPA 2014).

Moreover, inclusion of fish in Idaho's regulatory FCR implies that Idaho water quality standards can be used to improve the quality of those included fish. Therefore, the Idaho Department of Environmental Quality (DEQ) limited the FCR to only those fish that are likely to pick up their contaminant body burden in Idaho waters and that can subsequently be expected to have reduced contaminant body burdens as a result of criteria implementation.

Market Fish versus Idaho Fish

The proposed rule excludes most market fish from the FCR used to calculate ambient water quality criteria largely because Idaho does not regulate the contaminant load of market fish. Although Idaho does have an active aquaculture industry, Idaho does not support a commercial fishing industry.[1] Therefore, it is reasonable to assume that nearly all fish purchased in the market are from outside of Idaho and that Idaho water quality standards will have little or no effect on their contaminant burden. The one exception is Rainbow Trout, as discussed below.

Importation of Market Fish

Approximately 90% of seafood consumed in the US is imported from foreign countries (i.e., not regulated under the Clean Water Act).[2] The top 10 seafood species consumed in the United States are largely imported from Asia (Table 1, Figure 1).

[1] *www.st.nmfs.noaa.gov/st1/commercial/landings/annual_landings*

[2] *www.fishwatch.gov/wild_seafood/outside_the_us*

Table 1. US per capita consumption (in 2011) and likely origin of the 10 most popular species of market seafood.[a]

Species	Per Capita Consumption (pounds)	Origin
Shrimp	4.2	>90% foreign farmed
Canned tuna	2.6	Imported from Thailand, Philippines, Vietnam, Ecuador
Salmon	1.952	Two-thirds is farmed, mainly imported from Norway, Chile, and Canada, with a small amount grown domestically
Pollock	1.12	Most is wild-caught in Alaska
Tilapia	1.287	Aquaculture. China supplies most of the tilapia in our markets, followed by Ecuador, Indonesia, and Honduras
Pangasius	0.628	Aquaculture, primarily Vietnam, with production increasing in China, Cambodia, Laos, and Thailand
Catfish	0.559	Farm-raised in the US
Crab	0.518	Wild-caught in US waters
Cod	0.501	Wild-caught in US waters. Our Alaska fisheries for Pacific cod account for more than two-thirds of the world's Pacific cod supply
Clams	0.331	Wild-caught and farm-raised in the US

[a] *Source*: *www.fishwatch.gov/features/top10seafoods_and_sources_10_10_12*

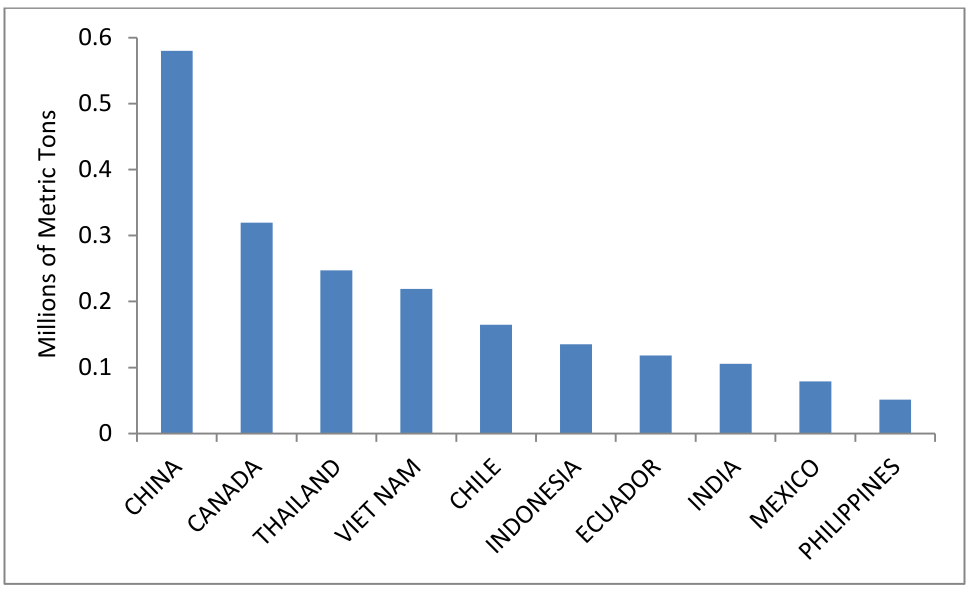

Figure 1. Top ten countries of origin for imported US seafood. Data available from *www.st.nmfs.noaa.gov/commercial-fisheries/foreign-trade/applications/monthly-product-by-countryassociation***.**

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Rainbow Trout

Idaho does have an active aquaculture industry and is a national leader in trout production, accounting for 52% of the total value of fish sold by trout growers in the US.[3] Because of the high likelihood that a trout purchased in the market originated in Idaho waters, we chose to include market trout in our regulatory FCR.

Anadromous Fish

As articulated in DEQ discussion paper #5—dated July 2014—the issue when considering anadromous fish for inclusion in an FCR is where they acquire their burden of contaminants and how that should be handled in developing water quality criteria that are applied to Idaho.

DEQ proposed excluding anadromous salmon from our regulatory FCR for reasons related to their life history and the limits of our regulatory authority. Although anadromous salmon spend key parts of their lifecycle in Idaho waters, the majority of their growth, and subsequent body burden of environmental contaminants, is derived from the marine environment.

Relative Time in Marine versus Idaho Waters

Idaho salmon spend more of their life outside than within Idaho waters. The majority of Idaho Chinook Salmon emigrate as subyearling smolts, with the remainder emigrating as yearlings. Copeland et al. (2013) found that subyearling smolts accounted for up to 60% of all Chinook emigrants (and an even larger proportion of wild Chinook emigrants) moving downstream at Lower Granite Dam (Figure 2).

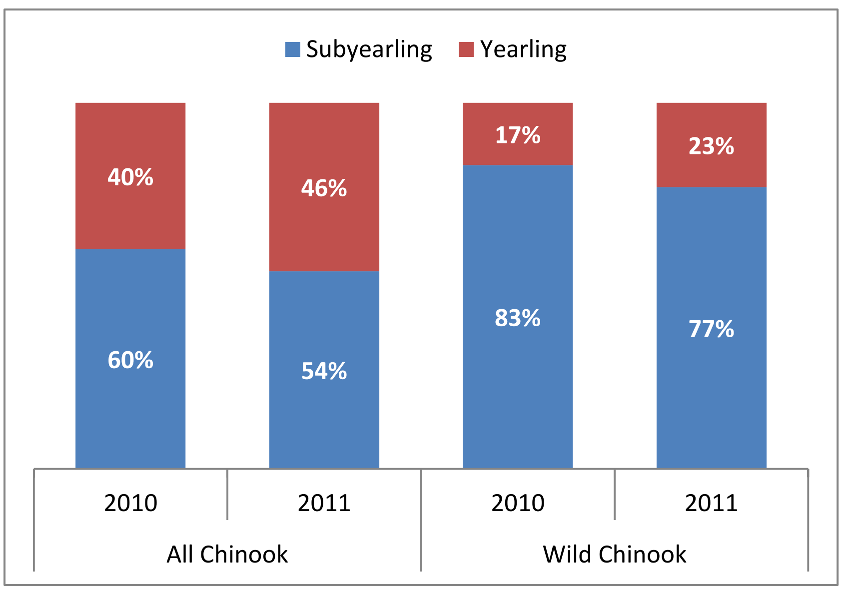

Figure 2. Percent of juvenile Chinook emigrants that were subyearling and yearling for all Chinook and wild Chinook at Lower Granite Dam, 2010 and 2011. The majority emigrate as subyearlings.

[3] *http://usda.mannlib.cornell.edu/usda/current/TrouProd/TrouProd-03-06-2015.pdf*

Most of these fish spend 2 or 3 years at sea before returning to Idaho waters to spawn. According to data from the Fish Passage Center (*www.fpc.org*), from 2000 to 2012 more than 90% of Chinook Salmon returning over Lower Granite Dam had spent at least 2 years at sea (Table 2).

Table 2. Percent of Chinook Salmon spending 1, 2, 3, or 4 years at sea before returning over Lower Granite Dam on the Snake River.

Migration Year	1 Year at Sea (%)	2 Years at Sea (%)	3 Years at Sea (%)	4 Years at Sea (%)
2000	1.5	44.6	53.7	0.2
2001	4.3	63.8	31.9	0.0
2002	10.0	75.5	14.6	0.0
2003	3.4	69.3	27.3	0.0
2004	2.3	64.8	32.0	0.8
2005	6.1	57.6	36.4	0.0
2006	7.0	72.1	20.9	0.0
2007	9.6	78.1	12.3	0.0
2008	13.1	66.6	20.2	0.0
2009	9.1	64.7	26.3	0.0
2010	18.1	59.2	22.7	0.0
2011	10.9	78.7	10.5	0.0
2012	23.1	76.9	0.0	0.0
Total, 2000–2012	9.1	67.1	23.8	0.5

Relative Growth in Marine versus Idaho Waters

Salmon growth is largely achieved in the open ocean, with more than 98% of the final weight of a salmon being achieved at sea (Quinn 2005). In fact, for the average Chinook, Sockeye, and Coho Salmon, more than 99% of the total weight of adult fish is achieved at sea (Table 3)

Table 3. Generalized weights of salmon as they enter the ocean (smolts) and adult weights, as well as the percent of total adult weight achieved at sea. Summarized from Quinn (2005).

Species	Smolt Weight (grams)	Adult Weight (grams)	Percent Weight Achieved at Sea
Chinook	18	7,220	99.75
Sockeye	10	2,690	99.63
Coho	18	3,020	99.41

Relative Source of Body Burden of Contaminants

Although salmon are known to acquire contaminants in freshwaters during early life and spawning (Qiao et al. 2000; Johnson et al. 2007), the vast majority of their body burden of contaminants is acquired in the marine environment since the vast majority of their body mass is acquired at sea.

O'Neill and West (2009) found that while Chinook smolts from a highly contaminated stream acquired organic contaminants from their natal stream, this accounted for only 3.8% of their final body burden of these contaminants.

Hope (2012) modeled 16 scenarios for Chinook Salmon exposure to polychlorinated biphenyls (PCBs), a common and typical contaminant of Chinook Salmon and their prey. He found that exposure scenarios that only included exposure in the freshwater environment (instream or through contaminated hatchery food) could not approximate observed body burden of PCBs in Chinook Salmon. Moreover, scenarios that only included exposures in estuarine and marine environments did approximate actual, observed contaminant body burdens. These results suggest that current, observed levels of PCBs in anadromous fish are almost entirely acquired outside of freshwater; removing all PCBs from the freshwater environment will have virtually no effect on the concentration of contaminants in Idaho salmon.

EPA (2014) acknowledges the insignificant role that freshwater water quality has on the contaminant body burden of anadromous fish, classifying salmon as 96% marine, 0.5% freshwater, and 3.5% estuarine. The freshwater component accounts for kokanee, a landlocked form of Sockeye Salmon. EPA states that "the freshwater percent is landlocked Sockeye Salmon (kokanee) found natively in Alaska, Washington, and Oregon, but they have also been introduced to many other states for recreational fishing." Kokanee are an important and popular freshwater species harvested in Idaho. We did not include kokanee as part of our salmon grouping, but accounted for them separately and included them in our FCR.

Steelhead Trout

Compared to other anadromous salmonids, steelhead trout life histories are highly complex. It is difficult or impossible to generalize what fraction of their time is spent in saltwater as opposed to freshwater. The anadromous and resident forms often inhabit the same waters, where they often interbreed. Furthermore, offspring may develop either migratory life history strategy, regardless of the life history strategy of their parents.

Because of the complexity of life history strategies exhibited by steelhead, and because we are not able to accurately distinguish between anadromous steelhead and resident Rainbow Trout, steelhead are included as Idaho fish in our regulatory FCR.

Further Rationale for Excluding Anadromous Salmon

Idahoans who depend largely on anadromous salmon for subsistence are particularly susceptible to high levels of fish-borne contaminants. These individuals may be looking toward this rule-making effort as a way to reduce their exposure to these contaminants. If Idaho included anadromous salmon in the FCR, we would be implying that these criteria will reduce exposure from anadromous salmon, which is not the case.

By excluding the majority of anadromous salmon and using the relative source contribution (RSC) to account for the contribution from salmon (and market fish), we are being explicit about what Idaho's water quality criteria can affect and about Idaho's jurisdictional reach.

This approach is consistent with EPA's approach, as outlined in its FCR estimate used to develop the 2015 national recommended human health criteria (EPA 2014). In its FCR, EPA limited consumption to only inland and near-shore fish, since marine fish are exposed to contaminants outside the jurisdiction of the CWA. Furthermore, EPA (2014) assigned salmon as being 96% marine (excluded from FCR used for criteria recommendation), 3.5% estuarine, and 0.5% freshwater. Since Idaho does not have jurisdiction over any near-shore marine or estuarine waters, we are proposing to exclude the estuarine proportion of salmon as well.

Popularity of Idaho Gamefish Species

The Idaho Department of Fish and Game (IDFG) conducted an angler opinion survey in 2011 to inform their *Fisheries Management Plan* (IDFG 2012). Among other information, the survey identified the most popular gamefish in Idaho (Figure 3).

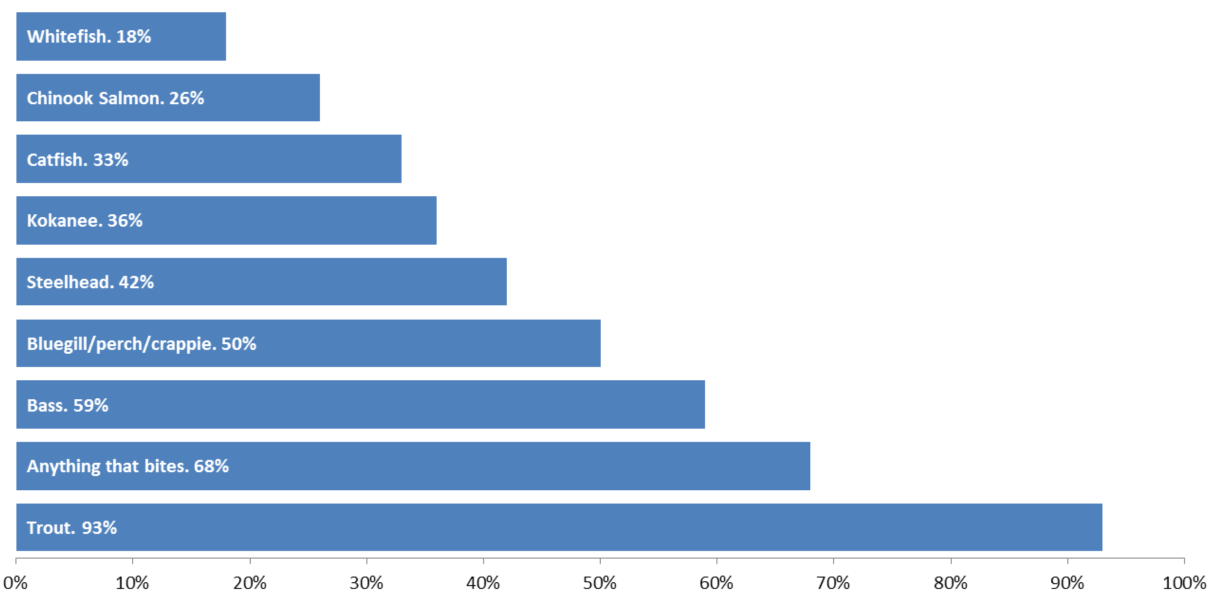

Figure 3. Gamefish most often targeted by Idaho anglers.

While the survey does not specifically address harvesting versus catch and release, it is reasonable to assume that anglers prefer to harvest fish in roughly the same proportions, making trout the most popular fish for Idaho anglers.

Suppression

Suppression of fish consumption can affect the rates reported in a survey of usual fish consumption rates. Fish consumption can be suppressed due to contamination of fishes, which in turn causes a decreased consumption of fish due to health concerns. Consumption of fish could also result from decreased availability of fish from historical levels.

From a regulatory perspective, human health water quality standards can only affect the first instance of suppression: when consumption is suppressed due to health concerns associated with contaminated fish. While there are certainly individuals in Idaho who may be limiting their fish consumption due to health concerns, this represents a very small percentage of the population: only 3% of respondents to Idaho's fish consumption survey (NWRG 2015) reported that they didn't consume seafood due to concerns about pollution or contamination. Conversely, nearly half (48%) of respondents indicated that they consumed fish at least in part for its health benefits.

Human-health based water quality standards cannot affect the second instance of suppression: when fish consumption is suppressed due to lack of availability or access to fish. Water quality standards are set to protect human health based on current conditions. Using contemporary rates is our best tool for protecting human health at current conditions. While heritage rates can be estimated, they do not reflect current reality. We believe requiring dischargers to meet criteria based on historical or future availability is unreasonable.

Fish Consumption has Increased

The concerns about suppression of fish consumption are real, and certain individuals have certainly reduced their consumption of certain fish due to both health concerns and lack of availability. Nonetheless, the broader view is that fish consumption has increased and the trend has been toward higher consumption. According to data provided by the US Department of Agriculture, since 1980, the per capita consumption of fish for the United States has increased from 12.4 pounds per year to over 15 pounds per year (US Census Bureau 2012). EPA's recommended FCR has similarly increased over the years (Figure 4). So, while localized suppression is occurring, overall fish consumption has been rising, and so has the level of consumption accounted for in the water quality criteria. Thus, concerns that suppressed fish consumption is causing a downward spiral in fish quality is not evident.

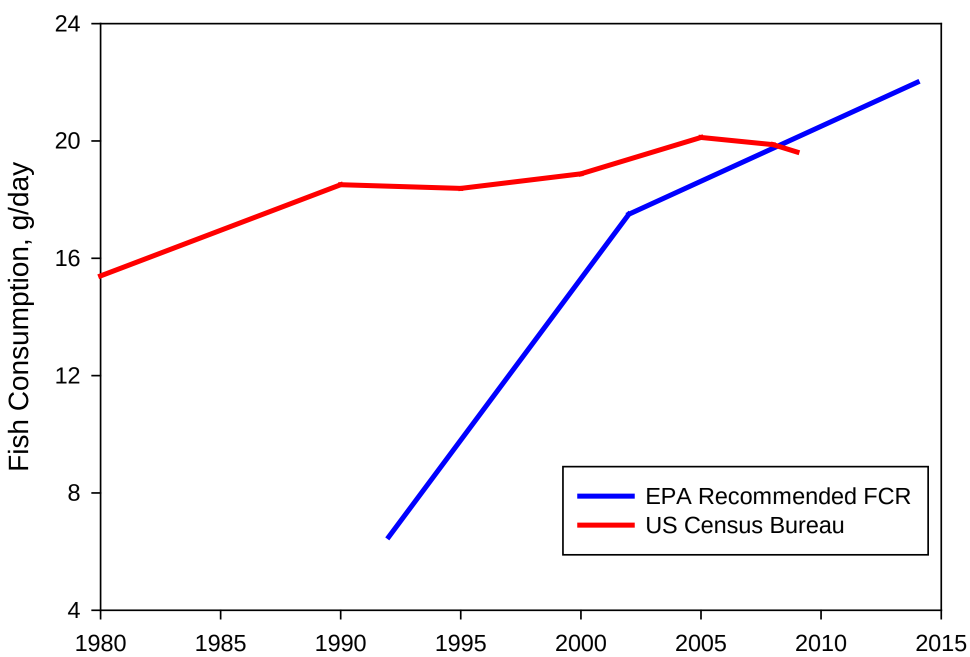

Figure 4. Per capita consumption of fish in the United States and EPA-recommended fish consumption rate (FCR), 1980–2014.

If fish become more readily available, and fish consumption increases, it is highly likely that Idaho will revise its standards and associated FCR. In fact, Idaho water quality standards have been moving toward more stringent criteria. In Idaho's 2005 update of human health criteria, our FCR increased from 6.5 to 17.5 grams/day. In 2015, we are again looking at more stringent criteria, or at least keeping them the same. Based on EPA's 2014 proposed national 304(a) criteria, we would have an increased FCR of 22 grams/day and a drinking water intake increased from 2 liters/day to 2.4 liters/day. These trends are likely to continue in the future.

References

Copeland, T., M.W. Ackerman, M.P. Corsi, P. Kennedy, K.K. Wright, M.R. Campbell, and W.C. Schrader. 2013. *Wild Juvenile Steelhead and Chinook Salmon Abundance and Composition at Lower Granite Dam, Migratory Years 2010 and 2011*. Boise, ID: Idaho Department of Fish and Game.

EPA (US Environmental Protection Agency). 2014. *Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)*. Washington, DC: EPA. EPA-820-R-14-002.

Hope, B.K. 2012. "Acquisition of Polychlorinated Biphenyls (PCBs) by Pacific Chinook Salmon: An Exploration of Various Exposure Scenarios." *Integrated Environmental Assessment and Management* 8:553–562.

IDFG (Idaho Department of Fish Game). 2012. *Fisheries Management Plan 2013–2018*. Boise, ID: IDFG.

Johnson, L.L., G.M. Ylitalo, M.R. Arkoosh, A.N. Kagley, C. Stafford, J.L. Bolton, J. Buzitis, B.F. Anulacion, and T.K. Collier. 2007. "Contaminant Exposure in Outmigrant Juvenile Salmon from Pacific Northwest Estuaries of the United States." *Environmental Monitoring and Assessment* 124:167–194.

Northwest Research Group (NWRG). 2015. *Idaho Fish Consumption Survey*. Seattle, WA.

O'Neill, S.M. and J.E. West. 2009. "Marine Distribution, Life History Traits, and the Accumulation of Polychlorinated Biphenyls in Chinook Salmon from Puget Sound, Washington." *Transactions of the American Fisheries Society* 138:616–632.

Qiao, P., A.P.C. Gobas, and A.P. Farell. 2000. "Relative Contributions of Aqueous and Dietary Uptake of Hydrophobic Chemicals to the Body Burden in Juvenile Rainbow Trout." *Archives of Environmental Contamination and Toxicology* 39:369–377.

Quinn, T.P. 2005. *The Behavior and Ecology of Pacific Salmon and Trout*. Seattle, WA: University of Washington Press.

US Census Bureau. 2012. *Statistical Abstract of the United States: 2012*, 131st ed. Washington, DC: US Census Bureau. Available at *www.census.gov/compendia/statab/*.

from other aircraft operating in visual weather conditions. The area would be depicted on appropriate aeronautical charts thereby enabling pilots to circumnavigate the area or otherwise comply with IFR procedures. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL SD E5 South Dakota, SD [New]

That airspace extending upward from 1,200 feet above the surface within an area bounded on the north by latitude 43°40′00″ N, on the east by longitude 100°05′00″ W, on the south by the South Dakota, Nebraska border, an on the west by longitude 102°00′00″ W.

* * * * *

Issued in Des Plaines, Illinois on May 7, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–13261 Filed 5–20–97; 8:45 am]

BILLING CODE 4910–13–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–5828–4]

National Emission Standards for Hazardous Air Pollutants, Proposed Rule for Pharmaceuticals Production

AGENCY: U.S. Environmental Protection Agency (U.S. EPA).

ACTION: Extension of public comment period.

SUMMARY: The EPA is announcing the extension of the public comment period on the proposed national emission standards for hazardous air pollutants (NESHAP) for pharmaceuticals production (62 FR 15754), which was published on April 2, 1997.

DATES: Written comments must be received on or before July 2, 1997.

ADDRESSES: Submit comments in duplicate if possible to: Air Docket Section (LE–131), Attention: Docket No. A–96–03, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. The EPA requests that separate copies be sent to the appropriate contact person listed below. The docket may be inspected at the above address between 8:00 a.m. and 5:30 p.m. on weekdays, and a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For information concerning the NESHAP, contact Mr. Randy McDonald at (919)541–5402, Organic Chemicals Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. For information concerning the effluent limitation guideline pretreatment standards or new source performance standards, contact Dr. Frank Hund at (202) 260–7786, Engineering and Analysis Division (4303), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20406.

SUPPLEMENTARY INFORMATION: In response to a request from the Pharmaceutical Research and Manufacturers of America (PhRMA), EPA is extending the public comment period on the proposed standards from June 2, 1997 to July 2, 1997. The EPA agrees with PhRMA that an extension of the comment period will provide for more meaningful, constructive comments on the proposed rule. Having extended the comment period, EPA nonetheless encourages commenters to submit their comments (or as many of their comments as possible) before July 2; this would assist EPA in its considerations of the issues raised. Because the EPA has continued during the comment period to examine the issues outlined in the solicitation of comments section in the preamble of the proposed rule, EPA does not believe the extension of the comment period will disrupt the Agency's schedule for promulgating this regulation.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: May 14, 1997.

Richard Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 97–13322 Filed 5–20–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[FRL–5827–8]

Withdrawal From Federal Regulations of the Applicability to Alaska of Arsenic Human Health Criteria

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule and request for comments.

SUMMARY: In 1992, EPA promulgated federal regulations establishing water quality criteria for toxic pollutants for several states, including Alaska (40 CFR 131.36). In this action, EPA is proposing to withdraw the applicability to Alaska of the federal human health criteria for arsenic. EPA is providing an

opportunity for public comment on withdrawal of the federal criteria because the state's arsenic criteria differ from the federal criteria.

DATES: EPA will accept public comments on its proposed withdrawal of the human health criteria for arsenic applicable to Alaska until July 7, 1997. Comments postmarked after this date may not be considered.

ADDRESSES: An original plus 2 copies, and if possible an electronic version of comments either in WordPerfect or ASCII format, should be addressed to Sally Brough, U.S. EPA Region 10, Office of Water, 1200 Sixth Avenue, Seattle, Washington, 98101.

The official administrative record for the consideration of this proposal for arsenic is available for public inspection at EPA Region 10, Office of Water, 1200 Sixth Avenue, Seattle, Washington, 98101, between 8:00 a.m. and 4:30 p.m. Copies of the record are also available for public inspection at EPA's Alaska Operations Offices: 222 West 7th Avenue, Anchorage, AK and 410 Willoughby Avenue, Janeau, AK.

FOR FURTHER INFORMATION CONTACT: Fred Leutner at EPA Headquarters, Office of Water (4305), 401 M Street, SW, Washington, DC, 20460 (telephone: 202–260–1542), or Sally Brough in EPA's Region 10 (telephone: 206–553–1295).

SUPPLEMENTARY INFORMATION:

Potentially Affected Entities

Citizens concerned with water quality in Alaska, and with pollution from arsenic in particular, may be interested in this proposed rulemaking. Since criteria are used in determining NPDES permit limits, entities discharging arsenic to waters of the United States in Alaska could be affected by this proposed rulemaking. Potentially affected entities include:

Category	Examples of affected entities
Industry	Industries discharging arsenic to surface waters in Alaska.
Municipalities	Publicly-owned treatment works discharging arsenic to surface waters in Alaska.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility could be affected by this action, you should carefully examine the applicability criteria in § 131.36 of title 40 of the Code of Federal Regulations. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Background

On December 22, 1992, the Environmental Protection Agency (EPA or Agency) promulgated a rule to establish federal water quality criteria for priority toxic pollutants applicable in 14 states. That rule, which is commonly called the National Toxics Rule (NTR), is codified at 40 CFR 131.36. The specific requirements for Alaska are codified at § 131.36(d)(12) and among other criteria, include water quality criteria for the protection of human health from arsenic. EPA promulgated a human health criterion for Alaska of 0.18 μg/L to protect waters designated for water consumption (i.e., sources of drinking water) plus the consumption of aquatic life which includes fish and shellfish such as shrimp, clams, oysters and mussels. This criterion is located in column D1 in the criteria matrix at section 131.36(b)(1). EPA also promulgated a criterion of 1.4 μg/L for waters designated for the human consumption of aquatic life without considering water consumption. This criterion is located in column D2 in the criteria matrix. These concentrations are designed to not exceed an excess lifetime cancer risk of 1 in 100,000 (or 10^{-5}) and reflects Alaska's preference in recent rule adoptions and in correspondence with EPA's Region 10. See 57 FR 60848, 60867.

EPA's criteria for human health protection from arsenic toxicity used in the NTR were based on carcinogenic effects. Alaska had adopted by reference EPA's published Clean Water Act (CWA) section 304(a) criteria for human health into the state's water quality standards. However, EPA's criteria guidance for carcinogens was presented at 3 different cancer risk levels, and the state had never officially adopted a specific cancer risk level. Accordingly, since Alaska did not have human health criteria for arsenic in place, EPA promulgated such criteria for the state in the NTR.

Subsequent to the promulgation of the NTR, a number of issues and uncertainties arose concerning the health effects of arsenic. EPA determined that these issues and uncertainties were sufficiently significant to necessitate a careful evaluation of the risks of arsenic exposure. Accordingly EPA has undertaken a number of activities aimed at reassessing the risks to human health from arsenic. [See Basis and Purpose section below.]

In light of EPA's review of the health effects of arsenic, the State of Alaska has proposed that the Safe Drinking Water Act (SDWA) maximum contaminant level (MCL) for arsenic of 50 μg/L currently in the state's water quality standards be used as meeting the requirements of the Clean Water Act in lieu of the current human health criteria in the NTR. As adopted by Alaska, the MCL for arsenic applies to all fresh waters that have the public water supply designated use. (According to the state, this includes all but 20 fresh-water segments.) For the reasons discussed subsequently, EPA finds that the MCL for arsenic in freshwaters designated for public water supply, in conjunction with Alaska's aquatic life criteria for arsenic, meets the requirements of the CWA, and accordingly proposes to withdraw the applicability to Alaska of the human health criteria for arsenic promulgated in the NTR.

If EPA removes the applicability of the NTR arsenic human health criteria to Alaska, the state has in place a chronic marine aquatic life criterion of 36 μg/L, a chronic freshwater aquatic life criterion of 190 μg/L, and the freshwater criterion of the MCL of 50 μg/L for waters designated for public water supply discussed above. The aquatic life criteria are in place for all of the state's marine and estuarine waters, and in those few cases where the MCL is not applicable in freshwaters.

Basis and Purpose

There are a number of ongoing national activities that may affect and/or necessitate a future change in the arsenic criteria for both ambient and drinking water in Alaska. The National Academy of Sciences (NAS) has initiated a study of the health risks posed by arsenic in water. Results of the study are expected in the Spring of 1998. Moreover, EPA is in the process of re-evaluating the risk assessments for arsenic as part of a pilot program for reconfiguring the Integrated Risk Information System (IRIS). EPA originally planned this re-evaluation to cover aspects of both cancer and non-cancer risks and to include examination of data not previously reviewed. With the initiation of the NAS study, EPA redirected the focus of the IRIS re-evaluation to the application of the proposed revisions to EPA's Guidelines for Cancer Risk Assessment. The IRIS re-evaluation of arsenic is expected in

1997. EPA encourages the state to review its water quality criteria for arsenic as this new information becomes available.

EPA has recognized the use of appropriate MCLs in establishing water quality standards under the CWA. Agency guidance notes the differences between the statutory factors for developing SDWA MCLs and CWA section 304(a) criteria, but provides that where human consumption of drinking water is the principal exposure to a toxic chemical, then an existing MCL may be an appropriate concentration limit. See guidance noticed in 54 FR 346, January 5, 1989. Similarly, the CWA section 304(a) human health guidelines are consistent with this position. See 45 FR 79318, November 28, 1980.

To determine whether the MCL could appropriately be used in lieu of the NTR's human health criteria for arsenic, EPA has prepared an exposure analysis to estimate the significance of human consumption of fish and shellfish containing the amounts of inorganic arsenic indicated as present in representative samples of fish and shellfish, in conjunction with the consumption of water containing concentrations of arsenic currently existing in the Nation's waters. See EPA's ''Arsenic and Fish Consumption Concerns'' in the administrative record for this rulemaking. This analysis first recognizes that the most important toxic form of arsenic is inorganic arsenic. Inorganic arsenic is the principal form in surface waters and almost the exclusive form in ground waters. However, the arsenic in fish and most shellfish is largely present as organic arsenic (mostly arsenobetaine). Available information indicates that arsenobetaine passes through these organisms with minimal retention in the fish and shellfish tissues.

In the NTR, EPA based the promulgated criteria on the human health criteria methodology contained in the 1980 human health guidelines. To estimate the ambient water concentration of a pollutant that does not represent a significant risk to the public (i.e., the criteria levels), the methodology makes certain assumptions about human exposure to pollutants. The methodology assumes that for most people, drinking water intake is 2 liters per day, and that fish consumption is 6.5 grams per day (a little less than one-half pound per month). The methodology incorporates a bioconcentration factor (BCF) to account for a pollutant's concentration in fish and shellfish tissue versus its concentration in the water. The methodology also assumes that all of the water and fish consumed is contaminated at the criteria levels (the ''safe'' levels).

Using these same exposure factors from the methodology, EPA has assessed the effect of using the arsenic MCL. Assuming that the concentration of arsenic in water is at the MCL of 50 μg/L, most people would be exposed to 100 μg of arsenic from their drinking water intake (i.e., 2 L/day × 50 μg/L = 100 μg/day), and 0.6 μg/day of inorganic arsenic from consuming 6.5 grams of fish and shellfish collected from water at the arsenic MCL concentration and assuming the BCF used in the NTR. (See derivation in EPA's ''Arsenic and Fish Consumption Concerns'' in the record.) The total estimated exposure would be 100.6 μg/day which could consist entirely of inorganic arsenic. EPA considers the small increment of exposure from fish consumption to be insignificant. EPA therefore concludes that when applied to fresh waters in Alaska, use of 50 μg/L generally provides a level of protection equivalent to that provided by the MCL. A full characterization of other exposure scenarios is contained in EPA's exposure analysis described above. This analysis is in the administrative record for this proposal and is currently undergoing external peer review. The results of the peer review will be considered before final action is taken on this rule.

For regions in Alaska where high levels of arsenic in the potable water are accompanied by high levels of fish and shellfish consumption, the State of Alaska should develop site-specific criteria for the surface waters involved considering the arsenic content of the drinking water and fish consumed. In developing site-specific criteria the state should characterize the size and location of the population of concern and determine their fish/shellfish and water intake rates. The fish and shellfish consumption should consider the species and dietary intake on a per species basis. Actual total arsenic and inorganic arsenic values for the species consumed and actual concentrations in drinking water should be used in the exposure calculations whenever possible.

The Agency solicits comment on whether there are any locations in Alaska where the arsenic criteria in the NTR should not be removed. For such locations, EPA solicits data documenting such existing conditions which indicate that fish consumers may be at an unacceptable risk of arsenic toxicity, and whether some other site-specific arsenic human health criteria may be appropriate. EPA solicits any information such as that described above concerning possible site-specific criteria to be developed by the State of Alaska.

Regulatory Procedural Information

This proposed withdrawal of human health criteria for arsenic in Alaska is deregulatory in nature and would impose no additional regulatory requirements or costs. Therefore, it has been determined that this proposed action is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

Based on the fact that this action is deregulatory in nature and would impose no regulatory requirements or costs, pursuant to section 605(b) of the Regulatory Flexibility Act, the Administrator certifies that this action will not have a significant economic impact on a substantial number of small entities. EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for state, local and tribal governments, in the aggregate, or to the private sector in any one year. EPA has also determined that this action contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's action is not subject to the requirements of sections 202, 203 and 205 of the UMRA.

This proposed rule does not impose any requirement subject to the Paperwork Reduction Act.

List of Subjects in 40 CFR Part 131

Environmental protection, Water pollution control, Water quality standards.

Dated: May 14, 1997.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 131 of the Code of Federal Regulations is proposed to be amended as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

§ 131.36 [Amended]

2. In § 131.36(d)(12)(ii) the table is amended under the heading ''Applicable Criteria'', in the entry for ''Column D1'' and three entries for

''Column D2'' by removing the number ''2'' from the list of numbers.

[FR Doc. 97–13325 Filed 5–20–97; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[MD Docket No. 96–186]

Assessment and Collection of Regulatory Fees For Fiscal Year 1997

May 16, 1997.

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking; availability of documents.

SUMMARY: The Commission has placed several documents in the docket file associated with this proceeding which provide background information used in developing its regulatory fee proposals for FY 1997.

FOR FURTHER INFORMATION CONTACT: Peter W. Herrick, Office of Managing Director at (202) 418–0443, or Terry D. Johnson, Office of Managing Director at (202) 418–0445.

SUPPLEMENTARY INFORMATION:

Additional Cost of Service Information Related to Establishing Regulatory Fees for Fiscal Year 1997 Available in MD Docket No. 96–186

The Office of the Managing Director, in response to a request by Comsat International Communications, has provided to Comsat additional documents related to the Commission's distribution of costs among services and other information utilized in the development of its annual regulatory fees. *See letter* to Robert A. Mansbach, Esquire from Andrew S. Fishel, Managing Director, dated April 4, 1997. Relevant information provided to Comsat and other information related to the development of the Commission's regulatory fees, including actual FY 1996 payment information, has been placed in the docket file for the Commission's proceeding to establish its regulatory fees for Fiscal Year 1997. These materials are available for public inspection during regular business hours in the Commission's Public Reference Room (Room 239) at its headquarters, 1919 M Street, N.W., Washington, D.C. *See* notice of proposed rulemaking re assessment and collection of regulatory fees for Fiscal Year 1997, MD Docket No. 96–186, 62 FR 10793, March 10, 1997. Copies of materials contained in the docket file may be purchased from the Commission's copy contractor, International Transcription Services (ITS), in Room 246 or by calling 202–857–3800.

Federal Communications Commission.

LaVera F. Marshall,

Acting Secretary.

[FR Doc. 97–13368 Filed 5–20–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–131, RM–9078]

Radio Broadcasting Services; Twin Falls, ID

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed on behalf of JTL Communications Corporation requesting the allotment of Channel 294A to Twin Falls, Idaho, as an additional local FM broadcast service at that community. Coordinates used for Channel 294A at Twin Falls are 42–33–42 and 114–28–12.

DATES: Comments must be filed on or before July 7, 1997, and reply comments on or before July 22, 1997.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: J. Frederick Mack and Bradley J. Wiskirchen, Esqs., Holland & Hart, Suite 1400, U.S. Bank Plaza, 101 South Capitol Boulevard, PO Box 2527, Boise, ID 83701.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 97–131, adopted May 7, 1997, and released May 16, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–13285 Filed 5–20–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–130; RM–8751]

Radio Broadcasting Services; Galesburg, IL and Ottumwa, IA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Northern Broadcast Group proposing the substitution of Channel 224B1 for Channel 224A at Galesburg, Illinois, and the modification of Station WGBQ(FM)'s license accordingly. To accommodate the upgrade, petitioner also requests that the allotment reference coordinates for now vacant and unapplied-for Channel 224C3 at Ottumwa, Iowa, be modified. Channel 224B1 can be allotted to Galesburg, in compliance with the Commission's minimum distance separation requirements with a site restriction of 13.4 kilometers (8.3 miles) northwest at petitioner's requested site. The coordinates for Channel 224B1 at Galesburg are North Latitude 41–02–50 and West Longitude 90–27–30. *See* Supplementary Information, *infra.*

DATES: Comments must be filed on or before July 7, 1997 and reply comments on or before July 22, 1997.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554. In addition to filing comments with the

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0064; FRL–9929–77–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Steel Pickling, HCl Process Facilities and Hydrochloric Acid Regeneration Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Steel Pickling, HCl Process Facilities and Hydrochloric Acid Regeneration Plants (40 CFR part 63, subpart CCC) (Renewal)'' (EPA ICR No. 1821.08, OMB Control No. 2060–0419) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through June 30, 2015. Public comments were previously requested via the **Federal Register** (79 FR 30117) on May 27, 2014 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before July 29, 2015.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0064, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This rule applies to all facilities that pickle steel using hydrochloric acid or regenerate hydrochloric acid, and are major sources or are part of a facility that is a major source.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Any owner/operator subject to the provisions of this part shall maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, maintenance reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the United States Environmental Protection Agency (EPA) regional office.

Form Numbers: None.

Respondents/affected entities: Steel pickling, hydrochloric acid process and regeneration facilities.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 100 (total).

Frequency of response: Initially, occasionally and semiannually.

Total estimated burden: 35,100 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3,530,000 (per year), includes $10,600 annualized capital or operation & maintenance costs.

Changes in the Estimates: The increase in burden and cost from the most recently approved ICR is due to an adjustment. It is not due to any program changes. During the 2012 RTR, EPA did not add additional requirements, other than reporting performance test results through the WebFIRE interface if the test methods used are those supported by the Electronic Reporting Tool (ERT). However, we updated the estimated number of average number of respondents subject to Subpart CCC from 72 to 100. The increase in the number of facilities results in an overall increase in the respondent and Agency burden and in O&M costs.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2015–15796 Filed 6–26–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2014–0135; FRL–9929–85–OW]

Final Updated Ambient Water Quality Criteria for the Protection of Human Health

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) announces the final updated recommended ambient water quality criteria for the protection of human health for ninety-four chemical pollutants to reflect the latest scientific information and implementation of existing EPA policies found in *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000).* The EPA issued the draft updated human health criteria on May 13, 2014 and accepted written views from the public until August 13, 2014. The EPA prepared responses to those public comments. The EPA's recommended ambient water quality criteria for the protection of human health provide technical information for states and authorized tribes to establish water quality standards (*i.e.,* criteria) to protect human health under the Clean Water Act. These final 2015 updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

FOR FURTHER INFORMATION CONTACT: Jamie Strong, Office of Water, Health and Ecological Criteria Division (4304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 566–0056; email address: *strong.jamie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. How can I get copies of this document and other related information?

1. *Docket.* EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2014–0135; FRL–9929–85–OW. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

2. *Electronic Access.* You may access this **Federal Register** document electronically from the Government Publishing Office under the ''**Federal Register**'' listings at FDSys (*http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR).* EPA's final criteria documents for the ninety-four chemical pollutants, the response to views from the public on the draft criteria, and supporting information are also available on EPA's Web site *http://water.epa.gov/scitech/swguidance/standards/criteria/health/.*

II. What are EPA's recommended water quality criteria?

EPA's recommended water quality criteria are scientifically derived numeric values that EPA determines will generally protect aquatic life or human health from the adverse effects of pollutants in ambient water.

Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish and, from time to time, revise criteria for protection of water quality and human health that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended Section 304(a) criteria provide technical information for states and authorized tribes to consider and use in adopting water quality standards that ultimately provide the basis for assessing water body health and controlling discharges of pollutants into waters of the United States. Under the CWA and its implementing regulations, states and authorized tribes are required to adopt water quality criteria to protect designated uses (*e.g.,* public water supply, aquatic life, recreational use, or industrial use) and that are based on sound scientific rationale. EPA's recommended criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized tribes have the discretion to adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations. Ultimately, however, such criteria must protect the designated use and be based on sound scientific rationale.

III. Information on EPA's 2015 final updated human health criteria

EPA announces the availability of final updated national recommended water quality criteria for the protection of human health for ninety-four chemical pollutants. These revisions are based on EPA's existing methodology for deriving human health criteria in *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000) (EPA–822–B–00–004, October 2000). The methodology describes EPA's approach for deriving national recommended water quality criteria for the protection of human health. Table 1 presents the updated human health criteria for ninety-four chemical pollutants.

TABLE 1—REVISED HUMAN HEALTH WATER QUALITY CRITERIA

Pollutant	CAS No.	Human health water quality criteria for the consumption of	
		Water + organism (µg/L)	Organism only (µg/L)
1,1,1-Trichloroethane	71–55–6	10,000	200,000
1,1,2,2-Tetrachloroethane	79–34–5	0.2	3
1,1,2-Trichloroethane	79–00–5	0.55	8.9
1,1-Dichloroethylene	75–35–4	300	20,000
1,2,4,5-Tetrachlorobenzene	95–94–3	0.03	0.03
1,2,4-Trichlorobenzene	120–82–1	0.071	0.076
1,2-Dichlorobenzene	95–50–1	1,000	3,000
1,2-Dichloroethane	107–06–2	9.9	650
1,2-Dichloropropane	78–87–5	0.90	31
1,2-Diphenylhydrazine	122–66–7	0.03	0.2
1,3-Dichlorobenzene	541–73–1	7	10
1,3-Dichloropropene	542–75–6	0.27	12
1,4-Dichlorobenzene	106–46–7	300	900
2,4,5-Trichlorophenol	95–95–4	300	600
2,4,6-Trichlorophenol	88–06–2	1.5	2.8
2,4-Dichlorophenol	120–83–2	10	60
2,4-Dimethylphenol	105–67–9	100	3,000
2,4-Dinitrophenol	51–28–5	10	300
2,4-Dinitrotoluene	121–14–2	0.049	1.7
2-Chloronaphthalene	91–58–7	800	1,000
2-Chlorophenol	95–57–8	30	800
2-Methyl-4,6-Dinitrophenol	534–52–1	2	30

TABLE 1—REVISED HUMAN HEALTH WATER QUALITY CRITERIA—Continued

Pollutant	CAS No.	Human health water quality criteria for the consumption of	
		Water + organism (μg/L)	Organism only (μg/L)
3,3′-Dichlorobenzidine	91–94–1	0.049	0.15
3-Methyl-4-Chlorophenol	59–50–7	500	2,000
Acenaphthene	83–32–9	70	90
Acrolein	107–02–8	3	400
Acrylonitrile	107–13–1	0.061	7.0
Aldrin	309–00–2	0.00000077	0.00000077
alpha-Hexachlorocyclohexane (HCH)	319–84–6	0.00036	0.00039
alpha-Endosulfan	959–98–8	20	30
Anthracene	120–12–7	300	400
Benzene	71–43–2	0.58–2.1	16–58
Benzidine	92–87–5	0.00014	0.011
Benzo(a)anthracene	56–55–3	0.0012	0.0013
Benzo(a)pyrene	50–32–8	0.00012	0.00013
Benzo(b)fluoranthene	205–99–2	0.0012	0.0013
Benzo(k)fluoranthene	207–08–9	0.012	0.013
beta-Hexachlorocyclohexane (HCH)	319–85–7	0.0080	0.014
beta-Endosulfan	33213–65–9	20	40
Bis(2-Chloro-1-Methylethyl) Ether	108–60–1	200	4,000
Bis(2-Chloroethyl) Ether	111–44–4	0.030	2.2
Bis(2-Ethylhexyl) Phthalate	117–81–7	0.32	0.37
Bis(Chloromethyl) Ether	542–88–1	0.00015	0.017
Bromoform	75–25–2	7.0	120
Butylbenzyl Phthalate	85–68–7	0.10	0.10
Carbon Tetrachloride	56–23–5	0.4	5
Chlordane	57–74–9	0.00031	0.00032
Chlorobenzene	108–90–7	100	800
Chlorodibromomethane	124–48–1	0.80	21
Chloroform	67–66–3	60	2,000
Chlorophenoxy Herbicide (2,4–D)	94–75–7	1,300	12,000
Chlorophenoxy Herbicide (2,4,5–TP) [Silvex]	93–72–1	100	400
Chrysene	218–01–9	0.12	0.13
Cyanide	57–12–5	4	400
Dibenzo(a,h)anthracene	53–70–3	0.00012	0.00013
Dichlorobromomethane	75–27–4	0.95	27
Dieldrin	60–57–1	0.0000012	0.0000012
Diethyl Phthalate	84–66–2	600	600
Dimethyl Phthalate	131–11–3	2,000	2,000
Di-n-Butyl Phthalate	84–74–2	20	30
Dinitrophenols	25550–58–7	10	1,000
Endosulfan Sulfate	1031–07–8	20	40
Endrin	72–20–8	0.03	0.03
Endrin Aldehyde	7421–93–4	1	1
Ethylbenzene	100–41–4	68	130
Fluoranthene	206–44–0	20	20
Fluorene	86–73–7	50	70
gamma-Hexachlorocyclohexane (HCH)	58–89–9	4.2	4.4
Heptachlor	76–44–8	0.0000059	0.0000059
Heptachlor Epoxide	1024–57–3	0.000032	0.000032
Hexachlorobenzene	118–74–1	0.000079	0.000079
Hexachlorobutadiene	87–68–3	0.01	0.01
Hexachlorocyclohexane (HCH)-Technical	608–73–1	0.0066	0.010
Hexachlorocyclopentadiene	77–47–4	4	4
Hexachloroethane	67–72–1	0.1	0.1
Indeno(1,2,3-cd)pyrene	193–39–5	0.0012	0.0013
Isophorone	78–59–1	34	1,800
Methoxychlor	72–43–5	0.02	0.02
Methyl Bromide	74–83–9	100	10,000
Methylene Chloride	75–09–2	20	1,000
Nitrobenzene	98–95–3	10	600
Pentachlorobenzene	608–93–5	0.1	0.1
Pentachlorophenol	87–86–5	0.03	0.04
Phenol	108–95–2	4,000	300,000
p,p′-Dichlorodiphenyldichloroethane (DDD)	72–54–8	0.00012	0.00012
p,p′-Dichlorodiphenyldichloroethylene (DDE)	72–55–9	0.000018	0.000018
p,p′-Dichlorodiphenyltrichloroethane (DDT)	50–29–3	0.000030	0.000030
Pyrene	129–00–0	20	30
Tetrachloroethylene (Perchloroethylene)	127–18–4	10	29
Toluene	108–88–3	57	520

TABLE 1—REVISED HUMAN HEALTH WATER QUALITY CRITERIA—Continued

Pollutant	CAS No.	Human health water quality criteria for the consumption of	
		Water + organism (µg/L)	Organism only (µg/L)
Toxaphene	8001–35–2	0.00070	0.00071
trans-1,2-Dichloroethylene (DCE)	156–60–5	100	4,000
Trichloroethylene (TCE)	79–01–6	0.6	7
Vinyl Chloride	75–01–4	0.022	1.6

The revision of these criteria is a systematic update of EPA's national recommended human health criteria. EPA previously described its process for publishing revised criteria [see National Recommended Water Quality Criteria—Correction (64 FR 19781; or EPA–822–Z–99–001) or the **Federal Register** Notice for EPA's 2000 Methodology (65 FR 66444)]. EPA updated the human health criteria using externally peer-reviewed information sources.

On May 13, 2014, EPA announced the availability of the draft updated human health criteria in the **Federal Register** notice ''Updated National Recommended Water Quality Criteria for the Protection of Human Health'' (79 FR 27303) and announced that written views would be accepted from the public until July 14, 2014. In response to stakeholder requests, on June 23, 2014, EPA announced in the **Federal Register** (79 FR 35545) an extension of the public comment period for an additional 30 days, until August 13, 2014. EPA reviewed and considered all public comments received and prepared responses to those comments.

EPA developed chemical-specific science documents for each of the ninety-four chemical pollutants. These documents detail the latest scientific information supporting the final human health criteria, particularly the updated toxicity and exposure input values. A fact sheet and a summary of updated input parameters (*e.g.,* health toxicity values, bioaccumulation factors) used to derive the final updated criteria are provided. All these documents, including EPA's responses to views received during the comment period, are available on EPA's Web site at *http://water.epa.gov/scitech/swguidance/standards/criteria/health/.*

IV. What is the relationship between EPA's 2015 final updated human health criteria and state or tribal water quality standards?

Section 303(a)–(c) of the CWA requires states and authorized tribes to adopt water quality standards for their waters. As part of the water quality standards triennial review process set forth in section 303(c) of the CWA, states and authorized tribes are required to review and revise, if appropriate, their water quality standards at least once every three years.

States and authorized tribes must adopt water quality criteria that protect designated uses. 40 CFR 131.11(a)(1). Criteria must be based on a sound scientific rationale and contain sufficient parameters or constituents to protect the designated uses. Id. Criteria may be expressed in either narrative or numeric form. EPA's regulations provide that states and authorized tribes should adopt numeric water quality criteria based on:

(1) EPA's recommended section 304(a) criteria; or

(2) EPA's recommended section 304(a) criteria modified to reflect site-specific conditions; or

(3) Other scientifically defensible methods. (40 CFR 131.11(b)).

It is important for states and authorized tribes to consider any new or updated section 304(a) recommended criteria as part of their triennial review process to ensure that state or tribal water quality criteria reflect sound science and protect applicable designated uses. EPA recently proposed revisions to its water quality standards regulations that would, if finalized without substantive change, require states during their triennial reviews to consider new or updated section 304(a) recommended criteria and, if they do not adopt new or revised criteria for such pollutants, provide an explanation to EPA and the public as to why the state did not do so. These final updated section 304(a) human health criteria recommendations supersede EPA's previous recommendations.

Dated: June 22, 2015.

Kenneth J. Kopocis,

Deputy Assistant Administrator, Office of Water.

[FR Doc. 2015–15912 Filed 6–26–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice

June 25, 2015.

TIME AND DATE: 10:00 a.m., Thursday, July 9, 2015.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor* v. *Newtown Energy, Inc.,* Docket No. WEVA 2011–283 (Issues include whether the Administrative Law Judge erred by concluding that the violation in question was not significant and substantial and was not the result of an unwarrantable failure to comply.).

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Sarah Stewart,

Deputy General Counsel.

[FR Doc. 2015–16049 Filed 6–25–15; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the

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HON. ROBERT S. LASNIK

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

SIERRA CLUB; and CENTER FOR ENVIRONMENTAL LAW AND POLICY, Plaintiffs, and THE SPOKANE TRIBE OF INDIANS, Plaintiff-Intervenor v. DENNIS McLERRAN; GINA MCCARTHY and U.S. ENVIRONMENTAL PROTECTION AGENCY, Defendants. and SPOKANE COUNTY; KAISER ALUMINUM OF WASHINGTON LLC; and STATE OF WASHINGTON DEPARTMENT OF ECOLOGY, Defendant-Intervenors.	No. 2:11-cv-01759-RSL EPA'S CONSOLIDATED BRIEF (A) IN SUPPORT OF ITS CROSS-MOTION FOR SUMMARY JUDGMENT AND (B) IN OPPOSITION TO PLAINTIFFS' AND INTERVENOR-PLAINTIFF TRIBE OF SPOKANE INDIANS' RESPECTIVE MOTIONS FOR SUMMARY JUDGMENT Filed pursuant to order on briefing schedule Oral Argument Requested

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INTRODUCTION AND SUMMARY

Defendants United States Environmental Protection Agency, et al., (collectively "EPA"), oppose Plaintiffs' and Intervenor Spokane Tribe of Indians' motions for summary judgment and cross-move for summary judgment in EPA's favor.

The Washington State Department of Ecology ("Ecology") has a robust program establishing total maximum daily loads ("TMDLs") throughout Washington State. Over the past fifteen years, Ecology has established hundreds of TMDLs, and it is continuing to develop others for waterbody segments that do not meet water quality standards, including many within the Spokane River Basin. Notwithstanding such ongoing TMDL work, because many TMDLs remain to be completed, Ecology has had to make necessarily difficult choices regarding the priority and timing of which TMDLs will be developed before others, how to allocate limited resources among competing environmental demands, and the establishment of interim, supplemental steps to reduce pollution until required TMDLs are completed. Among its many prioritization decisions, Ecology determined that a TMDL for polychlorinated biphenyls ("PCBs") for the Spokane River should be a lower priority, primarily due to the lack of critical information and analysis, and that Ecology will devote its efforts and resources in the interim to reduce PCBs in the River through a Task Force created for this purpose comprised of State and local agencies, dischargers of pollutants, and environmental groups created for this purpose. If these or other supplemental measures are not enough for the Spokane River to attain applicable PCB standards, Ecology has committed to develop a Spokane River PCB TMDL. Based upon EPA's review of Ecology's plans and the rest of the record in this case, EPA reasonably concluded that Ecology has not renounced its obligation to develop and establish a Spokane River PCB TMDL and that the absence of such a State-submitted TMDL at this time does not constitute Ecology having constructively submitted "no" PCB TMDL (i.e., a State determination that none will be needed). Accordingly, the Clean Water Act ("CWA") does not require that EPA approve or disapprove such a constructive submission.

Plaintiffs and the Spokane Tribe invoke the constructive submission theory in an effort to circumvent and undermine this and other ongoing State decisions as to how best to protect the environment. By demanding a PCB TMDL for the Spokane River, which Plaintiffs and the Tribe believe should be prioritized before all other TMDLs and other State efforts to reduce pollution, and by seeking a court order that EPA establish that particular TMDL, Plaintiffs and the Tribe ask the Court to usurp Ecology's role and substitute their own priorities for the State's reasonable pollution prevention and remediation plans. Plaintiffs and Intervenor are understandably focused on concerns posed by PCBs in the Spokane River. There are, however, other, ongoing efforts to reduce PCBs and other pollutants in the Spokane River and in numerous other impaired water-bodies throughout the State that also require the attention of limited State and federal resources.

Section I.A below demonstrates that as a matter of law the constructive submission theory is not applicable where, as here, parties seek to compel the establishment of one particular TMDL above all others, and that such claims must therefore be dismissed and summary judgment entered for EPA. Section I.B explains that Plaintiffs have waived their right to challenge EPA's administrative finding that there has been no constructive submission, because they elected not to brief that Administrative Procedure Act challenge in their summary judgment motion. Section I.C demonstrates that EPA reasonably concluded that Ecology has not disavowed establishing a PCB TMDL for the Spokane River, that Ecology has a reasonable plan for reducing PCBs in the Spokane River and obtaining needed information, and that Ecology remains committed to developing a TMDL if necessary. Ecology, therefore, has not made a constructive submission, and thus EPA has no duty to approve or disapprove such a submission. Section II responds to the arguments proffered by Intervenor Spokane Tribe. Finally, Section III demonstrates that even if there is a constructive submission, Plaintiffs and the Tribe are not entitled to the relief they seek.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

The Clean Water Act establishes a comprehensive program "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters" through the reduction and eventual elimination of the discharge of pollutants into those waters. 33 U.S.C. § 1251(a). States are primarily responsible for achieving these goals. *Id.* § 1251(b); *Chevron U.S.A. v. Hammond*, 726 F.2d 483, 489 (9th Cir. 1984) ("[T]he states maintain primary responsibility for abating pollution in their jurisdictions."); *District of Columbia v. Schramm*, 631 F.2d 854, 860 (D.C. Cir. 1980) (the CWA "scheme . . . impose[s] major responsibility for control of pollution on the states"). State lists of water quality limited segments ("WQLS") within their boundaries ("Section 303(d) lists") and Total Maximum Daily Loads ("TMDLs") are but one part of the complex water pollution control regime created by the CWA.

A. The NPDES Permit Program

The CWA's central regulatory features are established by the National Pollutant Discharge Elimination System ("NPDES") permit program. 33 U.S.C. § 1342(a)(1); 40 C.F.R. §122.44(a), (d)(1). Pollutant discharges from point sources[1]/ into waters of the United States are prohibited unless in compliance with specified sections of the CWA. 33 U.S.C. § 1311(a). If the conditions of a permit are violated, they may be enforced by the United States, or any interested person, including a State. *Id.* § 1319. Forty-six States, including Washington, are authorized to administer NPDES permit programs under their State laws and regulations, though EPA retains an oversight role. *Id.* § 1342(b). In the remaining States, EPA issues the permits. *Id.* § 1342(a). EPA first approved Washington's NPDES permitting program in 1973. 54 Fed. Reg. 40517 (Oct. 2, 1989).

NPDES permits control water pollution from point sources by means of two different overarching strategies. The first approach, the "technology-based" approach, reduces pollution by requiring dischargers to achieve specified restrictions on the quantities, rates, and concentrations (known as "effluent limitations") based on specific process-based controls. 33 U.S.C. §§ 1311, 1314, 1316-17, 1363(11). The CWA requires EPA to develop and promulgate national technology-based regulations establishing minimum levels of wastewater treatment for categories of industrial sources. *Rybachek v. EPA*, 904 F.2d 1276, 1283 (9th Cir. 1990). During the 1970s

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[1]/ A "point source" is defined as "any discernible, confined and discrete conveyance ... from which pollutants are or may be discharged." *Id.* § 1362(14) (*e.g.*, industrial, commercial and municipal discharges). This statutory definition excludes "agricultural stormwater discharges and return flows from irrigated agriculture." *Id.* § 1362(14). The term "nonpoint source" commonly refers to any source of water pollution that is not a point source and is typically associated with diffuse sources and rural areas.

and 1980s, EPA gave priority to developing the new technology-based regulations, which EPA and the states implemented through the new NPDES permit program. Because of the magnitude and scope of the national water pollution control task, and consistent with stated Congressional intent, EPA and the States dedicated implementation resources to developing these technology-based controls and basic programs, deferring action on the next level of controls based on water quality standards. *See* 1A *Leg. History of the Water Pollution Control Act Amendments of 1972* (Comm. Print 1973), at 171. Accordingly, EPA has issued technology-based regulations for more than 50 major categories of industrial dischargers. 40 C.F.R. Pts. 405-471. After establishment of NPDES permitting programs, including technology-based controls, regulatory efforts focused on the difficult task of determining the desired water quality for each waterbody and establishing effluent limits based upon such standards.

B. Water-Quality-Based Controls

The CWA is designed to ensure that water quality standards would be attained even if technology-based controls were insufficient to do so. CWA § 303 directs the States, with federal approval and oversight, to adopt water quality standards for each particular waterbody or waterbody segment within their boundaries. 33 U.S.C. § 1313(a), (b) & (c)(1). Water quality standards identify (1) the "designated uses" for each waterbody (e.g., public water supply, propagation of fish, and/or recreational uses) and (2) the "water quality criteria" expressed as levels (e.g., concentrations and/or conditions) that must not be exceeded in order for the waterbody to support those uses (e.g., oxygen concentrations necessary for healthy fish). *Id.* § 1313(c)(2). EPA either approves a State's proposed water quality standards or, if it disapproves, proposes and promulgates standards for the State. *Id.* § 1313(c)(3).

After adoption and approval of water quality standards, CWA section 303(d) directs the States to identify and prioritize the impaired or threatened waters within their borders, known as water-quality-limited segments ("WQLSs"). *Id.* § 1313(d)(1)(A) & (B); 40 C.F.R. § 130.7(b)(1). States are then to develop plans, known as total maximum daily loads ("TMDLs") for pollutants in those WQLSs. 33 U.S.C. § 1313(d).

CWA § 303(d)(2) requires that each State submit "from time to time" its list of WQLSs. *Id.* § 1313(d)(2). EPA's regulations specify that the States submit their lists of WQLSs (the "Section 303(d) list") to EPA on a biennial basis. 40 C.F.R. § 130.7(d). EPA must approve or disapprove Section 303(d) lists within 30 days after submission. 33 U.S.C. § 1313(d)(2). If EPA disapproves, it must identify the WQLSs to be added within 30 days from the date of disapproval. *Id*. Although States submit their priority rankings of WQLSs for TMDL development with their Section 303(d) lists, EPA does not approve or disapprove the substance of these rankings. *Id.* Moreover, if a WQLS on a 303(d) list subsequently achieves the water quality standard for which it is impaired, it may be removed from the next Section 303(d) list and thus a TMDL is no longer required. 40 C.F.R. §§ 131.7(b)(1) & 130.2(j).

States are required to establish a priority ranking for TMDL development for WQLSs included on the Section 303(d) list. 33 U.S.C. § 1313(d)(1)(A). In establishing priority ranking, States must consider the severity of the pollution and the uses of the listed waterbody. *Id.* § 1313(d)(1)(A). Beyond these two statutory factors, States retain considerable discretion and may consider other factors, including: vulnerability of particular waters; recreational, economic, and aesthetic importance of particular waters; restoration potential; degree of public interest and support; State or national policies and priorities; technical considerations, such as the complexity of the impairment; availability of adequate data and models; and implementation of watershed-based permitting programs or basin planning cycles. *See* V.1, T.47 at 971-72; V.1, T.19 at 242.[2]/

States identify those WQLSs targeted for TMDL development in the next two years. 40 C.F.R § 130.7(b)(4) & (d)(1). States have discretion in selecting higher and lower ranked waters for TMDL development based on the numerous factors described above.

TMDL development requires States to identify the maximum amount of pollutant

[2]/ The administrative record for judicial review in this case was filed on April 22, 2013, in paper form, in five binders (or volumes), as well on a compact disc. Dkt. No. 60. References in this brief to that record are to the volume and document number (or tab), cited as "V._, T._, at __." Page numbers are to the bate-stamped number, except as indicated. Documents supplementing the Court's review were filed September 17, 2013, Dkt. 79, and are bate-stamped beginning with "Supp." Some exhibits to Plaintiffs' brief attach only selected pages from the record, with Plaintiffs' underlining that is not in the record.

"loading", *i.e.*, quantity of a particular pollutant that the WQLS can receive from all combined sources and still meet the relevant water quality standard for a pollutant. 33 U.S.C. § 1313(d)(1)(C); 40 C.F.R. § 130.2(e). Each TMDL must, among other things: (1) be designed to meet water quality standards; (2) include, as appropriate, both wasteload allocations from point sources and load allocations from non-point sources; (3) consider the impacts of background pollutant contributions; (4) consider seasonal variations; (5) include a margin of safety; and (6) be subject to public participation. *Id.* §§ 130.7, 130.7(c)(1), 130.2(g)-(i). Developing a TMDL often requires a significant amount of work, and may take years once initiated depending, among other things, upon the information and studies required. Once a State submits a TMDL to EPA, the CWA requires that EPA approve or disapprove that TMDL within 30 days of its submittal by the State, and if EPA disapproves a particular TMDL, EPA must establish a federal TMDL for the WQLS within 30 days of the Agency's disapproval. 33 U.S.C. § 1313(d)(2).

The CWA does not requires States to develop and submit TMDLs to EPA on any particular schedule, requiring instead that States submit TMDLs to EPA "from time to time." *Id.* § 1313(d)(2). In 1997 Guidance, EPA recommended that States normally plan to establish TMDLs for all WQLSs on their 1998 Section 303(d) lists and subsequent lists within eight to thirteen years of initial listing, but recognized that shorter or longer times may be needed depending on State-specific factors.[3]/ These factors may include: number of impaired segments; length of river miles, lakes or other bodies for which TMDLs are needed; proximity of list waters to each other within a watershed; number and relative complexity of TMDLs; number and similarities or differences among the source categories to be allocated; availability of monitoring data or models; and relative significance of the environmental harm or threat. *Id.*

Importantly, TMDLs function primarily as planning devices and are not self-executing. *Pronsolino v. Nastri*, 291 F.3d 1123, 1129 (9th Cir. 2002). A TMDL does not, by itself, prohibit any conduct or require any actions. Instead, each TMDL represents a goal that may be

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[3]/ *See* http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/upload/2003_10_21_tmdl_ratepace 1997guid.pdf (at p.3). Though not part of the administrative record in this case, the Court may take judicial notice of this document for the purpose for which it is introduced.

implemented by adjusting pollutant discharge requirements in individual NPDES permits and/or by establishing nonpoint source controls. *Sierra Club v. Meiburg*, 296 F.3d 1021, 1025 (11th Cir. 2002). Thus, TMDLs form the basis for further State actions that may require or prohibit conduct with respect to particularized pollutant discharges. Regardless of whether a TMDL has been established, States must include effluent limits as stringent as necessary to meet water quality standards in NPDES permits. 33 U.S.C. § 1311(b)(1)(C); 40 C.F.R. § 122.44(d)(1)(vii)(A).

Where a TMDL has been established for a WQLS, the TMDL may provide allocation information for individual NPDES permits for point sources and/or establish goals for non-point source controls. The absence of TMDLs does not prevent NPDES permitting authorities from otherwise assuring that point source discharges do not cause or contribute to exceedances of water quality standards. *See* 43 Fed. Reg. 60,662, 60,665 (Dec. 28, 1978). EPA guidance to permitting agencies explains how to derive water-quality-based permit limits, both prior to establishment of a TMDL and consistent with any applicable TMDL once established.[4]/ Where a TMDL has not been established, EPA's guidance recommends that the permit writer establish as part of the process to develop a specific NPDES permit, a facility-specific allocation, sometimes referred to in this context as a discharge-specific concentration allowance. Manual at 6-31--6-35. In this process, the more current and reliable the underlying information, the more effective and defensible the allocation. *See id.* at 6-30--6-31. Where numeric effluent limitations are infeasible to calculate, NPDES permits may include best management practices. 40 C.F.R. § 122.44(k)(3).

C. The Constructive Submission Theory

The CWA requires that EPA approve or disapprove a TMDL within 30 days of its submittal by the State, and if EPA disapproves, EPA must establish a federal TMDL for the WQLS at issue within 30 days of disapproval. 33 U.S.C. § 1313(d)(2). On its face, however, the CWA imposes no duty for EPA to establish TMDLs if a State fails to establish and submit them to

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[4]/ [NPDES] Permit Writers' Manual, EPA-833-K-10-001 (2010) ("Manual"), Ch. 6, 6-30–6-35 (available at: http://cfpub.epa.gov/npdes/writermanual.cfm?program_id=45). Though not part of the administrative record in this case, the Court may take judicial notice of this document for the purpose for which it is introduced.

EPA. In the past, many States were not able to develop any TMDLs while implementing technology-based approaches to address water pollution. Because a State's refusal to submit any TMDLs over a prolonged period of time could frustrate the TMDL program, some courts adopted what came to be known as the "constructive submission" theory. The theory holds that the prolonged failure by a State to submit *any* TMDLs may constitute the "constructive" submission of no TMDLs (*i.e.*, that none are necessary), which submission EPA must approve or disapprove. *San Francisco Baykeeper v. Whitman*, 297 F.3d 877, 881 (9th Cir. 2002). If EPA disapproves such a constructive submission, this triggers the requirement that EPA establish TMDLs for the State.

D. Judicial Review Under the Clean Water Act

The CWA jurisdictional scheme restricts the types of claims that can be brought against EPA. The citizen suit provision allows suits to be brought in district court against the "the Administrator [of EPA] where there is alleged a failure of the Administrator to perform any act or duty under this chapter which is not discretionary with the Administrator." 33 U.S.C. § 1365(a)(2). Such citizen suit claims are available only where Congress has imposed a clear-cut, mandatory duty for EPA to act in the statute. *Infra* at 26, n.12. The reasonableness of the content of EPA's action or prospective action, however, cannot be dictated or reviewed by the Court under the citizen suit provision. *Scott v. City of Hammond, Ind.*, 741 F.2d 992, 995 (7th Cir. 1984).

In contrast, content-based review of certain EPA final actions, not at issue here, is available under the CWA exclusively in the U.S. Courts of Appeal. 33 U.S.C. § 1259(b)(1). Review of other "final agency actions" not covered by that Section is based upon the Administrative Procedure Act, in federal district court, under the APA's arbitrary, capricious or not in accordance with law standard of review. 5 U.S.C. § 706(2)(A).

NPDES permit decisions by Ecology are reviewed in the appropriate State tribunals.

II. FACTUAL BACKGROUND

A. The Development of Washington's Section 303(d) Program

Ecology's first Section 303(d) list was prepared in 1992. The 1996 Section 303(d) list had

666 WQLS listed. Ecology subsequently submitted, and EPA approved, 303(d) lists in 1998, 2004, 2008, and 2010. See V.1, T.16 & 21; V.2, D.40. As Ecology has continued to monitor the numerous waterbody segments throughout Washington, it has added additional WQLS to its 303(d) lists. Ecology's 2010 303(d) list, which EPA approved on December 21 2012, contains 4009 WQLSs for TMDL development. V.2, D.40 at 672..

In 1998, after two environmental groups filed a lawsuit in this Court, EPA entered into an out-of-court settlement agreement by which Ecology would complete a large number of TMDLs by December 31, 2013. The agreement provides that EPA would complete the TMDLs, if Ecology failed to do so. V.1, D.32 at 446-447. Ecology has since devoted significant resources to TMDL development. Since 1999, Ecology has completed 1372 TMDLs. V.1, T.A, at 1 n.1; V.1, D.16 at 220. Ecology is currently working on the development of TMDLs in 23 sub-watersheds throughout the State for numerous pollutants, including temperature, dissolved oxygen, bacteria, and pH. The Administrative Record in this case amply documents Ecology's TMDL output and its continued commitment to develop TMDLs. *E.g.*, V.1, T.A, 3, 5, 6, 8-14, 16-17 & 19-29.

Four segments of the Spokane River and one tributary (called the Little Spokane River) were first listed for PCBs on its 1996 Section 303(d) list. Dkt. 79, at Supp. 2710 & 2732. Over the years, as Ecology continued to gather information, the numbers of segments and parameters for the Spokane watershed continued to increase. There are currently 15 waterbody segments of the Spokane exceeding standards for PCBs. V.1, D.15 at 80. Ecology spent over 12 years completing work on dissolved oxygen TMDLs that addressed elevated levels of phosphorus, ammonia and CBOD (carbonaceous biochemical oxygen demand) in the Spokane River. V.1, D.4 at 503. EPA approved these nine Spokane River and Lake Spokane Dissolved Oxygen TMDLs in May 2010. V.1, D.17 at 000224. Ecology also developed 23 TMDLs for waters impaired by temperature, bacteria and turbidity in a major tributary to the Spokane River, Hangman (Latah) Creek. EPA approved these TMDLs in September 2009. *Id.* at 222-23. Ecology also developed 36 TMDLs for waters impaired by temperature, bacteria and turbidity in the Little Spokane River. EPA approved these TMDLs in April, 2012.[5] In 1999, Ecology developed, and EPA approved, five TMDLs for cadmium, lead, and zinc in the Spokane watershed. *See* V.1, T.15 at 82. Ecology is currently working on an additional TMDL to address the dissolved oxygen and pH impairments on the Little Spokane River. Even with these TMDLs, the Spokane watershed remains impaired for temperature, fecal coliform, and dioxin, as well as PCBs.

B. Ecology's Preliminary Work on a PCB TMDL for the Spokane River

1. The Nature of PCB Pollution

PCBs were first produced for commercial use in 1929 and have been used for hundreds of purposes. Production continued until a 1979 ban on all PCB manufacturing, processing, and distribution due to evidence that PCBs build up in the environment and concerns about possible human carcinogenicity. V.1, T.15 at 91. PCBs are released into the environment through improper disposal or leakage. *Id.* Even after their release, PCBs do not break down readily in the environment and can bioaccumulate. *Id.* at 92. Many of the same properties that made PCBs commercially desirable - their stability and resistance to degradation - make them extremely persistent in the environment. *Id.* at 92. Thus, in important respects, PCBs are a legacy pollutant.

Washington State's water quality standards include a human health criterion for PCBs at 170 picograms per liter ("pg/l"). V.1, T.15 at 83-84. When this lawsuit was filed, the Spokane Tribe water quality standard included a PCB human health criterion set at 3.37 pg/l. *Id.* at 83.[6] Based on elevated levels of PCBs and other pollutants in Spokane River fish, the Washington Department of Health and the Spokane Regional Health District issued an advisory in 2003, updated in 2008, to avoid or limit consumption of fish in parts of the Spokane River. *Id.* at 97.

Though PCBs can pose significant environmental concerns, they are one of many pollutants that demand attention within Washington's waterways. As discussed above, numerous

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[5] *See* http://www.ecy.wa.gov/programs/wq/tmdl/littlespokane/ (EPA's April 2012 approval is available by clicking the link in next to last paragraph of this page). Though not part of the record in this case, the Court may take judicial notice of this document for the purpose for which it is introduced.

[6] EPA recently approved, on December 19, 2013, a revised Tribal criterion set at 1.3 pg/l.

WQLSs continue to require attention, and Ecology continues to prioritize this task consistent with its assessment of the environmental benefits that would be realized and the resources available.

2. Ecology's Efforts to Obtain Information Necessary for a Spokane River PCB TMDL

While devoting significant resources to investigations supporting TMDL development for numerous WQLSs on its 303(d) lists, Ecology also conducted preliminary investigations into PCBs and the Spokane River. For example, Ecology's environmental assessment program identified numerous ongoing projects to which it intended to commit resources in Fiscal Year 2003, including TMDL development. V.5, T.105. Among many TMDL projects, Ecology explained that it was initiating certain preliminary work for potential use in developing a PCB TMDL in the Spokane River, pertaining to the "numerous variables [that] present sampling and analytical difficulties in developing predictive models of PCB behavior in the environment." *Id.* at 002426. This would "develop a sampling and monitoring strategy for gathering information to understand PCB dynamics in wastewaters, sediment, surface waters, and fish tissue from the Spokane River." *Id.*

By June of 2006, Ecology had prepared a document titled "Spokane River PCBs Total Maximum Daily Load[:] Water Quality Improvement Plan." V.3, T.90, at 1319-1645. This document includes the header "Draft – 6-19-06 – Do not cite or quote," *id.* at 1319, and was submitted for inclusion in the administrative record in this case by Plaintiffs. *See* V.1, T.B & C. Although this draft document focused on portions of the Spokane River administered by Washington, Ecology used the more stringent PCB water quality standard adopted by the Spokane Tribe as the basis for any such potential TMDL. V.3, D.90 at 1331. Although this document included, in preliminary draft form, some elements of a proposed TMDL, it failed to include critical information in numerous areas, primarily because more investigation remained necessary. For example, in a section titled "What Needs to be Done?," *id.* at 1419, the draft document explains that "PCB Source Identification" must occur in numerous significant areas. *Id.* The draft document states that stormwater discharges contribute significantly to PCBs in the Spokane River

(55 percent of known source categories). The draft explained, however, that particular sources of PCBs in stormwater are not generally known and thus could not be targeted for reduction, *id.* at 1419-21, and that the stormwater data available was not reliable.[7/] The draft document stated that "more thorough sampling needs to be conducted in this first step in this process," *id.* at 1419, explaining that "PCB source identification begins with determining how the PCBs have entered the storm drains and if ongoing sources exist." *Id.* at 1420. The draft explained the similar need to identify PCB sources within the sanitary sewer system. *Id.* at 1421.

Another example of critical, missing information involves the fact that "[t]he Spokane River at Stateline [the Idaho/Washington border] contributes about 25 percent of the PCB load to the system." *Id.* The draft document explains that "data needs to be gathered on the potential sources of PCBs (e.g, point sources, stormwater, contaminated and/or potential contaminated sites) in the Idaho portion of the Spokane River." *Id.* A similar need exists to identify PCB sources from watersheds draining to the Little Spokane River, which enters the Spokane River. *Id.*

Finally, the 2006 draft document identified the total daily loading of PCBs into the relevant reach of the Spokane River (3,664 mg/d), V.3, D.90 at 1401, but failed to identify PCB sources or otherwise account for nearly half (46.3%) of that daily loading. *Id.*[8/] Thus the 2006 draft document does not account for 46.3% of the PCB loading, in addition to the lack of information described above regarding PCB loading from the Spokane stormwater, the Spokane sanitary sewer, the Stateline border, and the Little Spokane River source categories. Because of the limited information available and inability to assign reductions to unknown sources, the draft document suggested that for the known categories of PCB sources very aggressive reductions could be necessary for the known catagories of PCB sources, in some cases exceeding 99%. *Id.* at 1402-03.

[7/] *See id.; also id.* at 1413 ("Stormwater from Spokane has the potential to deliver large PCB loads to the river (1,100 mg/d) and may account for a significant portion of loading from exogenous sources. However, stormwater sampling was limited and since data had not been previously collected from this source in the Spokane River basin, the representativeness of those data is uncertain.")

[8/] The chart at 1401 (V.3, T.90) shows a total daily PCB load of 3,664 mg/d, but identifies sources totaling only 1968.9 mg/d, which includes the loading of 477 mg/d at the Idaho border. Thus the 2006 draft document fails to identify sources or categories of sources or otherwise account for 46.3% of the PCB loading.

The draft document contemplated that some of the missing information and analysis may be included in a separate, future document to be developed by Ecology that would be called a "Water Quality Implementation Plan." *Id.* at 1417-21. The draft did not suggest a strategy to identify the sources or otherwise account for the very high percentage of unidentified PCB loading to the River.

Ultimately, given the significant information gaps about PCB occurrences and sources in the Spokane River, Ecology recognized that considerable new studies and analyses would be necessary before a PCB TMDL for the Spokane River could be completed. *See, e.g.,* V.1, T.14A at 503; *infra* at 16-17 (Ecology's decision not to prioritize the completion of the PCB TMDL). Thus the State did not issue the 2006 draft document for the public notice and comment that would be required for any proposed TMDL prior to deeming it complete for submission to EPA.[9]/ Rather, Ecology initiated additional investigations regarding PCBs in the Spokane River. For example, to better understand the role of stormwater and obtain more reliable data, the State conducted a study "to refine PCB loading estimates to the Spokane River from the City of Spokane's stormwater drainage system" and, as "[a] secondary goal . . . to begin PCB source identification for future mitigation efforts," and issued a report in 2007 based on its findings.[10]/

Thereafter, the State further sought to identify other information gaps and the means to close those gaps. One 2009 draft document, entitled "Draft Spokane River PCBs TMDL: Volume 1. Water Quality Study Findings," which also includes the header "DRAFT – 7-09 – Do not cite or quote," V.3, T.69 at 1102, was submitted to EPA by Plaintiffs for inclusion in the administrative record in this case. V.1, T.B &C. This draft document is not a draft TMDL – it does not, for

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[9]/ Although some Ecology reports suggest that Ecology submitted a proposed Spokane River PCB TMDL for the public notice and comment required before it could be finalized, V.2, T.42 at 705; V.1, T.14 at 503, EPA believes that this statement is in error. The administrative record in this case does not contain any such proposal, public notice, public comments nor Ecology responses to comments from such a process, and EPA has no record that it ever occurred.

[10]/ *See* Spokane River PCB TMDL Stormwater Loading Analysis Final Technical Report, at v. (abstract) (December 2007). Although not included in the administrative record in this case, this report is available on the State's web site, https://fortress.wa.gov/ecy/publications/publications/0703055.pdf, and the Court may take judicial notice of it for the purpose for which it is introduced.

example, contain proposed load allocations for sources. Rather, as its subtitle indicates, it is a draft technical study that could be used in developing a future draft TMDL V.2, T.68 at 1217 ("This project constitutes a technical water quality study to support TMDL development for PCB contaminants in the Spokane River."); *also id.* at 1121-21.

In part to better reflect this draft document's contents, and the fact that it was not itself a draft TMDL, in 2011 Ecology issued this report, in modified and final form, titled "Spokane River PCB Source Assessment 2003-2007." V.1, T.15 at 63-216. Although this 2011 report indicates progress in addressing some information gaps and data reliability issues in some areas, *see* V.5, T132 at 2675, it did not, among other things, identify or otherwise account for the large unknown sources of PCB loadings into the relevant reach of the Spokane River. For example, of the total daily PCB loading of 3,664 mg into the River, only a total loading of 1571 mg/day from seven categories of sources were identified, including 477 mg/day at the Stateline. V.1, T.15 at 163. Based upon its updated data, this 2011 report could not account for 57% of the PCB loading in the relevant reach of the River. The 2009 precursor draft also lacks this information. V.3, T.69 at 1205.

C. Ongoing State Efforts to Reduce PCBs and Other Toxics in the Spokane River

Ecology has worked to reduce PCBs in the Spokane River while investigating PCBs and their sources for a potential PCB TMDL. Ecology has utilized available information and taken significant steps to reduce and cleanup toxics in or that may enter the River, including PCBs. For example, as detailed in Ecology's 2012 Spokane River Toxics Reduction Strategy, V.2, T.42, Ecology in 2007 provided oversight as contractors removed PCB-contaminated soil from Donkey Island in the Spokane River. *Id.* at 701. Prior to that, Ecology directed contractors in 2006 to cap over PCB-contaminated sediments on the river bottom near the Upriver Dam. *Id.* PCBs at several other sites have either been cleaned up or are undergoing required investigation of appropriate remedial options pursuant to the State's cleanup laws to address past pollution. *Id.* at 701-2; V.2, T.68, at 1091-93. In addition to these cleanup efforts focused on PCBs, the 2012 Spokane River Toxics Reduction Strategy details the State's ongoing efforts to reduce other toxics in the Spokane

River, such as dioxins and furans, metals such as arsenic, cadmium, lead and zinc, and pharmaceuticals and personal care products. *Id.* at 692-95 & 697-712.

Ecology has also worked closely with the City of Spokane, which in 2011 entered into a settlement agreement with the Spokane Riverkeeper to develop an adaptive management plan for reducing PCB discharges from Spokane's stormwater as much as possible, by:

> 1. Analyzing, organizing, and interpreting existing PCB sampling data as it relates to the City's stormwater NPDES permit.
> 2. Identifying likely sources of PCBs and prioritizing appropriate remedial actions to be accomplished and best management practices to be followed.
> 3. Developing and designing an adaptive approach for additional data collection and additional remedial actions that further reduce PCBs within the City and in the Spokane River for the long term.

Id. at 707-708.

In addition, in 2011, the Department of Ecology, together with PCB dischargers in the Spokane River Basin, conservation and environmental groups, local and regional government agencies, EPA, and other interested parties created the Spokane River Regional Toxics Task Force ("Task Force"). V.1, T.4, at 14. The final January 23, 2012, Memorandum of Agreement establishing the Task Force explains that its "goal . . . will be to develop a comprehensive plan to bring the Spokane River into compliance with applicable quality standards for PCBs." *Id.* This includes the more stringent PCB water quality standard adopted by the Spokane Tribe. *Id.* at 15. To accomplish that goal, the Task Force's functions include:

> – Identify data gaps and collect necessary data on PCBs and other toxics . . . for the Spokane River
>
> – Further analyze the existing and future data to better characterize the amounts, sources and locations of PCBs and other toxics as defined above entering the Spokane River.
>
> – Prepare recommendations for controlling and reducing the sources of listed toxics in the Spokane River.
>
> – Review Toxic Management Plans, Source Management Plans, and BMPs [Best Management Practices].
>
> – Monitor and assess the effectiveness of toxic reduction measures. . . .

Id. at 14.

Members of the Task Force include the Washington Departments of Ecology and Health, the City of Spokane, Spokane County, and the Spokane Regional Health District, the Lake Spokane Association, the Spokane Riverkeeper, the Lands Council, Kaiser Aluminum Washington, LLC, and the Inland Empire Paper Co. *Id.* at 30-40. EPA has also committed its support for and participation in the Task Force. V.1, T.7. All holders of Washington NPDES permits that may discharge PCBs into the Spokane River are required, as a condition of their permit, to participate in the Task Force. *See, e.g.*, V.2, T.45, at 845. The Spokane Tribe was invited to join the Task Force. Although it initially supported the Task Force and its efforts, V.3, T.89 at 1317, it ultimately elected not to participate in it. Plaintiffs in this case also elected not to participate in the Task Force.

The first draft work plan of the Task Force, adopted October 24, 2012, explains in detail specific work plan elements for the years 2012 through 2016, which include "<u>Work Plan Element 1 – Data review, data gap evaluation, analysis, and implementation plan</u>," V.2, T.41 at 679-81 (emphasis in orig.), and "<u>Work Plan Element 5 – Develop strategy for reduction of point sources and non-point sources of PCBs</u>," *id.* at 683-84 (emphasis in org.). The Task Force's documents its monthly activities and other information regarding its operation on its web site (www.srrttf.org). Thus, the Task Force works to identify PCB sources and to develop strategies for reducing PCBs.

Current PCB concentrations in fish tissue are lower than they have been historically. Between 1996 and 2005 there has been a significant decrease in the PCB levels in Mountain Whitefish and Rainbow Trout in the Spokane River. V.1, D.15 at 152-53.

D. Ecology's Decision to Defer Continued Development of a Spokane River PCB TMDL for Submission to EPA at This Time

Ecology has determined not to continue to devote its limited resources for the development and completion of a PCB TMDL for the Spokane River at this time. Ecology's reasons for deferring completion of the TMDL are documented in the administrative record in this case. As an initial matter, Ecology has a robust TMDL program, and Ecology is continuing to devote its limited resources to the development of other TMDLs, both within the Spokane Basin Watershed and in other water-quality-limited segments throughout the State. *See supra* at 9-10. Against this backdrop, Ecology explained several specific reasons for deferring a PCB TMDL at this time. First, there are significant data gaps that precluded it from completing a TMDL at this time, with much work remaining. *See, e.g.*, V.1, T.A at pp 3-4*;* V.2, T.42 at 705; V.1, T.15 at 173 & V.1, T.35 at 481-83 (data to be obtained). In this regard, Ecology employee Jim Bellatty, testifying on behalf of Ecology in 2013 before the Washington State Pollution Control Hearings Board, explained that Ecology's draft PCB TMDL could not be finalized because sources for 57% of the PCB loading in the relevant reach of the Spokane River have not been identified. V.5, T.132, at 2671-72 & 2683. In light of key gaps in information, Ecology is concerned that any TMDL at this time would be highly uncertain, inequitable, and impracticable. *Id.* at 7671 & 2683. In addition, Ecology had recently devoted a great deal of its resources, spanning 12-years, in a difficult process to complete in 2010 a dissolved oxygen TMDL for the Spokane River. V.1, D.4 at 503; V.5, T132 at 2671-72. In light of that experience, Ecology was concerned that, given the significant information gaps for PCBs, and absent a cooperative approach, the continued development to finalization of a PCB TMDL at this time would suffer lengthy delays and expend considerable resources, without resulting in timely environmental benefits. *Id.; also* V.1, T.A at p.4. At the same time, Ecology was aware that community support exists for it to make as much direct progress as possible to reduce PCBs through its Task Force (described *supra*), rather than to delay such potential progress until after a TMDL is completed. V.2, T.42 at 706; V.1, T.1.

Ecology has also made clear that the Task Force's work is not in lieu of development of a Spokane River PCB TMDL. V.1, T.1, at 2. The Task Force serves as a measure designed to obtain critical information about PCBs and their sources in the Spokane River and to implement strategies that can obtain near-term PCB reductions where possible. *Supra* at 15-16; V.1, T.35. Ecology expressly recognized that it would still be obliged to complete a PCB TMDL for the Spokane River if the Task Force or other measures fail to achieve applicable water quality standards. V.2, T.44 at 706 ("a PCB TMDL still remains a tool and will be necessary if ongoing toxics reduction strategies do not result in compliance with water quality standards.").

E. EPA's April 12, 2013, Letter Determining That Ecology Has Not Renounced Establishing a Spokane River PCB TMDL If One Is Required and That EPA Is Therefore Not Required to Establish Such a TMDL Under Plaintiffs' Constructive Submission Theory

Plaintiffs' original, one-count Complaint in this action (Dkt. No. 1, ¶¶ 23-26) alleged that Ecology's failure to finalize a PCB TMDL for the Spokane River constitutes its intent to never complete such a TMDL and thus the constructive submission of no PCB TMDL, the disapproval of which by EPA would create a mandatory duty under the CWA citizen suit provision for EPA to establish a PCB TMDL for the Spokane River. On November 6, 2012, this Court held that review in this case is limited to the administrative record. Dkt. No. 49. Thereafter, in December 2012, Plaintiffs submitted two letters to EPA, attaching numerous documents not in EPA's administrative record, for EPA to review administratively. V.1, T.B & C. These documents included several internal Ecology draft documents, many of which are described above. Based on these documents, Plaintiffs contend that Ecology has disavowed submitting an actual PCB TMDL for the Spokane River, thereby constructively submitting no TMDL; Plaintiffs thus requested that EPA approve or disapprove that constructive submission, and if disapproved, to establish a PCB TMDL. *Id.*

EPA reviewed the full administrative record in this case, including the new documents submitted by Plaintiffs, and on April 12, 2013, issued its administrative determination, concluding that "Ecology's decision to delay completion of a PCB TMDL for the Spokane River is within the discretion of the State of Washington" and that "Ecology has not renounced completion of a PCB TMDL for the Spokane River if one is required." V.1, T.A, at 1 (internal citation). EPA thus concluded that there has not been a constructive submission by Ecology of a PCB TMDL and that EPA is not "required to issue such a TMDL in lieu of Ecology." EPA also detailed the bases for its findings. EPA first noted that Ecology has "demonstrated its commitment to develop and implement" a robust TMDL program under Section 303(d) of the Act over the past fifteen years, and that "Ecology is continuing to establish large numbers of TMDLs each year in accordance with its judgment of how best to protect the environment and allocate its limited resources." *Id.*

Ecology established and EPA approved 1372 TMDLs since 1999 using EPA's national counting system. *Id. & n.1*. EPA further explained Ecology's priority-setting process, and noted that in December 2012 EPA approved Ecology's 303(d) list and found "that the state's process for targeting waters for TMDL development in this period is appropriate." *Id.* at 2 (internal citation).

In its administrative determination, EPA expressed support for Ecology's use of interim, supplemental approaches to achieve water quality standards, especially for those WQLSs for which a TMDL will not be issued in the near term, in an effort to reduce pollution and achieve water quality standards. This approach is reasonable because "[i]f water quality standards are attained through implementation of such interim, supplemental approaches, development of a TMDL [for that WQLS] would not be necessary." *Id.* EPA explained that Ecology's use of the Task Force to make progress achieving the applicable PCB standards represents such a measure, and that EPA supports the Task Force's work. *Id.* at 3.

EPA also explained its support for the Task Force's reasonable goal of completing the work outlined in its work plan by 2016 to reduce PCBs, *id.*, Ecology's commitment in its May 2012 letter (V.1, T.1 at 1-2) that it will in five years "evaluate progress in reducing PCB contamination in the Spokane River," and Ecology's acknowledgment that "[i]f Ecology determines that the [Task Force] is failing to make measurable progress toward meeting applicable water quality criteria for PCBs, Ecology . . . will proceed with development of a TMDL in the Spokane River for PCBs if necessary." V.1, T.A at 3. EPA further reviewed Ecology's acknowledged commitment to proceed with development of a TMDL for PCBs in the Spokane River if necessary, and explained that this "leads EPA to conclude that Ecology has not repudiated its legal obligation to develop a PCB TMDL if needed." *Id.* at 4.

EPA noted that a "straight to implementation" ("STI") project is a type of interim approach used by Ecology, *id.* at 2-3 (describing such approaches), and that Ecology may have once intended to develop an STI project for the Spokane River, but that as Ecology further developed its STI program, it appeared that the Task Force was not an STI. *Id.* at 2-3. EPA noted, however, that the name given to a particular project or project type is not important, so long as it remains "an interim, supplemental tool that does not displace ultimate TMDL development if needed." *Id.* at 3 n.10.

EPA also reviewed Ecology's decision to defer the continued development and completion of a PCB TMDL for the Spokane River at this time, and found them reasonable. In particular, EPA highlighted the significant information gaps that led Ecology not to finalize its draft PCB TMDL, and Ecology's experience of lengthy delays and large resource expenditures establishing the dissolved oxygen TMDL for the Spokane River. *Id.* at 4. "These factors support Ecology's decision not to finalize a PCB TMDL for the Spokane River prematurely, e.g., before adequate information and resources are available." *Id.* Further, the Task Force has "the potential to fill the existing data gaps and to achieve PCB reductions until such time that a needed PCB TMDL is issued." *Id.*

Finally, EPA explained that Ecology's approach reflects its priorities to "balance[] its available resources for issuing TMDLs with other effective tools to reduce pollution within its borders where TMDLs have not yet been issued." *Id.* at 4. EPA thus concluded that it would not be appropriate "in these circumstances for it to usurp Ecology's authority by issuing a PCB TMDL for the Spokane River at this time." *Id.* EPA therefore concluded that "Ecology has not constructively submitted to EPA a PCB TMDL for the Spokane River, and to the extent that such a constructive submission could be considered to have occurred, EPA declines to disapprove such a constructive submission." *Id.* EPA explained that it will monitor Ecology's efforts to reduce PCB pollution in the Spokane River, including "its ongoing progress in issuing TMDLs for other water bodies," and that it "may reconsider this decision if significant relevant circumstances change." *Id.*

After EPA issued this determination, Plaintiffs filed an amended complaint on April 22, 2013, which retained Plaintiffs' original constructive submission claim under the Clean Water Act citizen suit provision, Dkt. No. 61 ¶¶ 36-39, and added a new, second claim challenging EPA's April 12, 2012, determination under the Administrative Procedure Act. *Id.* ¶¶ 41-42.

F. The Pollution Control Hearing Board's July 2013 Decision

In 2011, Ecology issued the Spokane County Regional Water Reclamation Facility an NPDES permit for discharges into a water-body segment that is not listed as impaired for PCBs under Washington's 303(d) lists. Plaintiffs in this case challenged that permit before the Washington Pollution Control Hearing Board (the "Board"), alleging that it unlawfully authorized PCB discharges. Board Decision pg.1 (attached hereto as Exhibit A). The Board agreed with Ecology that the available data was not adequate for preparation of a numeric effluent limit for PCBs in the permit, *id.* pg.22, that the permit therefore required best management practices, or narrative effluent limits, *id.*, and that any narrative limits used in such a circumstance must "require defined steps towards compliance with standards." *Id.* at p.24. Therefore, the Board remanded the matter to Ecology with instructions, among other things, that Ecology (a) include deadlines and mandatory requirements for identification and implementation of measures to reduce PCBs coming into the treatment facility, (b) identify the expected reductions in toxicant loadings and the schedule for initiating such reductions; and (c) requiring the use of ongoing monitoring data to set a numeric effluent limitation at the earliest possible time. *Id. at* p.27. In so ruling, the Board reviewed the important role of the Task Force and stated that it "finds that the creation of the Task Force is a positive step toward bringing the Spokane River into compliance with water quality standards for PCBs" and that "the actions undertaken by the Task Force are necessary to address the water quality problems in the Spokane River . . . ." *Id.*

<u>**STANDARD OF REVIEW**</u>

I. EPA'S DECISION MUST BE UPHELD UNLESS PLAINTIFFS ESTABLISH THAT EPA'S ACTION WAS ARBITRARY AND CAPRICIOUS.

Under the Administrative Procedure Act, EPA's final agency actions under the Clean Water Act must be upheld unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The scope of review under this standard is narrow, and a court may not substitute its judgment for that of the agency. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983); *Citizens to Preserve*

Overton Park v. Volpe, 401 U.S. 402, 416 (1971). Rather, "Congress has assigned the courts perform 'only the limited, albeit important, task of reviewing agency action to determine whether the agency conformed with controlling statutes,' and whether the agency has committed 'a clear error of judgment.'" *Maryland Dep't of Human Resources v. U.S. Dep't of Agric.*, 976 F.2d 1462, 1475 (4th Cir. 1992) (quoting *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 97 (1983), and *Overton Park*, 401 U.S. at 416).

The party asserting an APA challenge bears the burden of demonstrating that the agency's actions were arbitrary or capricious. *Nw. Ecosystem Alliance v. U.S. Fish & Wildlife Serv.*, 475 F.3d 1136, 1140 (9th Cir. 2007). This standard is a "highly deferential, presuming the agency action to be valid." *Id.* "The court may not set aside agency action as arbitrary or capricious unless there is no rational basis for the action." *Friends of the Earth v. Hintz*, 800 F.2d 823, 831 (9th Cir. 1986).

Under this deferential standard the agency's factual determinations are entitled to substantial deference. *Arkansas v. Oklahoma*, 503 U.S. 91, 112 (1992); *Central Arizona Water Cons. Dist. v. EPA*, 990 F.2d 1531, 1539-40 (9th Cir. 1993). As long as the agency's factual determinations are supported by the administrative record they should be upheld, even if there are alternative findings that could also be supported by the record. *Arkansas*, 503 U.S. at 112. Even an agency decision "of less than ideal clarity" may be upheld by the court "if the agency's path may reasonably be discerned." *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1525 (9th Cir. 1995) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Ins.*, 463 U.S. 29, 43 (1983)). Further, when examining agency scientific findings made within an area of an agency's technical expertise, a reviewing court must generally be at its most deferential. *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 376-77 (1989).

II. JUDICIAL REVIEW IS LIMITED TO THE ADMINISTRATIVE RECORD AND IS CONDUCTED THROUGH A SUMMARY JUDGMENT PROCEEDING.

In a case such as this, judicial review is limited to the administrative record prepared by the agency for its decision. *Overton Park*, 401 U.S. at 419-20; *Vermont Yankee Nuclear Power Corp.*

v. NRDC, 435 U.S. 519, 549 (1978). This rule implements the well-settled principle that judicial review of agency action is confined to review of the record that was before the agency when it made its decision, and not extra-record material that was not considered by the agency at the time that it took final action. *Federal Power Comm'n v. Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976). Extra-record declarations, however, may be submitted by the Agency to clarify or explain information contained in the record. *See Camp v. Pitts*, 411 U.S. 138, 142-43 (1973). This Court has held that review in this case is limited to the administrative record. Dkt. No. 49.

Finally, because review is limited to the administrative record, resolution of this case is proper through summary judgment. *Adams v. United States*, 318 F.2d 861, 865 (9th Cir. 1963). In such a proceeding, the district court "is not required to resolve any facts in a review of an administrative proceeding. Certainly, there may be issues of fact before the administrative agency. However, the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985). The Parties to this matter have stipulated that all claims for relief in this case will be resolved through the instant summary judgment proceedings. *Infra* at 30 n.15.

ARGUMENT

I. ECOLOGY HAS NOT MADE A CONSTRUCTIVE SUBMISSION FOR A SPOKANE RIVER PCB TMDL, AND THEREFORE PLAINTIFFS' COMPLAINT SHOULD BE DISMISSED WITH PREJUDICE AND SUMMARY JUDGMENT ENTERED FOR EPA.

A. The Constructive Submission Theory May Not, As a Matter of Law, Apply Where, As Here, the State Has a Robust Program for Establishing TMDLs.

Plaintiffs invoke the nondiscretionary duty prong of the CWA citizen suit provision, 33 U.S.C. § 1365(a)(2), alleging that Ecology has constructively submitted no PCB TMDL for the Spokane River, and that this triggers EPA's nondiscretionary duty under CWA § 303(d)(2), *id.* § 1313(d)(2), to approve or disapprove that submission. Plaintiffs and the Spokane Tribe thus invoke the constructive submission doctrine in an effort to circumvent and undermine Ecology's decisions as to how best to protect the environment, by targeting a particular TMDL that they believe should be established before all others. As discussed below, the constructive submission theory is inapplicable where, as here, the State has a robust program for establishing TMDLs.

1. The Constructive Submission Caselaw Supports EPA's Interpretation.

Plaintiffs' claim depends on a novel, and untenable, reading of the CWA and the applicable caselaw that would expand the constructive submission theory well beyond the limited circumstances in which it applies. The Ninth Circuit explained in San Francisco Baykeeper v. Whitman, 297 F.3d 877, 881 (9th Cir. 2002), that the doctrine was created by the courts to address the narrow situation in which a State has submitted no TMDLs at all for a prolonged period of time, *id.* at 881 (i.e.,"a complete failure by a state to submit TMDLs"), and this State inaction is "construed as a constructive submission of no TMDLs, which in turn triggers the EPA's nondiscretionary duty to act." *Id.* If EPA disapproves the constructive submission of no TMDLs, EPA then becomes obliged to establish the TMDLs pursuant to section 303(d)(2). If EPA approves the constructive submission of no TMDLs, that decision is reviewable under the Administrative Procedure Act. *Hayes v. Whitman*, 264 F.3d 1017, 1023 (10th Cir. 2001) (citing *Scott*, 741 F.2d at 995 & 997). In *Baykeeper,* the Ninth Circuit concluded that California's actions, having submitted at least eighteen TMDLs, "preclude any finding that the state has 'clearly and unambiguously' decided not to submit any TMDLs." *Id.* at 883 (citing *Hayes*, 264 F.3d at 1024).

In its decision adopting the constructive submission theory, the Ninth Circuit carefully reviewed the caselaw, and explained that since its first formulation in *Scott v. City of Hammond*, 741 F.2d 992 (7th Cir. 1984), the theory has been narrowly interpreted and applied "only when 'the state fails to submit any TMDLs and has no plans to remedy this situation.'" *Baykeeper*, 297 F.3d at 882 (explaining and quoting the district court's interpretation of *Scott*); *id.* (concluding that "the district court's ruling is consistent with how other circuits have interpreted and applied *Scott*"). Thus the Ninth Circuit concluded that the doctrine may apply only where no TMDLs have been submitted by the State over a prolonged period of time and the State has no plan to remedy this situation. *Baykeeper*, 297 F.3d at 881-883.

In this case, there is no dispute that Ecology has an ongoing, robust program for establishing TMDLs, having submitted 1372 TMDLS to EPA since 1999. *Supra* at 9-10. Even where States have submitted far fewer TMDLs, the courts have declined to find a constructive submission. *See Baykeeper*, 297 F.3d at 882-83) (citing cases). Moreover, where the doctrine has been found to apply, the State has submitted no, or only very few, TMDLs over a prolonged period of time and had no intention of remedying that situation.[11]/

The theory is not available here, as a means to alter Ecology's priorities regarding the order or timing in which particular TMDLs should be established or how limited State resources should be allocated. Although Plaintiffs prefer that Ecology establish a PCB TMDL for the Spokane River immediately, a claim for such relief is simply not available. The Tenth Circuit stated in *Hayes,* 264 F.3d at 1024, the "constructive-submission theory is not designed to challenge the timeliness or adequacy of the state's TMDL submissions . . . ." *See also Sierra Club v. Browner,* 843 F.Supp. 1304, 1314 (D.Minn.,1993) ("the Act does not set deadlines for the development of a certain number of TMDLs."). And in the Ninth Circuit the law is clear that the theory may apply only where the State has submitted no TMDLs. *Baykeeper*, 297 F.3d at 882.

Plaintiffs' contend that the *Baykeeper* case is inapposite, because it involved what Plaintiffs call a "programmatic" challenge where the "plaintiffs complained of a state's overall failure to submit any or an adequate number of TMDL," Pl Br. at 24-25, whereas Plaintiffs here are concerned with one particular TMDL. Such a distinction cannot evade the rule in *Baykeeper.* A necessary corollary to the *Baykeeper* holding, *i.e.*, that an ongoing State TMDL program that has already established 18 TMDLs precludes finding a constructive submission, is the Ninth Circuit's acknowledgment that there are many more TMDLs in that State (California) to be established. For these remaining TMDLs, whether taken as a group or individually, the constructive submission doctrine cannot be used to upset the State's priorities and resource allocations. As explained in

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[11]/ *E.g., Kingman Park Civic Ass'n v. EPA*, 84 F. Supp. 2d 1, 6 (D.D.C. 1999) ("An eighteen-year failure to calculate and submit any TMDLs constitutes constructive – if not outright – determination that no TMDLs are necessary."); *Alaska Center for the Environment v. Reilly,* 762 F. Supp. 1422, 1426-27 (W.D. Wa. 1991) (holding that failure by state to submit to EPA any TMDL for over ten years was constructive submission).

section B below, the reason for so limiting the theory is clear. Courts quite properly are not willing to invoke the constructive submission theory, and the necessarily narrow nondiscretionary duty prong of the CWA citizen suit provision,[12]/ in order to second-guess and supersede discretionary policy choices Congress reserved to States to prioritize waters under their 303(d) programs and to allocate limited State resources as the State believes appropriate to protect the environment. That is why *Hayes* concluded that a constructive submission theory cannot challenge "the timeliness" of a State's TMDL submissions or their content, and the Ninth Circuit concluded that the doctrine may apply only where no TMDLs have been submitted.

Plaintiffs' reliance (at 25) on three other cases for their overly expansive view of the constructive submission theory is unavailing. Although the claim in *Scott* concerned TMDLs for only Lake Michigan, it arose in a context in which the State had submitted no TMDLs at all over a prolonged period, 741 F.2d at 996-97, and it is that circumstance that the Court explained that the theory may apply. *Id.* Here, Ecology has already submitted and EPA has approved 1372 TMDLs statewide and, for the Spokane River watershed alone, Ecology has already submitted and EPA has approved 73 TMDLS. *Supra* at 9-10. Moreover, as explained in *Baykeeper,* 297 F.3d at 882, the *Scott* court remanded the case to the district court instructing it "to proceed as if the states had submitted proposals of no TMDL's" and still left open the possibility that a constructive submission may not be found. *Scott*, 741 F.2d at 997 n.11.

Plaintiffs' reliance on *Hayes* is also misplaced. While the Court in one part of its opinion describes the constructive submission theory in the singular, referring to the clear intent to submit no TMDL for a particular waterbody, in others places it speaks in the plural, referring to the submission of no TMDLs needed to trigger the theory. 264 F.3d at 1023 (the theory applies "[o]nly upon this determination that the states' inaction was so clear as to constitute a 'constructive submission' of no TMDLs"). Moreover, as the Ninth Circuit in *Baykeeper*

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[12]/ Claims against EPA under citizen suit provisions are limited to "'clear-cut' nondicretionary dut[ies]." *Farmers Union Cent. Exchange, Inc. v. Thomas*, 881 F.2d 757, 760 (9th Cir. 1989) (reviewing the similar citizen suit provision under the Clean Air Act). Thus, the CWA citizen suit provision "cannot be employed to challenge the substance or content of an agency action." *Scott*, 741 F.2d at 996; *see also Sierra Club v. Thomas*, 828 F.2d 783, 791 (D.C. Cir. 1987).

explained, the key fact in *Hayes* for why no constructive submission was found was not the focus on a particular TMDL, but the fact that Oklahoma had submitted between three and twenty-nine TMDLs with a commitment for more. *Baykeeper*, 297 F.3d at 882. Accordingly, the Ninth Circuit explained that *Hayes* should be construed to mean the constructive submission theory may apply only when no TMDLs are submitted. *Id.* Finally, in *City of Arcadia v. EPA*, 411 F.3d 1103, 1105 (9th Cir. 2005), also relied upon by Plaintiffs, the court described the constructive submission theory using the singular, but it did so only in passing, in a background section, and the holding of the case did not involve application of the theory at all. This passing reference carries no weight whatsoever. In sum, Plaintiffs have not cited a single case in which the constructive submission theory has been applied to compel establishment of a single, particular TMDL from among the many that may ultimately be required, and EPA is not aware of such a case.

2. EPA's Reasonable Interpretation is Fully Supported by the CWA

EPA's interpretation is also fully supported by the CWA § 303(d) provisions regarding State TMDL prioritization and the cases interpreting it. The CWA vests States with authority to exercise their own judgment as to when particular TMDLs should be established and how their limited resources should be allocated, without the threat of judicial intervention requiring that EPA usurp that State discretion and decisionmaking. For example, while the CWA requires that States establish a priority ranking for TMDLs, EPA is not required to pass judgment on that prioritization or approve or disapprove the State's order. Although CWA § 303(d)(1)(A) requires that "[e]ach State shall identify those waters within its boundaries . . . * * * [and] establish a priority ranking for such waters," 33 U.S.C. § 1313(d)(1)(A), the CWA only requires each State "from time to time" to submit to EPA for approval "the <u>waters identified</u> and the <u>loads established</u>." *Id.* § 1313(d)(2) (emphasis added). Thus, the CWA is specific and clear: EPA must review only the 303(d) list (the "waters identified") and the TMDLs (the "loads") once they are submitted to EPA. Conspicuously absent from Section 303(d)(2) is any mention of EPA approval of priority rankings set by the States under Section 303(d)(1)(A). "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally-presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. U.S.*, 464 U.S. 16, 23 (1983).

Accordingly, the courts that have reviewed this question have agreed that EPA is not required to review and approve the particular priority ranking States establish for TMDL development. The Court in *Potomac Riverkeeper, Inc. v. EPA*, 2006 WL 890755, at 10 (D. Md. 2006), explained as follows:

> While a state's § 303(d) list must list waters 'targeted' for TMDL development within the next two years, this requirement is a form of goal setting. This requirement does not, however, require EPA, prior to approval, to ascertain, based on the state's historic average number of impairments resolved per year, whether the state can actually complete the 'targeted' TMDLs in the next two years. In addition, there is no provision that requires EPA to approve or disapprove a state's priority rankings.

Id. at 10 (footnote omitted).[13]/

Plaintiffs' theory in this lawsuit, therefore, contradicts the CWA's clear text and structure and is not supported by applicable caselaw. The constructive submission theory may not, as a matter of law, be used, as Plaintiffs' intend here, to supersede and reorder the State's priorities and decisions.

This limitation on the constructive submission theory is a corollary to the prohibition on its use to challenge the timing or content of State TMDLs, *Scott*, 741 F.3d at 995, and the Ninth Circuit's holding that the theory may apply only if no TMDLs have been submitted and the State

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[13]/ EPA also notes that, in *Sierra Club, Inc. v. Leavitt*, 393 F.Supp.2d 1263, 1273 (N.D. Fla. 2005) (N. D. Fla. 2005), *aff'd and rev'd in part; judgment vacated in relevant part*, 488 F.3d 904 (11th Cir. 2007), the district court declined to second-guess the State's particular priority ranking for completing TMDLs in a case challenging EPA's approval of a 303(d) list, explaining:

> No requirement is present that EPA approve the [States'] rankings. Importantly, in its Decision Document, while the EPA specifically approves or disapproves [the State's] decision to list, not list, or delist waters, the section discussing prioritization does not "approve" or "disapprove" [the State's] ranking; it merely concludes that Florida did, in fact, rank its waters and set a TMDL schedule accordingly. Because there is no requirement that the EPA actually approve or disapprove of a state's priority rankings, . . . summary judgment is granted in favor Defendants

On appeal, the Eleventh Circuit concluded that plaintiffs did not actually challenge the particular ranking of listed waters, and thus it did not address that issue and vacated district court's summary judgment on that claim and remanded. 488 F.3d at 917-918. Nevertheless, the district court properly addressed this issue.

has no plan to remedy that situation. *Baykeeper*, 297 F.3d at 882. This limitation also follows from the discretion CWA § 303(d) preserves for the States. A contrary ruling would open the floodgates to numerous lawsuits against EPA by groups dissatisfied with how limited State or federal resources were allocated, in an effort to redirect development to their preferred TMDL in lieu of other environmental projects or TMDLs in other communities. Such "special pleading" lawsuits on behalf of those groups' narrow priorities would ensnare the courts in disputes they are ill-suited and not authorized by statute to resolve, *i.e.*, second-guessing the States' judgments about how to best protect the environment in the face of limited resources. These are precisely the types of claims the CWA and caselaw foreclose.[14]/

EPA's interpretation is fully consistent with the plain meaning of Section 303(d) and the applicable caselaw. However, even were the statute ambiguous, EPA's construction is reasonable, and should be upheld. Accordingly, EPA has not failed to perform a nondiscretionary duty under the CWA citizen suit provision, and thus Plaintiffs' and the Tribe's complaints should be dismissed and summary judgment entered for EPA.

B. Plaintiffs Have Waived Their Right to Challenge EPA's Determinations That Ecology Has Not Renounced Establishing a PCB TMDL for the Spokane River If Necessary and That Ecology Has Thus Not Constructively Submitted Such a TMDL.

Even assuming, arguendo, that a constructive submission claim could be used to compel EPA to establish a particular TMDL, Plaintiffs have waived their right to raise such a claim here. As discussed *supra* at 18-20, on April 12, 2012, EPA reached its administrative determination that Ecology has not disavowed establishing a Spokane River PCB TMDL if needed and that Ecology has not therefore constructively submitted such a TMDL. In their amended complaint, Plaintiffs include an additional claim (claim two) against EPA under the Administrative Procedure Act challenging EPA's April 12, 2012, determination, alleging that EPA's "determination that Ecology has not submitted a Spokane River PCB TMDL is arbitrary, capricious, an abuse of discretion, and

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[14]/ EPA does not here opine on what recourse Plaintiffs may have on claims in State court directly against Ecology regarding its priorities under State law or regulations. That matter is not before the Court.

not in accordance with law, and their refusal to approve or disapprove the TMDL, and, if disapprove, to establish a TMDL as required by 33 U.S.C. § 1313(d)(2) constitutes agency action unlawfully withheld or unreasonably delayed." Dkt. No. 61¶ 41. Because Plaintiffs have elected not to argue their second claim to challenge EPA's determination in their motion for summary judgment, that claim is waived in accordance with the caselaw and the parties' stipulated agreement and the Court's Scheduling Orders that all claims in this case will be resolved by these summary judgment proceedings.[15]/

The rule in this Court is clear that such claims must be dismissed with prejudice. *See, e.g.,Wild Bainbridge v. Mainlander Services Corp.* 544 F. Supp. 2d 1159, 1167 (W.D. Wash. 2008) ("Pursuant to the parties' agreement that all claims against the federal defendants will be resolved by summary judgment, all claims not raised in Wild Bainbridge's summary judgment motion are dismissed as to the Corps."); *Thunderbird Trading v. U.S. Bureau of Alcohol, Tobacco and Firearms*, No. C92-5181, 2007 WL 1128810, at *10 (W.D. Wash. Ap. 16, 2007) (where all parties agreed that all issues are to be decided on summary judgment, on those issues in the Plaintiff's complaint not raised in the Plaintiff's brief "the Court presumes that Plaintiff has abandoned them. Therefore, to the extent that Plaintiff makes claims, if any, regarding these issues, Plaintiff's claims should be dismissed with prejudice and summary judgment for the Defendants should be granted.").[16]/

Accordingly, because Plaintiffs elected not to pursue its challenge to EPA's April 12, 2012, determination, the determination necessarily stands intact.

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[15]/ Order, dated April 8, 2013 (Dkt. No. 58) (entering the parties Stipulation and Proposed Order to Modify Scheduling Order at 2 & 4 ¶ 7); Order, dated September 12, 2013 (Dkt. No. 78) (entering the parties' Stipulation and [Proposed] Briefing Schedule, at 4 ¶ 5); *see also* Order, dated December 23, 2013 (Dkt. No. 88) (entering the parties Stipulation and [Proposed] Modified Briefing Schedule).

[16]/ *Also Mountain States Legal Found. v. Espy*, 833 F. Supp. 808, 813 nn.4-6 (D. Id. 1993) (where the plaintiff agreed that all claims in its complaint would be resolved through summary judgment, claims not raised in its summary judgment motion were waived and dismissed with prejudice); *City of Santa Clarita v. Dep't of Interior*, No. 02-00697, 2006 WL 4743970 at *11 (C.D. Cal. Jan. 30 2006) (same), *aff'd*, 249 Fed. Appx. 748 (9th Cir. 2007).

C. The Court Should Uphold EPA's Reasonable Determined That Ecology Has Not Renounced Submitting a PCB TMDL for the Spokane River if Needed and That Such a TMDL Has Not Been Constructively Submitted to EPA.

1. The Administrative Record Supports EPA's Finding That There Has Not Been a Constructive Submission.

Assuming, arguendo, that Plaintiffs can overcome the legal bars discussed above to either of their claims, the Court should uphold EPA's reasonable determination and reject those claims. As explained in detail, *supra* at 18-20, EPA in its April 12, 2013, determination concluded that "Ecology's decision to delay completion of a PCB TMDL for the Spokane River is within the discretion of the State of Washington" and that "Ecology has not renounced completion of a PCB TMDL for the Spokane River if one is required." V.1, T.A, at 1. EPA thus determined that there has not been a constructive submission by Ecology of a PCB TMDL. These determinations are amply supported by the record.

As detailed above, Ecology has a robust, ongoing TMDL program, having issued 1372 TMDLs since 1999, including 73 TMDLs in the Spokane River watershed, and Ecology is committed to continuing this progress. *Supra* at 9-10. Although Ecology initiated the process to develop a PCB TMDL for the Spokane River, those efforts disclosed significant information gaps and the need for additional study and analysis, which prevented Ecology from completing that TMDL. *Supra* at 11-14; V.1, T.A at p.4; V.5, D.132 at 2671, 2675, 2683. Ecology also recently completed a lengthy, technically complex and contentious twelve-year process to establish a dissolved oxygen TMDL for the Spokane River, V.1, T.A at p.4, V.1, D.4 at 503; V.5, T.132 at 2671-72, and based upon lessons it learned there, Ecology was concerned that pressing forward on a PCB TMDL for that same water-body, especially given the significant gaps in information and the importance of a cooperative approach, would result in further, lengthy delays in establishing such a TMDL. *Id.; supra* at 16-17. Ecology thus determined to devote its limited resources to other TMDLs at this time, and to supplemental measures, including the Task Force, to fill data gaps and to achieve near-term PCB reductions. *Id.* EPA supports the work of the Task Force and other interim measures until such time that a PCB TMDL can be completed if necessary. V.1, T.A at pp.2-3. Moreover, even if the Task Force or other measures fail to adequately reduce PCBs, the information gained by the Task Force would assist in the development of a TMDL. *Supra* at 15-16.

EPA also found reasonable Ecology's commitment to review the Task Force's progress in five years. V.1, T.A at 3. Ecology further committed to establish a PCB TMDL if the Task Force or other measures it may adopt fail to achieve applicable PCB water quality standards. V.2, T.44 at 706 ("a PCB TMDL still remains a tool and will be necessary if ongoing toxics reduction strategies do not result in compliance with water quality standards."); *also* V.1, T.1 at 2. If the applicable PCB water quality standards are met through supplemental measures, no TMDL would be required. EPA explained that this "leads EPA to conclude that Ecology has not repudiated its legal obligation to develop a PCB TMDL if needed." Id. at 4. EPA concluded that Ecology must retain discretion to manage and establish priorities for TMDL development, including how limited resources should be expended to reduce pollution where TMDLs have not yet been completed. *Id.*

In their effort to discredit Ecology's reasons for deferring a PCB TMDL, Plaintiffs argue that Ecology shared with EPA a "complete draft TMDL" to review, that this draft TMDL included all elements required in a TMDL for approval by EPA, and that Ecology's draft TMDL went through the public notice process required for TMDL development. This is incorrect. As an initial matter, the documents Plaintiffs contend are technically complete TMDLs are each marked "Draft . . . Do not cite or quote," V.3, T.90, at 1319; V.3, T.69 at 1102, which demonstrates that Ecology never believed them complete. Ecology also has not conducted the notice and comment proceedings required before a TMDL can be submitted to EPA. *Supra* at 13 n.9. Moreover, Ecology itself explained that significant gaps in information and need for additional new information prevented these preliminary drafts from being finalized. The background section of this brief details important areas where these draft documents are incomplete. *Supra* at 11-14, 17.

For example, the draft document that Plaintiffs and the Tribe contend is a complete and approvable PCB TMDL for the Spokane River could not identify the sources or categories of sources or otherwise account for 57% of the PCB loading in the relevant reach of the River. V.1, T.15 at 163 (figure 19); *supra* at 14. Further, in uncontested testimony in a proceeding before the

Pollution Control Hearing Board involving the same plaintiffs in this case, a spokesperson for Ecology explained as follows:

> Q And I believe you testified earlier that this draft TMDL failed to account or was unable to discover roughly 57 percent of the sources of PCB loading to the river?
> A Correct.
> Q Would Ecology develop a total maximum daily load for a pollutant if it didn't even know where 57 percent of the sources of that pollutant came from?
> A No.
> Q Why not?
> A It would leave too much uncertainty and I think it would require the dischargers to pay an inequitable amount of their resources to solve the rest of the PCB problem.

V.5, D.132 at 2683 (questions by counsel for Ecology; answers by Ecology employee Jim Bellatty); *id.* at 2671 (this large information gap "leaves a lot of unanswered questions and uncertainty with our ability to be able to do a TMDL"). This and the other record information readily rebuts Plaintiffs' conclusory assertions that political pressure prevented Ecology from finalizing the TMDL.

In sum, EPA fully explained the bases for its April 12, 2013, determination and the record amply supports EPA's findings. Plaintiffs' burden to demonstrate otherwise is particularly high in this case, where inherent in the State's decisions are judgments about how best to allocate limited resources to protect the environment.

2. Plaintiffs' Arguments Challenging EPA's Decision Are Without Merit.

Plaintiffs contend that a Memorandum of Agreement between EPA and Ecology in 1997 regarding Ecology's commitment to establish TMDLs, as well as Ecology's 303(d) lists from 1996 through 2010, required that Ecology have developed a PCB TMDL for the Spokane River by 2013. Pl. Br. at 26-27 & 34. This argument is flawed on several counts. First, neither that Memorandum of Agreement, V.1, T.34, nor the out-of-court settlement agreement that EPA entered in 1998 with two environmental groups regarding TMDL development, V.1, T.32, required Ecology to have established and submitted a Spokane River PCB TMDL to EPA by this time. Consistent with the CWA, those documents necessarily preserve Ecology's discretion to select which particular TMDLs to develop and when to do so. For example, Attachment A to the Memorandum of Agreement and settlement agreement describes Ecology's 303(d) prioritization process for initiating development of TMDLs in different management area watersheds throughout the State over five-year cycles, V.1, T.33, including the Spokane area. It does not require that the TMDL on which Ecology initiates development in the Spokane area be for PCBs. *Id.* at 457. Similarly, the settlement agreement preserves Ecology's discretion to substitute between TMDLs it intends to develop from the State's different 303(d) lists. V.1, T.32 at 47-48 (¶ 7).

Nor is there anything to Plaintiffs' claim that Ecology has departed from its prioritization process and ignored the Spokane River and its tributaries. As explained above, since 1999, Ecology submitted and EPA has approved 1372 TMDLs, many of which were for WQLSs in the Spokane River and its tributaries. Further, on April 12, 2012, EPA approved an additional 57 TMDLs submitted by Ecology for the Little Spokane River watershed, for fecal coliform bacteria, temperature and turbidity. [Is the 57 Included in the total?] Thus, Ecology has not, as Plaintiffs' claim, departed from its prioritization process and ignored the Spokane River. Rather, Ecology has exercised its discretion by prioritizing and completing the particular TMDLs that in its judgment will best protect water quality most efficiently with the State's finite resources.

Plaintiffs further argue that because Ecology initiated development of a PCB TMDL for the Spokane River, Ecology was required to have already completed and submitted that TMDL to EPA. However, as explained above, Ecology has adapted its priorities based upon the circumstances, deciding to defer establishing a PCB TMDL for the Spokane River and to establish other TMDLs at this time, and to adopt interim, supplemental measures to reduce PCBs in the Spokane River. Nothing in the CWA or EPA's regulations precludes Ecology from altering course in this manner. Moreover, while EPA's regulations direct States to submit 303(d) lists every two years, and to include a priority ranking of waters "targeted for TMDL development within the next two years," 40 C.F.R. § 130.7(d)(1), this language plainly does not require completion of such TMDLs within that two-year period. Nor could it, since, as discussed above, the CWA preserves the State's discretion in this regard, requiring only that States submit TMDLs to EPA "from time to time," 33 U.S.C. § 1331(d)(2). Rather than require TMDLs be submitted in two years, this language expressly preserves State discretion to determine when such TMDLs should be developed and submitted to EPA. Similar "time to time" language under a different Section 303 provision are construed precisely in this manner. *American Canoe,* 30 F. Supp. 2d at 923. Indeed, "courts have generally held that the use of the phrase 'time to time' does not create a nondiscretionary administrative duty." *Id.* [17]/

Plaintiffs argue that Ecology has decided to utilize a "straight-to-implementation project" ("STI") for reducing PCBs in the Spokane River, that STI projects necessarily preclude TMDLs, and that this demonstrates that Ecology has decided no PCB TMDL for the Spokane River will ever be established. Pl. Br. at 28. EPA reasonably addressed this in its April 2012 determination, explaining that STIs are a type of interim approach to identify PCB sources and practices to prevent contamination reaching the water body, and that Ecology's "definition and use of this term [i.e., STI] are changing over time." V.1, T.A at pp. 2-3. Further, while Ecology once appeared to refer to the Task Force or other measures to reduce PCBs in the Spokane as an STI, it no longer does so. *Id.* at p.3 n.10. The key point here, however, is that Ecology has committed to establish a PCB TMDL if it is ultimately needed, and that it therefore does not matter whether the Task Force, or any other interim, supplemental measures Ecology may adopt, may have once been or are called STIs. *Id.* Moreover, if Plaintiffs here intend to challenge STIs generally or in other contexts, that issue is not before the Court; neither the issues nor administrative record in this case provide the Court with the opportunity or ability to resolve whether STIs generally or in other contexts preclude TMDLs. And then, Plaintiffs depiction of STIs is incorrect, because an Ecology presentation in the record from 2011 states that an STI "does not preclude further TMDL

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[17]/ *See, e.g., NRDC v. Thomas*, 885 F.2d 1067, 1075 (2nd Cir. 1989) (Clean Air Act provision requiring revision of a list of air pollutants "from time to time" does not impose a nondiscretionary duty); *Oljato Chapter of the Navajo Tribe v. Train*, 515 F.2d 654, 661 (D.C. Cir. 1975) (Clean Air Act provision imposing a duty in which EPA may from "time to time" revise certain standards does not impose a nondiscretionary duty). Rather, a nondiscretionary duty is typically one in which the statute requires performance by a date certain. *Sierra Club*, 828 at 791 (absent a readily-ascertainable deadline, "it will be almost impossible to conclude that Congress accords a particular agency action such high priority as to impose upon the agency a 'categorical[] mandat[e]' that deprives it of all discretion over the timing of its work.").

pathway." V.3, T.86 at 1307.

Eventually, Plaintiffs frankly concede in their brief, as they must, that Ecology has not renounced its obligation to establish a PCB TMDL if one is ultimately necessary, but they then argue that Ecology has not adequately identified what "measurable progress," "activities," or "metrics" would make the TMDL "unnecessary." Pl. Br. at 28-29. Plaintiffs confuse the issue and distort Ecology's position; it is undisputed that the TMDL will ultimately not be needed if and when the Spokane River meets the applicable PCB water quality standards. *See supra* at 5. Moreover, Ecology's point is that, for now, it has chosen to pursue various interim measures, such as the Task Force, to reduce PCBs in the Spokane River, while development of the PCB TMDL is deferred for the reasons discussed above. At the same time, Ecology has clearly committed that it will evaluate the Task Force's progress in five years, V.1, T.1 at 1-2, and if "measurable progress" is not being made and other measures are not available, "Ecology would be obligated to proceed with development of a [Spokane River PCB] TMDL . . . ." *Id.* at 2. Thus Ecology explained that "it is committed to proceed with a TMDL should it be necessary." *Id.* Further, if such a TMDL is needed, Ecology will have the benefit of the additional needed information gathered (based on the work of the Task Force) for developing the TMDL. *Supra* at 15-16; V.1, T.35 at 481-84 (data to be gathered). Based upon this, EPA reasonably concluded that "Ecology has not repudiated its legal obligation to develop a PCB TMDL if needed," *V.1 T.A,* at 4.

Plaintiffs next complain that the Task Force is not adequate, alleging that it is "controlled by the NPDES dischargers." Pl. Br. at 29. Such an attack, however, is incorrect, given that several governmental entities and other environmental groups are members of the Task Force. *Supra* at 15. Indeed, Plaintiffs as well as the Spokane Tribe were invited to participate in the Task Force, but declined. Although Plaintiffs doubt that the Task Force will achieve its goal, this is no reason to fault Ecology for pursuing interim measures to reduce PCB pollution, much less to equate Plaintiffs' projections of the Task Force's failure to Ecology constructively renouncing ever establishing a TMDL. Nor is it a proper criticism that the Task Force did not, up-front, identify measures it will adopt to reduce PCB pollution, given that it was only recently established and part of its mission is to identify those measures. *Supra* at 15-16. Moreover, Plaintiffs inaccurately suggest that the Pollution Control Hearing Board was critical of the Task Force. To the contrary, while the Board merely concluded that participation in the Task Force is not a defense to NPDES permit compliance, Board Decision at p.27, a matter not at issue here, the Board stated that it "finds that the creation of the Task Force is a positive step toward bringing the Spokane River into compliance with water quality standards for PCBs" and that "the actions undertaken by the Task Force are necessary to address the water quality problems in the Spokane River . . . ." *Id.* at p.26.

Finally, Plaintiffs allege that absent a PCB TMDL for the Spokane River, NPDES permits issued by Ecology for PCB discharges into the Spokane River will be inadequate. Pl. Br. at 33. This argument is flawed for several reasons, and we address it in detail *infra* at 42-43 & 45. EPA highlights here that if Plaintiffs believe those State-issued permits are inadequate, the remedy is to challenge them through the State administrative process and court system, rather than improperly attempt to adjudicate their adequacy in this case. Plaintiffs' unsupported claims that NPDES permits will be inadequate thus provide no support for the claims in this case. Moreover, as explained *supra* at 7, even where a TMDL has not yet been established, States still must include effluent limits in NPDES permits as stringent as necessary to meet water quality standards, 33 U.S.C. § 1311(b)(1)(C); 40 C.F.R. § 122.44(d)(1)(vii)(A). Indeed, as explained below, the presence of a PCB TMDL may not result in any change in the stringency of NPDES permits.

In sum, Plaintiffs have not met the high burden to upset EPA's April 12, 2013, determination nad have not established that a constructive submission has occurred.

II. THE INTERVENOR SPOKANE TRIBE'S CLAIMS SHOULD BE REJECTED.

The Tribe in its second amended complaint asserts two claims for relief. In its first claim, under the CWA citizen suit provision, the Tribe incorporates portions of Plaintiffs' claim and alleges that "EPA breached its trust responsibility and fiduciary duty to the Tribe by failing to perform its nondiscretionary duties under 33 U.S.C. § 1313(d)(2)," Dkt. No. 74, Attach. 1 ¶ 22. The Tribe's second claim, after incorporating Plaintiffs' description, alleges that "EPA Defendants' April 12, 2013 determination failed to protect the interests of the Spokane Tribe, and

EPA Defendants have breached and will continue to breach their trust responsibility and minimum fiduciary duty owed to the Spokane Tribe because the April 12, 2013 determination is not in accordance with 33 U.S.C. § 1313(d)(2) and federal common law, and is in violation of 5 U.S.C. § 706(2)(A)&(D) [*i.e.*, APA standards of review]." *Id.* ¶ 24. This language explicitly limits the claims in this case to arguments that EPA's alleged failure to comply with the CWA, the APA, and any applicable common law, also constitutes a breach of EPA's alleged trust responsibility and fiduciary duty owed the Tribe.

In its brief, the Tribe argues that, for the downstream PCB-impaired water-body segment it administers within its jurisdiction, the Tribe has established PCB water quality standards that are more stringent than those adopted by Ecology for the upstream segments Ecology administers, to account for risks posed by the greater fish consumption assumed for Tribal members. The Tribe argues that unless PCBs upstream are adequately reduced, the Tribe's more stringent water quality standard in the downstream segment within its jurisdiction cannot be met. According to the Tribe, only an EPA-established TMDL for the upstream segment administered by Ecology will ensure NPDES limits within that segment that can accomplish PCB reductions downstream on the reservation, and that the general fiduciary duty weighs in favor of finding a constructive submission under the CWA citizen suit (claim one). In the alternative, the Tribe contends that EPA's determinations that Ecology has not renounced its obligation to establish a TMDL and that no constructive submission has occurred should be set aside under the Administrative Procedure Act (claim two). The Tribe's arguments miscast the nature of EPA's general trust responsibility and provide no basis to find a constructive submission or upset EPA's determination. As discussed below, there is no specific fiduciary duty owed the Tribe in this case. Moreover, nothing in EPA's decision undermines the Tribe's ability to enforce its tribal PCB standard.

A. EPA's Compliance with the CWA and its Regulations Satisfies its General Trust Responsibility.

Although the relationship between the United States and Indian tribes has been described as a trust, the scope of the federal trust responsibility is not defined by common law fiduciary duties or those imposed on a private trustee. *United States v. Jicarilla Apache Nation*, 131 S. Ct. 2313, 2323 (2011). Rather, tribes must point to specific statues and regulations that "establish [the] fiduciary relationship and define the contours of the United States' fiduciary responsibilities." *Id.* at 2325 (citation omitted). Thus the only cognizable breach of trust claim is one founded upon a definite and express fiduciary duty imposed on the federal government by administrative regulation or Act of Congress. *United States v. Navajo Nation*, 537 U.S. 488, 511 (2003); *United States v. White Mountain Apache Tribe,* 537 U.S. 465, 477 (2003). Accordingly, the federal common law trust duties applicable to private beneficiaries, which the Tribe seeks to impute to the federal government, *see* Tribe Br. at 15, do not provide independent bases for the claims asserted by the Tribe. *See Pacific Coast Fed'n of Fisherman's Ass'ns v. United States BLM,* 2005 U.S. Dist. *LEXIS* 36035, *34 (N.D. Cal. Mar 8, 2005).

There is a "distinctive obligation of trust incumbent upon the Government in its dealings with [Indian tribes]." *Gros Ventre Tribe v. United States*, 469 F.3d 801, 810 (9th Cir. 2006) (quoting *United States v. Mitchell*, 463 U.S. 206, 225 (1983)). However, "[w]ithout an unambiguous provision by Congress that clearly outlines a federal trust responsibility, courts must appreciate that whatever fiduciary obligation otherwise exists, it is a limited one only." *Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1476, 1482 (D.C. Cir. 1995). While that general trust relationship allows the federal government to consider and act in the tribes' interests in taking discretionary actions, it does not impose a duty on the federal government to take action beyond complying with generally applicable statutes and regulations. *Jicarilla*, 131 S. Ct. at 2325. Accordingly, in the absence of a specific duty that has been placed on the government with respect to the Tribe, the United States' general trust responsibility "is discharged by the agency's compliance with general regulations and statutes not specifically aimed at protecting Indian tribes." *Morongo Band of Mission Indians v. F.A.A.*, 161 F.3d 569, 574 (9th Cir. 1998); *Okanogan Highlands Alliance v. Williams*, 236 F.3d 468, 479 (9th Cir. 2000) (Bureau of Land Management's approval of gold mine satisfied trust obligations by the agency's compliance with NEPA); *Gros Ventre*, 469 F.3d at 814.

Here, the Tribe alleges in its CWA citizen suit claim that EPA breached fiduciary duties owed in the CWA by not establishing a TMDL. Second Amended Complaint ¶ 24 (Dkt. No. 73, Attach. 1). The Tribe does not identify where the CWA establishes a fiduciary duty mandating that EPA establish a PCB TMDL for the Spokane River, much less that a mandatory duty requires EPA do so at this time. Instead, the Tribe duplicates the arguments of Plaintiffs (which we refute above) based upon the government's general statutory and regulatory obligations under the CWA. Accordingly, EPA satisfied its general trust responsibility by its compliance with the CWA.

B. The Indian Law Canon of Construction Raise by the Tribe Does Not Apply, and Even if It Did, It Would Not Result in a Finding of a Constructive Submission.

The Tribe contends that an Indian law canon of construction requires that any statutory ambiguity be interpreted to benefit the Tribe, and that this canon is triggered in this matter because under CWA section 518(e), 33 U.S.C. § 1377(e), the Tribe has been granted the right "to be treated as a state," *id.*, for purposes of issuing water quality standards. Tribe Br. at 5-6. Even assuming arguendo this were accurate, this canon is inapplicable because, as demonstrated in Section 1.A above, the provision of the CWA at issue in this case is not ambiguous: the constructive submission theory does not, as a matter of law, apply in this case. And beyond that, the CWA calls for EPA to approve or disapprove TMDLs arises only if TMDL submissions (actual or constructive) have occurred, and there is no ambiguity in that statutory proposition. The canon of construction raised by the Tribe does not apply when the statue is clear. Thus the Court need not decide whether the canon cited by the Tribe applies here.

Even were the applicable law ambiguous, the referenced canon would not apply in this circumstance. This canon applies only to "'statutes passed for the benefit of dependant Indian tribes.'" *Hoonah Indian Ass'n v. Morrison*, 170 F.3d 1223. 1228 (9th Cir. 1999) (quoting *Bryan v. Itasca County, 426 U.S. 373, 392 (1976)).* Regardless of whether this canon may apply to ambiguous interpretations of the Tribe's authority under 33 U.S.C. § 1377(e), or the Tribe's administration of its own program, it certainly would not extend here to the Section 303(d) TMDL program administered by Ecology, *id.* § 1313(d), EPA's obligation to approve or disapprove a

TMDL once submitted, *id.* § 1313(d)(2), or the CWA provisions governing the Tribe's assertion that the Court must order EPA to establish a PCB TMDL and thereby usurp Ecology's role and substitute the Tribe's priorities for the State's reasonable pollution prevention and remediation plans. The latter generally applicable provisions of the CWA just discussed are the only provisions at issue in this case, and thus the referenced canon would not apply.

The Tribe also appears to rely upon the canon when recounting selected documents and information in the administrative record, which it construes in its favor, in an effort to establish that Ecology has renounced its obligation to issue a TMDL that may be necessary, and thus has constructively submitted a PCB TMDL to EPA. However, even if the canon somehow applied to the interpretation of the CWA, it does not apply to the judicial review of record information. Rather, the applicable arbitrary and capricious standard of the Administrative Procedure Act applies. The Tribe has not met its burden to demonstrate that EPA's determinations are arbitrary and capricious or contrary to law.

C. The Tribe's Arguments Based Upon Alleged Impacts to Its Fishing Rights Are Not Properly Before the Court, and Provide No Basis to Reject EPA's Determination.

In the context of its APA claim, the Tribe contends that EPA's April 12, 2013, decision is arbitrary, capricious or contrary to law because it "fails to preserve and protect the Tribe's fishing rights." Tribe Br. at 16. The Tribe appears to base its argument on its assertion that it has "a right to water quality that can sustain fish and other aquatic life." Tribe Br. at 6 (citing *United States v. Anderson*, 591 F. Supp. 1, 5 (E.D. Wash. 1982), *aff'd in part and rev'd in part*, 736 F.2d 1358 (9th Cir. 1984)). That case, however, involved an adjudication of the Tribe's water rights in the Chamokane Stream, and the Court addressed only "[t]he quantity of water needed to carry out the reserved fishing purposes" as it relates to "flow" and "water temperature." Moreover, this is far different than the circumstance here, where the issue is PCB contamination and the State's decision of how best to expend resources to reduce that pollutant. *See Hopi Tribe v. United States*, 113 Fed. Cl. 43, 49 (2013) (reserved water rights do not impose mandatory fiduciary duties on the United States to build drinking water infrastructure). This issue, however, is not properly before the Court, regardless of what the scope of the Tribe's fishing rights may be, and should be dismissed. Plaintiffs' second amended complaint does not include a claim based upon alleged violation of fishing rights. Stipulations entered by the Parties and filed in Court further demonstrate that the Intervenor Tribe's complaint was not to so expand the claims in this case.[18]/

Even if this issue were properly before the Court, the Tribe has not made the necessary showing to support its assertion that the lack of an EPA-issued TMDL adversely impacts the Tribe's fishing rights. TMDLs are not self-executing and thus do not themselves reduce pollution.

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[18]/ After this Court ruled that review in this case is limited to the administrative record, Dkt. No. 49, Plaintiffs requested that EPA review documents and approve or disapprove a constructive submission, V.1, T.B & C, which resulted in EPA's April 12, 2012, determination that no constructive submission had occurred, V.1, T.A, and the inclusion of additional documents in the record for judicial review. Dkt. No. 58 at 2, 4-5 (¶ 8) (Order dated April 8, 2013). Counsel for the Tribe did not, as part of that process, request that EPA consider or determine impacts to its fishing rights. *See id.* Moreover, Plaintiffs, and the Tribe, were to add an additional cause of action in their amended complaints only to secure their challenge to EPA's April 12, 2013, determination. That process, however, was not to enlarge the basic issues originally in this case. After the Tribe filed its First Amended Complaint, Dkt. No. 64, counsel for EPA contacted counsel for the Tribe and objected because the Tribe's new second and third causes of action added the claims that EPA failed to comply with certain specific alleged fiduciary duties, including primarily an alleged failure to consult with the Tribe as part of that process. *Id.* ¶¶ 19-23. Ultimately, to ensure no misunderstanding, through an exchange of emails and calls, the Parties' all agreed to the following:

> The Parties agree that in the Tribe's Second Amended Complaint, the Tribe is not raising a breach of trust/fiduciary duty claim based upon EPA's alleged failure to consult with the Tribe upon considering the additional documents and in issuing its April 12 letter. Thus, the Tribe, in the second claim of its second amended Complaint, may only challenge as a breach of trust/fiduciary duty the merits of EPA's decision that there has been no constructive submission.

Emails dated September 6 and 9, 2013, Attachment A hereto. Based on this agreement, the Parties' filed a joint stipulation, Dkt. No. 73, which the Court entered on September 12, 2013, Dkt. No. 74, thereby authorizing the filing of the Tribe's Second Amended Complaint, to ensure that the claims in this action were not expanded. The stipulation filed by the Parties explained as follows:

> To resolve disagreements regarding the scope of the amended complaint filed by the Tribe, the Parties hereby stipulate to the Intervenor-Plaintiff Spokane Tribe of Indians filing a second amended complaint, which is attached (Attachment 1). <u>This proposed second amended complaint is narrower than the Complaint previously filed by Intervenor-Plaintiff Spokane Tribe, and thus its filing will neither expand the claims in this lawsuit nor delay their resolution</u>, while also resolving disputes the Parties had regarding the scope of the first amended complaint previously filed by the Spokane Tribe of Indians.

Doc. Nos. 73 & 74, ¶ 3 (emphasis added). Accordingly, the Tribe's arguments in its motion for summary judgment alleging fishing rights have been violated are not properly before the Court and must be dismissed.

Even if EPA were required to establish a PCB TMDL, it may not result in any reduction in PCBs in the River or in fish located within the Tribe's fishing grounds. The Tribe contends that the lack of an EPA-issued PCB TMDL has resulted or will result in State-issued NPDES permits that lack adequate PCB limits or will not make adequate progress reducing PCBs in the Spokane River. They offer, however, only speculative and conclusory assertions in this regard, and neither the issues nor administrative record in this case provide the Court with the authority, or basis, to assess the adequacy of such future permits. As explained *supra* at 7, the lack of a TMDL does not preclude the inclusion of appropriate effluent limits in NPDES permits. Regardless of whether a TMDL has been established, NPDES permits still must include effluent limits as stringent as necessary to meet water quality standards. 33 U.S.C. § 1311(b)(1)(C); 40 C.F.R. § 122.44(d)(1)(vii)(A). A PCB TMDL, therefore, would not necessarily make NPDES permits any more stringent. Moreover, the Tribe's theory of how of its fishing rights are impacted inappropriately assumes the Task Force will fail to reduce PCBs. Ecology, however, reasonably reached the contrary conclusion, and the Pollution Control Hearing Board concurred that the work of the Task Force is necessary to reducing PCBs and meeting water quality standards. *Supra* at 37.

The Tribe's argument also fails because the issuance of NPDES permits will also take into account the Tribe's PCB water quality standard. The Tribe's recourse for inadequate NPDES permits is to appeal them. Thus, the Tribe has not demonstrated that an EPA-issued TMDL is required to protect the Tribe's fishing rights.

The Tribe also appears to argue that EPA was under a mandatory fiduciary duty to take into consideration impacts to the Tribe's fishing rights in deciding that Ecology has not constructively submitted a Spokane River PCB TMDL. Tribe Br. at 15-16. As noted *supra* at 42 n.18, as part of EPA's consideration of Plaintiffs' administrative request, the Tribe did not request that EPA determine or consider any potential impact to its fishing rights, and that issue is not properly raised in this case. In any event, the Tribe does not point to a source of law containing a specific mandatory fiduciary duty that would require that EPA disrupt Ecology's priorities and efforts to reduce PCBs and establish a federal PCB TMDL for the Spokane River at this time.

In sum, the Tribe's fishing rights claim is not properly before the Court. Even if it were, the Tribe has not shown that its fishing rights have been adversely affected by EPA's determination that there has not been a constructive submission, or that there is a mandatory fiduciary duty for EPA to establish a PCB TMDL for the Spokane River.

III. PLAINTIFFS ARE NOT ENTITLED TO THE REMEDY SOUGHT.

Plaintiffs request that the Court order EPA to establish a Spokane River PCB TMDL "within 90 days." Pl. Br. at 32. Plaintiffs' requested relief is unfounded and impracticable. Thus, even assuming that Plaintiffs were entitled to some relief, the requested relief should be denied.

Injunctive relief may not be granted as a matter of course. *Weinberger v. Romero-Barcelo,* 456 U.S. 305, 311 (1982); *Amoco Prod. v. Gambell,* 480 U.S. 531, 546 n.12 (1982). The Supreme Court explained in a citizen suit case that "the court [must] 'balance[] the conveniences of the parties and possible injuries to them according[ly] as they may be affected by the granting or withholding of the injunction." *Weinberger*, 456 U.S. at 312; *Amoco*, 480 U.S. at 542. In formulating a remedy, "the court must be careful not to intrude upon the agency's realm of discretionary decision making." *Idaho Sportsmen v. Browner*, 951 F. Supp. 962, 968 (W.D. Wash. 1996).

To the extent that the Court determines that some injunctive relief is appropriate here, the CWA citizen suit provision provides that the remedy is limited to "order[ing] the Administrator to perform [the nondiscretionary] act or duty" 33 U.S.C. § 1365(a) (i.e., a remand to EPA to approve or disapprove the constructive submission). A constructive submission triggers a mandatory duty on the part of the EPA Administrator to either approve or disapprove the constructive submission. *Hayes*, 264 F.3d at 1023. Only if the Administrator disapproves the constructive submission is the EPA Administrator under a duty to establish a TMDL. *Id.; also Scott*, 741 F.2d 997. Accordingly, imposing a schedule on EPA to establish a PCB TMDL is not an appropriate remedy. *See also American Canoe Ass'n v. EPA,* 30 F. Supp.2d 908, 922 & n.17 (E.D. Va. 1998) ("the appropriate remedy for the plaintiffs' TMDL [complaint] would appear to be an order directing EPA to approve or disapprove Virginia's constructive submission within 30 days . . . .").

Furthermore, EPA's determination on remand could be challenged by Plaintiffs as final agency action; the Court's role would then be limited to reviewing EPA's approval or disapproval determination. *Hayes*, 264 F.3d at 1023; *American Canoe*, 30 F. Supp. 2d at 923 n.17 ("[i]f the EPA approved the [constructive] submission, this would appear to be a final agency action which could be challenged for abuse of discretion under the Administrative Procedure Act").

Even assuming the Court's authority extends to ordering EPA to establish a Spokane River PCB TMDL, Plaintiffs' have not shown that the injury to them if the relief is not granted outweighs the damage to EPA and the public interest if it is. For example, Plaintiffs contend that the lack of a PCB TMDL has resulted or will result in State-issued NPDES permits that lack PCB limits necessary to reduce PCB discharges and achieve water quality standards. As explained *supra* at 7, 37, 42-43, such assertions lack any foundation. As explained, NPDES permits must require effluent limits that ensure water quality standards will be met, regardless of whether a relevant TMDL has been established, 33 U.S.C. § 1311(b)(1)(C); 40 C.F.R. § 122.44(d)(1)(vii)(A), and Plaintiffs' recourse if they believe State-issued permits are inadequate is to appeal such permits in the appropriate State administrative or judicial tribunal. Nor have Plaintiffs demonstrated that the Task Force will fail to reduce PCBs or that the relief they seek would result in any, let alone quicker, PCB reductions.

Plaintiffs also make no showing that the public interest will not be harmed by the Order they seek, due to the diversion of resources from equally or even more important State or federal TMDL development effort or other environmental projects. In this regard, it should be recognized that the entire docket of EPA involves issues affecting health and welfare. An increase in resources devoted to the PCB TMDL sought by Plaintiffs and Intervenor would result in a concomitant re-direction of resources devoted to other EPA programs designed to protect health and welfare.

If the Court were to conclude that an order requiring EPA to establish a PCB TMDL is appropriate, EPA should not be ordered to comply with Plaintiffs' proposed schedule to establish a PCB TMDL within 90 days. While Plaintiffs argue that this is reasonable "because the work has already been done to prepare a technically sound TMDL," Pl. Br. at 32, this is clearly not the case. As discussed above, there are significant gaps in the draft TMDL Ecology prepared that would require an extended period of time to address. In considering the time necessary for EPA to complete such a complex regulatory action, the Agency must have the time it reasonably determines necessary to investigate and develop the necessary information. Even once a complete proposal is prepared, for complex regulatory actions EPA must have the time to consider the "complex scientific, technological, and policy questions" raised, reach "considered results," and establish a defensible action that will protect the environment. *Sierra Club v. Thomas*, 828 F.2d at 798. "[B]y decreasing the risk of later judicial invalidation and remand to the agency, additional time spent reviewing a rulemaking proposal before it is adopted may well ensure earlier, not later, implementation of any eventual regulatory scheme." *Id*. at 798-99. Finally, EPA's consideration of what schedule might be possible would require the consideration of additional information well beyond that contained in the administrative record in this case.

In short, even if Plaintiffs prevailed under a constructive submission theory, they would not be entitled to any of the injunctive relief they seek.

CONCLUSION

For the reasons stated above, the Court should grant EPA's cross-motion for summary judgment and deny Plaintiffs' and Intervenor's motions for summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing filing was electronically filed with the Clerk of the Court on January 29, 2014, PST, using the Court's electronic filing system, which will send notification of said filing to the attorneys of record that have, as required, registered with the Court's system.

/S/ David Kaplan

2015 Annual Toxics Management Report
Spokane County Regional Water Reclamation Facility
NPDES Permit WA-0093317

2015 Annual Toxics Management Report
Spokane County Regional Water Reclamation Facility
NPDES Permit WA-0093317

BC Project 142892

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List of Abbreviations

Anatek	Anatek Labs, Inc.
ATSDR	Agency for Toxic Substances and Disease Registry
AXYS	AXYS Analytical Services
BMP	best management practice
CAS	Chemical Abstracts Service
COC	chain of custody
Consultant	Brown and Caldwell
County	Spokane County
DeBDE	decabromodiphenyl ether homolog group
DeCB	decachlorobiphenyl homolog group
DiBDE	dibromodiphenyl ether homolog group
DiCB	dichlorobiphenyl homolog group
Dioxin	2,3,7,8-Tetra-Chlorodibenzo-P-Dioxin
DMI	Dishman-Mica Interceptor
Ecology	Washington State Department of Ecology
EPA	U.S. Environmental Protection Agency
Facility	Spokane County Regional Water Reclamation Facility
HpBDE	heptabromodiphenyl ether homolog group
HpCB	heptachlorobiphenyl homolog group
HxBDE	hexabromodiphenyl ether homolog group
HxCB	hexachlorobiphenyl homolog group
HDPE	high-density polyethylene
L	liter(s)
LOD	limits of detection
mgd	million gallon(s) per day
MH	manhole
mL	milliliter(s)
MoBDE	monobromodiphenyl ether homolog group
MoCB	monochlorobiphenyl homolog group
ng/L	nanogram(s) per liter
NoBDE	nonabromodiphenyl ether homolog group
NoCB	nonachlorobiphenyl homolog group
NPDES	National Pollutant Discharge Elimination System
NVI	North Valley Interceptor
NVIPS	North Valley Interceptor Pump Station
OcBDE	octabromodiphenyl ether homolog group
OcCB	octachlorobiphenyl homolog group
PCB	polychlorinated biphenyl
PBDE	polybrominated diphenyl ether
PeBDE	pentabromodiphenyl ether homolog group
PeCB	pentachlorobiphenyl homolog group
Permit	NPDES Permit WA-0093317
pg/L	picogram(s) per liter
PMF	Positive Matrix Factorization
ppm	part(s) per million
Q1	first quartile
Q3	third quartile
QA/QC	quality assurance/quality control
QAPP	Quality Assurance Project Plan
R^2	correlation coefficient
Report	Annual Toxics Management Report
ROW	right-of-way
RSD	relative standard deviation
SCC	Spokane County Code
SCRWRF	Spokane County Regional Water Reclamation Facility
SRRTTF	Spokane River Regional Toxics Task Force
SVI	Spokane Valley Interceptor
SVIPS	Spokane Valley Interceptor Pump Station
TeBDE	tetrabromodiphenyl ether homolog group
TeCB	tetrachlorobiphenyl homolog group
TiO_2	titanium dioxide
TriBDE	tribromodiphenyl ether homolog group
TriCB	trichlorobiphenyl homolog group
TSCA	Toxics Substance Control Act
TSS	total suspended solids

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Executive Summary

Background

Spokane County (County) owns the Spokane County Regional Water Reclamation Facility (Facility, or SCRWRF), which provides advanced treatment for wastewater before discharging reclaimed water to the Spokane River in accordance with National Pollutant Discharge Elimination System (NPDES) Permit WA-0093317 (Permit), effective December 1, 2011.

Special Condition S13 of the Permit requires that the County help create and participate in a regional toxics task force. Accordingly, the County took a leading role in the creation of the Spokane River Regional Toxics Task Force (SRRTTF). The goal of the task force is to develop a comprehensive plan to bring the Spokane River into compliance with applicable water quality standards for PCBs. The County plans to use the information gained from the Special Condition S12 Toxics Management Action Plan to further the efforts of the SRRTTF.

PCBs are everywhere (Ecology, 2012). Global background alone could put any water body on the planet, including the Spokane River, over the human health water quality objectives. Consequently, this Report must be read in context with the fact that sources outside of the control of the County currently and in the future will continue to contribute PCBs to the County's collection system. Additionally, because this Report is based on a small data set, the analyses and recommendations in this Report may be subject to change based on data that is collected in the future.

Measurable Progress

In 2014, the County continued to make substantial measurable progress toward PCB load reduction and in the characterization of PCBs in the Spokane River and their sources. Comparison of the 2014 influent and effluent data shows that the Facility provided very effective treatment, **removing more than 99% of the total PCBs and PBDEs measured in the influent.** Dioxin was not detected in the influent or effluent samples collected during 2014. Through its participation in the SRRTTF, and through independent investigative activities, the County has helped improve understanding of PCB sources and implemented a range of measures to address them.

The Permit requires sampling and analysis of Facility influent and effluent for polychlorinated biphenyls (PCBs), 2,3,7,8-Tetra-Chlorodibenzo-P-Dioxin (Dioxin), and polybrominated diphenyl ethers (PBDEs). The Permit also requires preparation of an Annual Toxics Management Report (Report) that describes the monitoring results, potential sources of the measured compounds, and County management actions to reduce the discharge of PCBs to the Spokane River.

Although not explicitly required by the Permit, the County voluntarily designed and implemented a systematic "track-down" sampling program to help identify potential PCB sources to the wastewater collection system. In 2013, the County collected samples near the outlets to the three main basins in the wastewater collection system upstream of the Facility. In 2014, the County collected track-down samples from seven locations within the Dishman-Mica Interceptor (DMI) basin, which had the highest PCB concentrations in the 2013 track-down sampling. Specific sampling sites were selected based on tributary area, land use, and approximate age of development. The 2014 track-down sampling results did not identify specific sources or geographic hot-spots for PCBs. The results reinforce the fact that PCBs are a ubiquitous contaminant and suggest a low level presence throughout the wastewater collection system, rather than few large sources.

The County evaluated PCB and PBDE homolog patterns to help identify potential sources, as required by the Permit. While, the evaluation indicated that higher molecular weight homolog groups comprised a larger proportion of the influent samples as compared to the effluent samples, the evaluation was not able to discern potential sources. While not required by the Permit, the County performed an additional evaluation using Positive Matrix Factorization (PMF), an advanced source apportionment tool that has been used to identify PCB sources in water, sediment, and air. This more advanced PMF analysis was conducted to provide more definitive information on potential PCB and PBDE sources,.

The PMF analysis did an excellent job of reproducing the PCB data and identified seven distinct source types or factors that account for 90 percent of the total PCB mass across all samples. Most of the factors are strongly correlated to Aroclors and Aroclor mixtures. However, one factor (factor 2) is mainly composed of PCB-11, which is not from Aroclors but is often found in yellow dyes and pigments. This factor was more prevalent at the North Valley Interceptor Pump Station (NVIPS) than at the Spokane Valley Interceptor Pump Station (SVIPS). Factor 1, consisting of dissolved-phase, low molecular weight Aroclors, comprised the majority of the effluent. Factor 6, which is similar to unweathered Aroclor 1254, was particularly abundant in the December 2014 track-down sample from a subbasin of the collection system with older (1950s era) residential development. Aroclor 1254 has been found in building materials such as caulk, and other applications. Factor 3, which resembles a mixture of the four most common Aroclors, was much more prevalent in the SVIPS samples versus the NVIPS samples. The PMF analysis also did an excellent job of reproducing the PBDE data, accounting for nearly 100 percent of the PBDE mass found in the samples. The PMF showed that the main source of PBDE is from commercial formulations, such as Bromkal. The 2014 PMF results are similar to those of 2013; therefore, continued monitoring for PBDEs is unlikely to significantly improve the understanding of PBDE sources or management measures.

The County used the track-down sampling and PMF results to help refine its toxic management activities proposed in this Report for upcoming work.

Spokane County's accomplishments during 2014 included public education, participation in the SRRTTF, and many other activities, as follows:

- Revised purchasing ordinance which allows for testing of products for PCBs, similar to the state of Washington and the city of Spokane
- Continued a multimedia public outreach program focused on residential and commercial/industrial sewer customers
- Hired a water resources communications specialist to implement outreach and education and to participate on the Spokane River Regional Toxics Task Force (SRRTTF)
- Updated County web presence to include PCB information
- Developed and mailed a PCB primer to all County wastewater treatment customers, both commercial/industrial and residential (about 40,000 customers)
- Developed a PCB informational poster for display in the Water Resource Center and other venues
- Coordinated an Open House event at the Water Resource Center, including PCB information
- Coordinated a meeting with other regional municipal wastewater treatment entities to discuss outreach to commercial and pretreatment customers regarding toxics
- Sent letters to County industrial pretreatment customers requesting individual meetings to provide PCB information
- Presented at several area conferences regarding track-down influent and effluent sampling results
- Provided input to the Washington Legislature regarding revising the Toxics Management Act to reduce inadvertent production of PCBs

- Provided in-kind and financial support to the local EnviroStars program, a local source control/waste minimization program aimed at businesses
- Played an active role in the SRRTTF including financial support for administrative and technical tasks
- Provided financial support for PCB monitoring and education by the SRRTTF.

In 2015, Spokane County plans to continue and expand its activities as follows:

- Hold spring and fall open houses at the Water Resource Center
- Increase collaboration with non-dischargers to disseminate toxics management information (e.g., Spokane Riverkeeper)
- Provide updates as warranted to wastewater treatment customers regarding new and useful PCB information that can provide consumer guidance
- Update PCB information on the County website
- Meet with industrial pretreatment customers to review latest information on PCBs
- Present at area conferences and to citizen groups
- Provide input to the Legislature regarding impending legislation related to PCBs
- Continue in-kind and financial support to the local EnviroStars program
- Support industry-wide reformulation of products that can contain elevated concentrations of PCB-11 as well as commercial products that contain elevated PBDE concentrations (e.g., Bromkal)
- Continue to remove and dispose of remaining County-owned, PCB-containing materials and equipment as they are encountered
- Continue to contribute data on PCB concentrations and sources to the SRRTTF's regional clearinghouse to help increase understanding of the potential sources and to help regional management efforts
- Continue to play an active role in the SRRTTF including financial support for administrative and technical tasks
- Support the SRRTTF in identifying commercial products that could contain inadvertently produced PCBs
- Review the County wastewater customer database in light of the ongoing chemical fingerprinting analysis, and perform follow-up actions as appropriate.

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Section 1

Introduction

The County owns the Spokane County Regional Water Reclamation Facility (Facility, or SCRWRF), which provides treatment for wastewater before discharging reclaimed water to the Spokane River. The Facility is operated by a third-party operator, CH2M Hill, under contract with the County. Also under contract to Spokane County, a consultant team led by Brown and Caldwell (Consultant) is providing services for activities related to sampling and analysis of toxic compounds associated with the Facility and collection system. In addition to Brown and Caldwell, the Consultant team includes Landau Associates, AXYS Analytical Services, Anatek Labs, Inc., and Dr. Lisa Rodenburg of Rutgers University.

The Washington State Department of Ecology (Ecology) issued the Facility's National Pollutant Discharge Elimination System (NPDES) Permit WA-0093317 (Permit), effective December 1, 2011. Section S2 of the Permit requires routine sampling and analysis of Facility influent and effluent for polychlorinated biphenyls (PCBs), 2,3,7,8-Tetra-Chlorodibenzo-P-Dioxin (Dioxin), and polybrominated diphenyl ethers (PBDEs).

Special Condition S12 of the Permit requires preparation of an Annual Toxics Management Report (Report) by April 15 of each year. The Report must include:

- analytical results for PCBs, Dioxin, and PBDEs
- detection limits
- quality assurance/quality control (QA/QC) procedures
- pattern analysis of homologs
- potential sources suggested by the data analysis

Special Condition S12 also requires preparation of a Toxics Management Action Plan that addresses:

- future source identification activities
- locations and frequencies of future toxics sampling in the wastewater collection system
- source control and elimination of PCBs from contaminated soils and sediments, stormwater entering the wastewater collection systems, and industrial or commercial sources
- eliminating active sources such as:
  - older mechanical machinery
  - older electrical equipment and components
  - construction material content such as paints and caulking
  - commercial materials such as inks and dyes

Special Condition S12 also requires that the County consider changes in procurement practices and ordinances to control and minimize toxics, including preferential use of PCB-free substitutes for those products containing PCBs below the regulated levels in sources such as:

- construction materials such as paints and caulking
- commercial materials such as inks and dyes
- soaps and cleaners

As stated in Special Condition S12, the goals of the Toxics Management Action Plan are to:

- reduce toxicant loadings, including PCBs, to the Spokane River to the maximum extent practicable, realizing statistically significant reductions in influent concentration of the toxicants to the Facility over the next 10 years
- reduce PCBs in the effluent to the maximum extent practicable so that in time the effluent does not contribute to PCBs in the Spokane River exceeding applicable water quality standards

Special Condition S13 of the Permit requires that the County help create and participate in a regional toxics task force. Accordingly, the County took a leading role in the creation of the Spokane River Regional Toxics Task Force (SRRTTF). The goal of the task force is to develop a comprehensive plan to bring the Spokane River into compliance with applicable water quality standards for PCBs. The County plans to use the information gained from the Special Condition S12 Toxics Management Action Plan to further the efforts of the SRRTTF.

PCBs are everywhere (Ecology, 2012). Global background alone could put any water body on the planet, including the Spokane River, over the human health water quality objectives. Consequently, this Report must be read in context with the fact that sources outside of the control of the County currently and in the future will continue to contribute PCBs to the County's collection system. Additionally, because this Report is based on a small data set, the analyses and recommendations in this Report may be subject to change based on data that is collected in the future.

1.1 Study Area Description

The Facility treats wastewater from portions of unincorporated Spokane County, the cities of Spokane Valley and Millwood, and portions of Liberty Lake. Two influent trunk lines, the North Valley Interceptor (NVI) and the Spokane Valley Interceptor (SVI), convey wastewater to the Facility via two pump stations (see Figure 1-1).

The NVI sewershed encompasses approximately 13,000 acres. The sewershed land use composition is approximately 46 percent residential, 35 percent commercial/industrial/right-of-way (ROW), and 19 percent open space. There are a total of 5,970 customers in the NVI sewershed, of which 5,580 are residential and 390 are commercial/industrial. The NVI wastewater collection system includes approximately 130 miles of gravity pipe, 11 miles of force main, and 2,650 manholes (MHs).

The SVI sewershed encompasses approximately 24,000 acres. The sewershed land use composition is approximately 66 percent residential, 30 percent commercial/industrial/ROW, and 4 percent open space. There are a total of 22,135 customers in the SVI sewershed, of which 21,109 are residential and 1,026 are commercial/industrial. The SVI wastewater collection system includes approximately 360 miles of gravity pipe, 11 miles of force main, and 7,200 manholes.

The two pump stations shown on Figure 1-1 convey wastewater from the NVI and SVI sewersheds to the Facility. Typically, all of the wastewater in the NVI Pump Station (NVIPS) and SVI Pump Station (SVIPS) is pumped to the Facility, but occasionally a small portion is conveyed to the City of Spokane Riverside Park Water Reclamation Facility.

Seven active dischargers are covered by the County's industrial pretreatment program. In addition, one industrial customer is permitted to haul wastewater to the Facility.

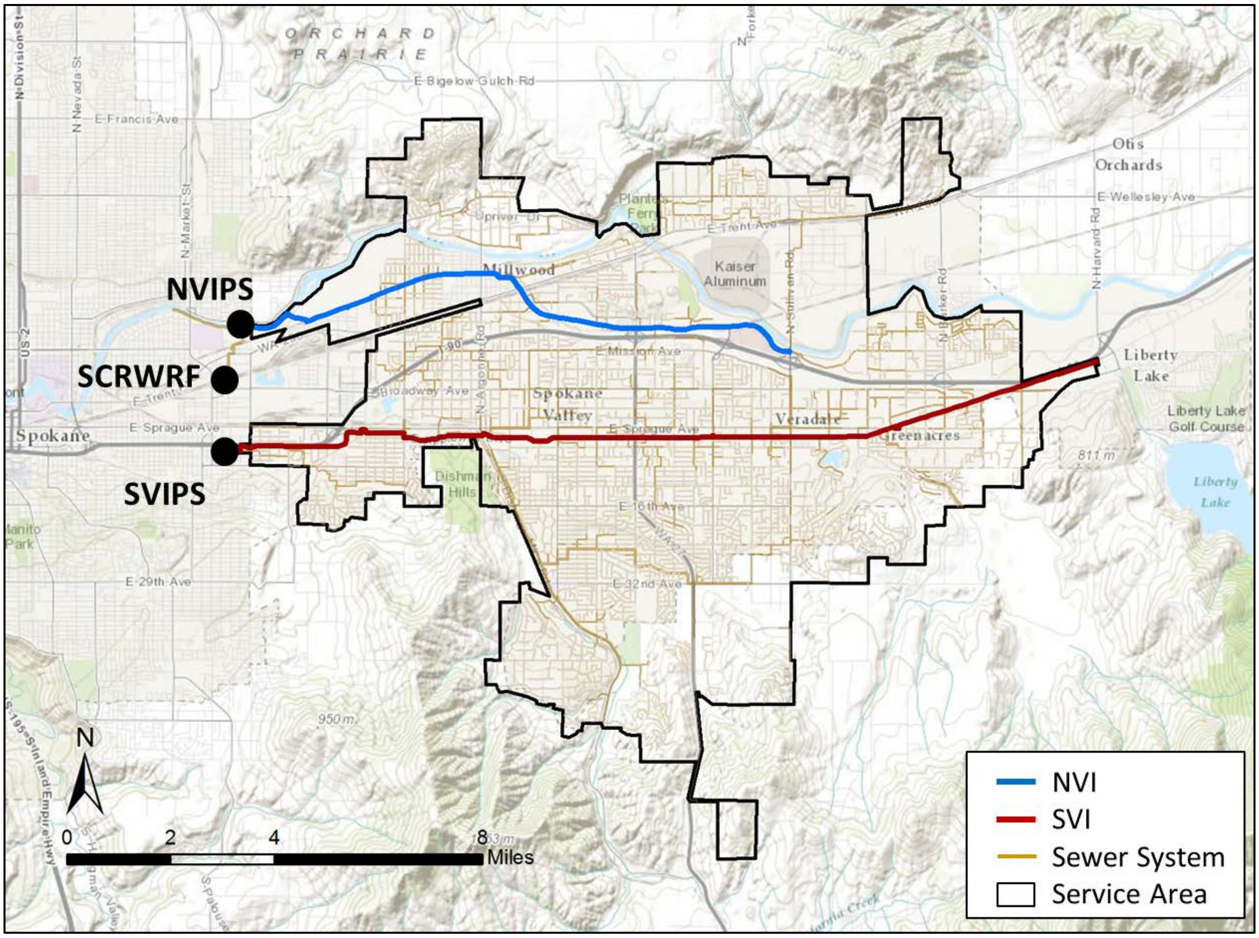

Figure 1-1. Study area

1.2 Organization of This Report

Section 2 of this document contains the Annual Report required for Special Condition S12 of the NPDES Permit. It describes the toxics monitoring and source identification activities performed by the County during the preceding year.

Section 3 of this document contains the Toxics Management Action Plan required for Special Condition S12. It describes the County's proposed source identification and source control measures for the subsequent year of operation.

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Section 2

Annual Toxics Management Report

This section summarizes the framework of the sampling program, including quality objectives, sampling methods, laboratory procedures, and quality control, as well as the sampling results and source assessment.

The Facility's NPDES Permit requires the following sampling program per Special Condition S2:

- total PCBs in each influent trunk line: bimonthly (once every 2 months)
- Dioxin in each influent trunk line: bimonthly (once every 2 months)
- PBDEs in each influent trunk line: quarterly (once every 3 months)
- total PCBs, Dioxin, and PBDEs in the Facility effluent: quarterly (once every 3 months)

The toxic compounds listed above have very limited solubility in water so they are often associated with particulate matter. Total suspended solids (TSS) data could help discern potential relationships between measured toxics concentrations and suspended solids. Therefore, the County is voluntarily analyzing samples for TSS (per Standard Method 2540D) even though this is not required by the Permit.

Sampling commenced in October 2012, and a total of 14 sampling events had been conducted as of December 31, 2014. The County's first Annual Toxics Management Report (April 2013) presented the results for the Permit-required sampling of influent and effluent. The April 2013 report also described the strategy for track-down sampling in the County's collection system to help identify potential sources of PCBs and PBDEs.

The County began track-down sampling at locations upstream of each trunk line in June 2013. Between June and December 2013, track-down samples were taken from three manholes during four sampling events (bimonthly samples), and were analyzed for PCBs and PBDEs. The April 2014 Annual Report recommended track-down sampling at seven manholes, and analysis of the samples for PCBs only. PBDES were not included in the proposed 2014 track-down sampling, based on the 2013 results. Track-down sampling began in June 2014 after Ecology approved the Annual Report. Section 2.1 describes the track-down sampling locations and methods in more detail...

The sampling was conducted by the Consultant. AXYS Analytical Services (AXYS), located in Sidney, B.C., Canada, performed the toxics analyses and Anatek Labs, Inc. (Anatek), located in Spokane, Washington, performed the TSS analyses.

2.1 Sampling Locations and Methods

Ecology approved the County's Quality Assurance Project Plan (QAPP) for toxics monitoring on October 1, 2012. The QAPP details the project schedule, quality objectives, sampling procedures, measurement procedures, analytical requirements, quality control, and data validation protocols for Section S2 monitoring. The QAPP was revised in 2013 and 2014 to reflect updates to the track-down sampling locations and methods. Ecology approved both QAPP revisions.

2.1.1 Influent Trunk Lines and Effluent

In accordance with the Permit, the County collects samples from the Facility's effluent line and its two influent trunk lines. The two influent trunk lines were sampled at the SVIPS and NVIPS. These pump stations direct flow from each interceptor to the Facility. Sampling was conducted at the influent channel of each pump station. Facility effluent was sampled at a manhole within the Facility property. The manhole is part of the Facility outfall and is located downstream of all treatment plant processes.

For the influent trunk lines and effluent sampling, an Isco 3700 automated composite sampler was used to collect 24 time-weighted samples at hourly intervals. The sampler used a peristaltic pump to draw samples from the liquid stream. Samples were collected into pre-cleaned, glass bottles. This composite sample was well mixed and aliquoted in the field into pre-cleaned amber glass bottles provided by AXYS for PCB, Dioxin, and PBDE analyses. For TSS analysis, a sample was taken from the composite sample and placed in high-density polyethylene (HDPE) bottles provided by Anatek.

2.1.2 Collection System Track-Down Samples

Based on the 2013 track-down sampling results for the NVIPS and SVIPS (as reported in the County's *2014 Annual Toxics Management Report*), the County focused its efforts in 2014 on sampling from manholes (MH) in the Dishman-Mica Interceptor (DMI) basin. In addition to sampling at two major branch points (DMI MHA and DMI MHB), five upstream subbasins were sampled to assess potential relationships between the year of home/commercial construction and PCB concentration in the sewage (DMI MHC through DMI MHG). Figure 2-1 and Table 2-1 summarize the seven locations sampled in 2014.

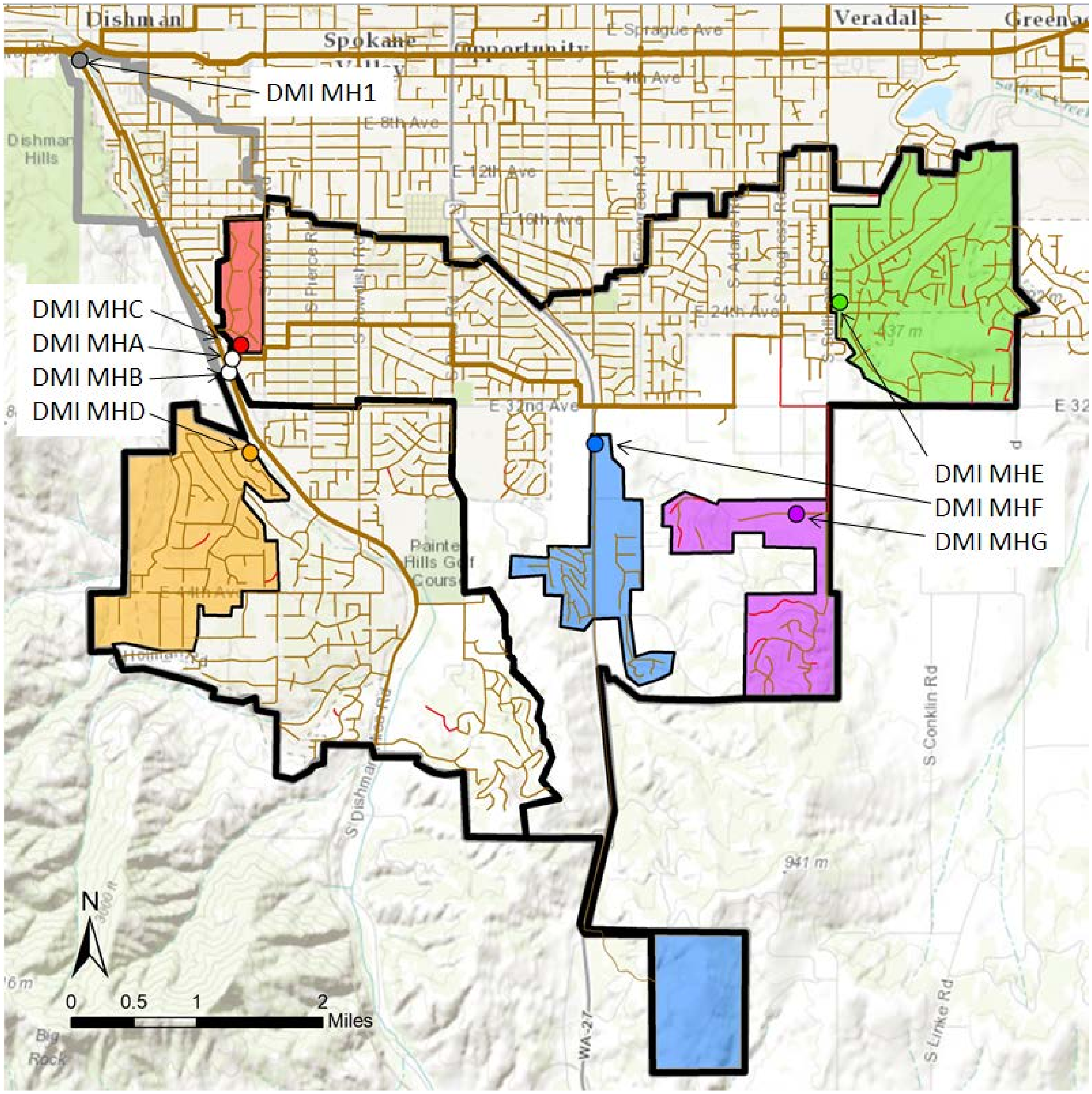

Figure 2-1. 2014 track-down sampling locations in five tributary sub basins

Table 2-1. Summary of 2014 Track-Down Sampling Locations										
Site	Manhole ID	Parcels	Land use [a]				Year of construction [a,b]			
			Resid.	Comm.	Ind.	Other [c]	<1960	1960–79	1980–99	2000+
DMI MHA	104.8/28	6,315	98%	1%	0%	2%	11%	49%	27%	13%
DMI MHB	104/29	2,498	73%	6%	0%	21%	1%	57%	33%	9%
DMI MHC	105.3/26.8	148	94%	4%	0%	2%	73%	15%	11%	1%
DMI MHD	105.7/36	509	76%	1%	0%	23%	1%	63%	26%	10%
DMI MHE	156.8/23.2	936	75%	2%	0%	24%	1%	27%	37%	35%
DMI MHF	135.1/35.2	229	33%	33%	0%	34%	0%	4%	60%	36%
DMI MHG	Bella Vista PS	348	85%	0%	0%	15%	0%	17%	69%	13%

a. *Percentages refer to land area for land use, and number of parcels for year of construction.*

b. *Year of construction of primary structure on the parcel.*

c. *Other includes undeveloped land, parks, and utilities.*

DMI MHA and DMI MHB divide the DMI basin at 28th Avenue. DMI MHA receives flow from the eastern two-thirds of the basin. DMI MHB receives flow from the southern third of the basin. The DMI MHA basin is nearly all residential, while the DMI MHB basin has a small commercial component, and includes a number of large undeveloped parcels.

Most of the homes in the DMI MHC subbasin were built prior to 1960. The DMI MHD subbasin contains homes built in the 1960s and 1970s. DMI MHE, DMI MHF, and DMI MHG all contain newer homes. The newest of these is the DMI MHF subbasin, where only 4% of homes were built prior to 1980.

Collection of 24-hour composite samples from the track-down locations was impractical because of traffic control requirements and lack of power and security for automated equipment. Therefore, the track-down samples consisted of composite samples collected over a period of 40 minutes. Samples were collected on weekdays, and the sampling times were arranged to vary by event, so the same sites were sampled at different times during each event. However, all samples were collected between 8 a.m. and 3 p.m. Other than the short collection period, the sampling protocol was similar to the influent trunk line and effluent sampling locations.

2.2 Sampling and Laboratory Procedures

Procedures to maintain the custody and integrity of the samples began at the time of sampling and continued through transport, sample receipt, preparation, analysis and storage, data generation and reporting, and sample disposal. Records concerning the custody and condition of the samples are maintained in field and laboratory records.

Field personnel maintain chain-of-custody (COC) records for all field and field QC samples. A sample is defined as being under a person's custody if any of the following conditions exist:

- it is in his/her possession
- it is in his/her view, after being in his/her possession
- it was in his/her possession and was subsequently locked
- it is in a designated secure area

The following information concerning the sample is documented on the contract laboratory COC form:

- sample identification
- date and time of sample collection
- source of sample (including name, location, and sample type)
- preservative used (if any)
- analyses required
- name of sample collector(s)
- custody transfer signatures and dates and times of sample transfer from the field to transporters and to the laboratory or laboratories

All samples are uniquely identified, labeled, and documented in the field at the time of collection. Samples collected in the field are transported to the laboratory via overnight shipping. Samples are packed in ice to keep them cool during collection and transportation.

2.2.1 Permit Requirements

Analytical methods are either specified or recommended for the constituents included in the NPDES Permit monitoring requirements. The Permit provisions related to the analytical portion of this monitoring effort are summarized below:

- Special Condition S2.A(7)(15): For PCBs use U.S. Environmental Protection Agency (EPA) Method 1668. Reporting limits are described in the QAPP.
- Special Condition S2.A(7)(17): For PBDEs use draft EPA Method 1614. Reporting limits are described in the QAPP.
- Special Condition S2 does not specify an analytical method for Dioxin. Appendix A of the Permit recommends EPA Method 1613 for analysis of Dioxin (Chemical Abstracts Service [CAS] No. 176-40-16).

Table 2-2 lists the methods used to analyze samples collected from the Facility influent and effluent, as per the approved QAPP.

Table 2-2. Analytical Methods

Constituent	Analytical protocol
PCB congeners	EPA 1668A
PBDEs	EPA 1614
Dioxin	EPA 1613B

2.2.2 Quality Objectives and Control

Quality objectives are established for this project to control the degree of total error in data results. These objectives are established to achieve an acceptable level of confidence in decisions made from the collected data. The established objectives include the following:

- implement procedures for field sampling, sample custody, equipment operation and calibration, laboratory sample analysis, data reduction, and data reporting that will provide for the consistency and thoroughness of data generation
- assess the quality of data generated to ensure that collected data are scientifically valid, of known and documented quality, and legally defensible, where appropriate
- ensure that the QAPP and associated project plans are properly implemented

- document field conditions, sampling, and other activities using appropriate field reports to sufficiently re-create each sampling, analytical, testing, and monitoring event

Data quality control is determined by the analysis of sample blanks and duplicates.

Three types of blanks are used in this study:

- Rinsate blanks, also called “equipment blanks,” are collected by running a sample of ultrapure water prepared by AXYS through the sampling equipment after it has been cleaned but before it is used for sampling. The rinsate blank indicates the extent to which contaminants are introduced through the sampling procedure, equipment, or exposure to ambient air during the sample collection. Rinsate blanks were collected at the NVIPS, SVIPS, and effluent sampling locations during the October 2012 event, and at one sampling location for all subsequent events. An additional rinsate blank was collected at the DMI MH1 track-down sampling location for the June 2013 sampling event. Rinsate blanks were tested for the toxic pollutants subject to testing at a given site during a given event. Rigorous decontamination procedures were followed to minimize equipment contamination (e.g., sampler tubing was shipped to AXYS for cleaning prior to each sampling round).
- Travel blanks are bottles of ultrapure water, prepared by AXYS, that accompany the samples en route from the sampling locations to the laboratory. The travel blank remains unopened until analyzed and helps to distinguish between potential bias introduced by contamination of sample water during transfer, shipping, and handling as opposed to contamination from sampling equipment. Travel blank(s) are prepared and provided by AXYS for each sample event. Travel blanks were tested for all pollutants subject to testing at a given site during a given event.
- Laboratory blanks are samples of ultrapure water prepared by AXYS that never leave the laboratory. They are tested alongside the samples and are used to determine potential sources of contamination or bias in the laboratory itself.
- Field duplicates are used to assess repeatability of sampling and analysis, and to evaluate analytical precision. One field duplicate was collected during each sampling event, and analyzed by the laboratory as a blind, meaning that the lab was not informed where the sample was collected. Field duplicates were tested for a single pollutant (PCBs, Dioxin, or PBDE) during each event.

In addition to rinsate, travel, and laboratory blanks, matrix spikes are used to assess analytical interferences related to the sample matrix. The laboratory tests known quantities of specific analytes in samples of ultrapure water and in field samples, and determines the percent recovery of the analyte in the field sample. Matrix spikes were performed on every sample.

The Quality Control Comment/Action Records for each test event are included in Appendix A.

2.3 Sampling Results

This section summarizes the analytical results from the toxics sampling conducted from October 2012 through December 2014. NVIPS and SVIPS were sampled bimonthly and the effluent was sampled quarterly in compliance with the NPDES Permit requirements. Track-down samples from the collection system were taken from June 2013 through December 2014. Appendix B contains the complete laboratory results for the samples collected in 2014. In the County’s previous Annual Reports, PCB totals were reported without adjusting for blank contamination. However, the City of Spokane, the largest wastewater discharger to the Spokane River, has been calculating total PCBs using a 10x all-blanks censoring approach. Ecology used a similar blank censoring method for its recent study of PCBs in the Palouse River watershed (Lubliner, 2009). To facilitate comparison with the City data, this Annual Report shows all total PCB data (influent, effluent, and trackdown samples) calculated using a 10x all-blanks censoring approach.

2.3.1 Influent/Effluent

Table 2-3 lists the total daily flows at the NVIPS and SVIPS on the sampling dates. On several dates the total amount pumped to the Facility was slightly less than the total flow in the interceptors because some flow was conveyed to the City of Spokane Riverside Park Water Reclamation Facility. On average, the NVIPS and SVIPS accounted for roughly 28 percent and 72 percent, respectively, of the total flow entering the Facility on the sampling dates.

Table 2-3. NVIPS and SVIPS Daily Flows

Year	Sampling dates	Flow pumped to Facility (mgd) [a]		
		NVIPS	SVIPS	Total
2012	October 10–11	1.82	4.87	6.69
	December 18–19	1.83	4.42	6.25
2013	February 6–7	1.84	5.06	6.90
	April 16–17	1.83	4.90	6.73
	June 25–26	1.99	4.48	6.47
	August 20–21	2.03	5.11	7.14
	October 22–23	1.73	4.98	6.71
	December 17–18	1.95	5.13	7.08
2014	February 10–11	1.94	5.21	7.15
	April 21–22	1.97	4.40	6.37
	June 23–24	2.03	4.43	6.45
	August 12–13	2.10	5.16	7.26
	October 20-21	2.00	5.21	7.20
	December 8–9	2.06	5.31	7.37

a. The interceptors can send flow to the Facility or to the City of Spokane Riverside Park Water Reclamation Facility. Listed flows do not include flows in the interceptor that were pumped to the City of Spokane Riverside Park Water Reclamation Facility.

PCBs have been sampled from the influent pump stations during 14 sampling events from October 2012–December 2014. The effluent was sampled during nine different events. The total PCB concentrations measured at influent trunk line and effluent sampling locations throughout the entire sampling period are plotted in Figure 2-2.

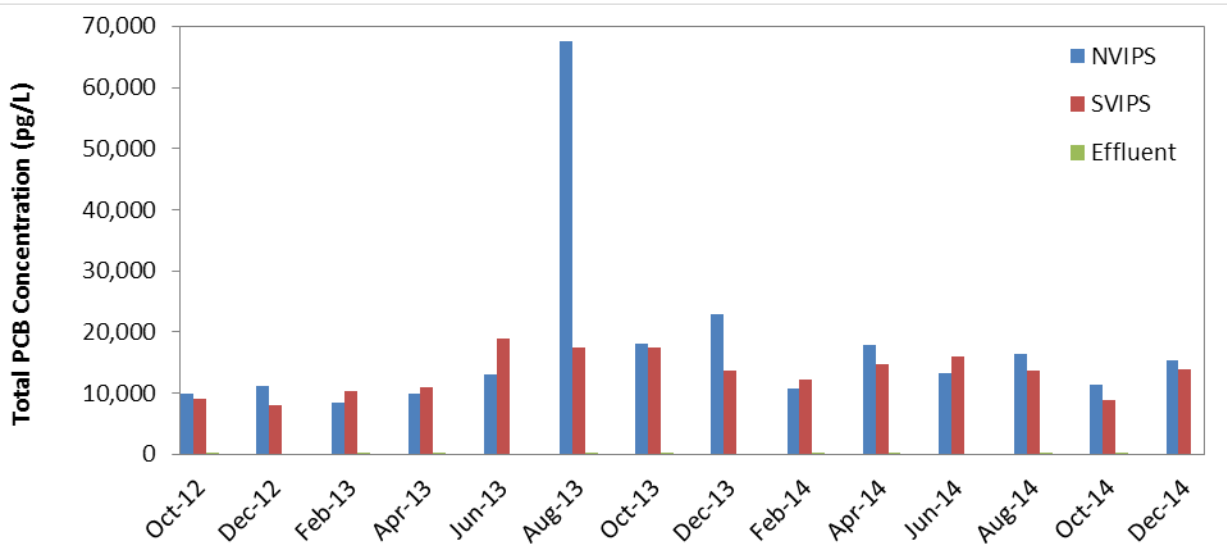

Figure 2-2. Total PCB concentrations in influent trunk line and effluent samples, Oct. 2012–Dec. 2014

Figure 2-3 presents the same effluent sampling data shown in Figure 2-2, zoomed in 100x on the y-axis to show the very low levels of PCBs in the effluent samples as compared to the influent samples.

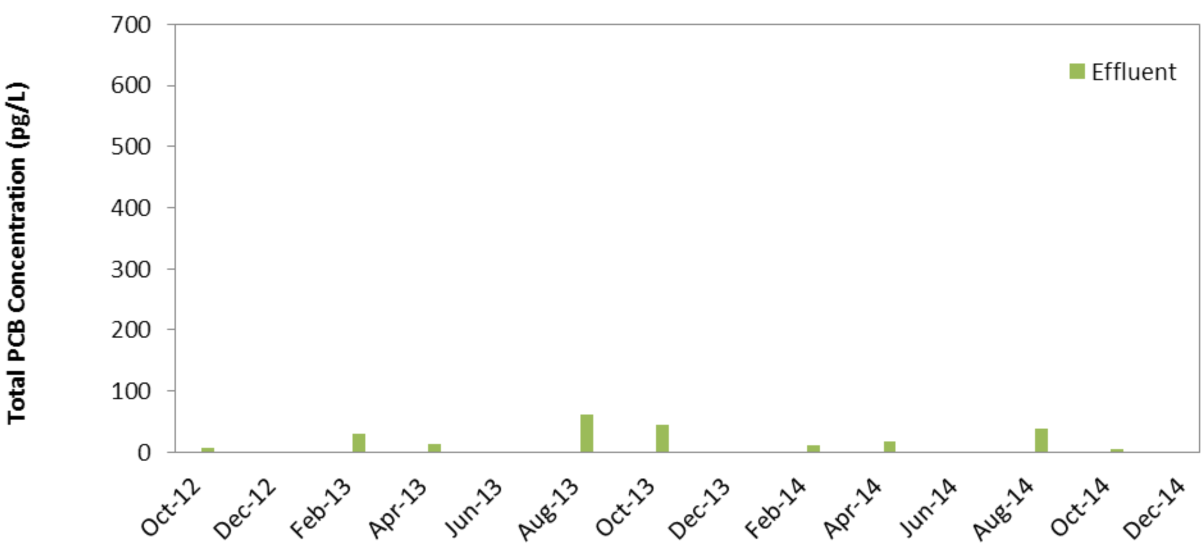

Figure 2-3. Total PCB concentrations in effluent samples, Oct. 2012–Dec. 2014

Table 2-4 summarizes the total PCB concentrations in influent trunk line and effluent samples measured during 2012-2014. Figure 2-3 shows the statistical variation in the data for each sample for the entire sampling period. PCB concentrations in the NVIPS and SVIPS samples ranged from 8,060 to 67,630 picograms per liter (pg/L). Effluent PCB concentrations ranged from 6 to 62 pg/L.

Table 2-4. Total PCB Concentrations (pg/L) and Statistics for 2012--2014 for Influent Trunk Line and Effluent Samples

Statistics	NVIPS	SVIPS	Effluent
Number of Samples	14	14	9
Mean	17,580	13,240	30
Standard Deviation	14,960	3,480	20
Minimum	8,370	8,060	6
Maximum	67,630	18,920	62

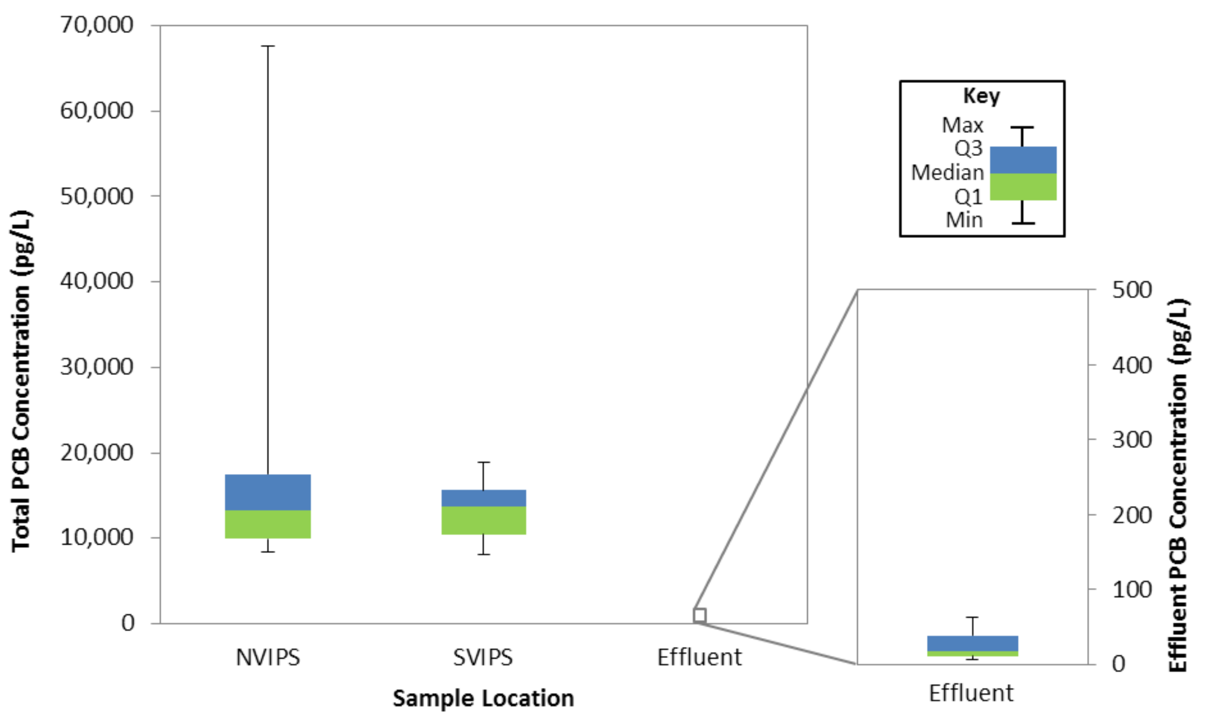

Figure 2-4. Box-whisker plot of total PCB concentrations in influent trunk line and effluent samples

For the majority of the sampling events, the total PCB concentration in the NVIPS and SVIPS samples were similar. If the August 2013 total PCB concentration at the NVIPS is excluded, the total PCB concentrations averaged 13,730 and 13,240 pg/L for the NVIPS and SVIPS, respectively. The August 2013 event is discussed in detail in the 2014 Annual Report.

PCB concentrations in effluent samples were much lower than the influent (NVIPS and SVIPS) samples. In Figure 2-4, the box-whisker plot shows the median, first and third quartile, and minimum and maximum values for the influent and effluent samples. The first quartile (Q1) represents the value where 25 percent of the data is less than this value. The third quartile value (Q3) represents the value where 75 percent of the data is less than this value. Based on the average concentrations of PCBs and flows measured at the NVIPS, SVIPS, and effluent locations, the Facility is removing greater than 99 percent of the total mass of PCBs entering the Facility.

Table 2-5 presents Dioxin results for 2012-2014. Only 1 of the 37 influent and effluent samples contained Dioxin at levels above the laboratory quantitation criteria. This sample (NVIPS, June 2013) had a reported concentration of 1.03 pg/L. Based on these results, continued Dioxin analysis is unlikely to improve the County's toxics management program.

Table 2-5. Summary of Dioxin Data (pg/L)			
Statistics	NVIPS	SVIPS	Effluent
Total number of samples	14	14	9
Number of detected samples	1	0	0
Range of concentration detected	1.03	--	--
Range of detection limit	0.498–0.62	0.496–0.91	0.497-0.543

PBDEs were sampled from the influent pump stations and effluent during nine events during 2012–14. The total PBDE concentrations are summarized in Figures 2-5 and 2-6 and Table 2-6. The total PBDE concentrations presented in this section represent the sum of 46 compounds. The total PBDE concentrations do not include estimated concentrations of compounds that fell below laboratory quantitation criteria, or congeners that were not detected at the reporting level. Figure 2-5 shows the total PBDE concentrations measured at influent trunk line and effluent sampling locations throughout the entire sampling period.

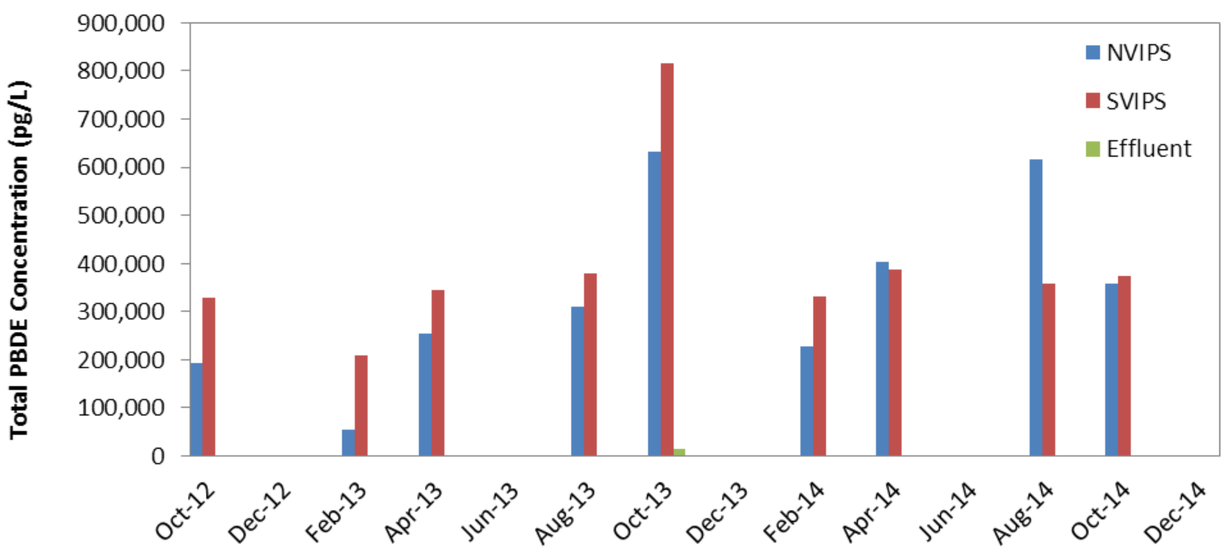

Figure 2-5. Total PBDE concentrations in influent trunk line and effluent samples, Oct. 2012–Dec. 2014

Figure 2-6 presents the same effluent sampling data shown in Figure 2-5, zoomed in on the y-axis to show the low levels of PBDEs in the effluent samples as compared to the influent samples.

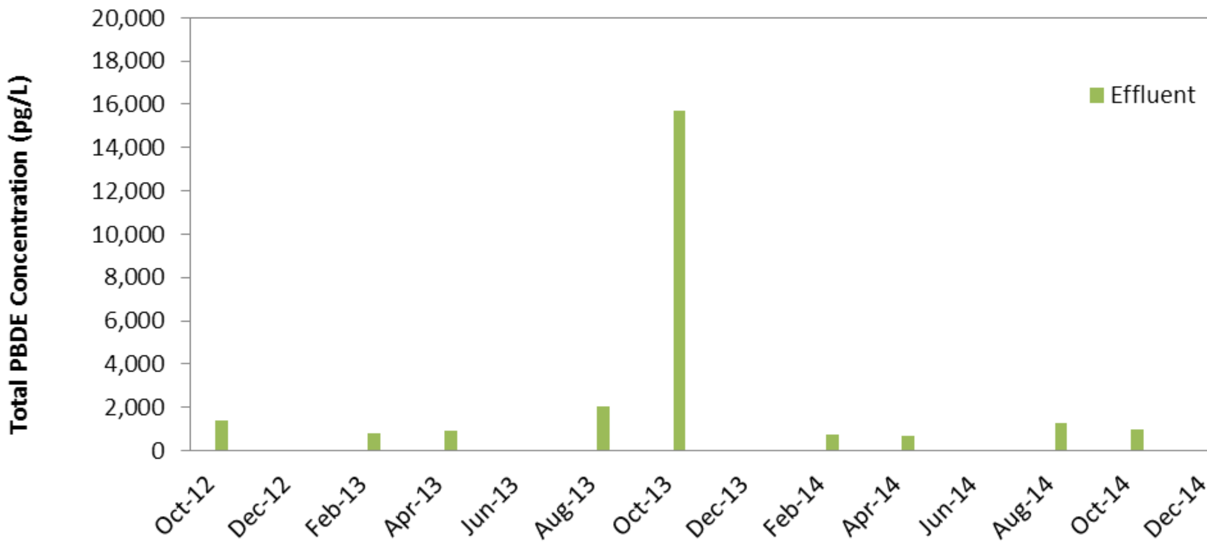

Figure 2-6. Total PBDE concentrations in effluent samples, Oct. 2012–Dec. 2014

Table 2-6. Total PBDE Concentrations (pg/L) and Statistics for 2012 – 2014			
Statistics	NVIPS	SVIPS	Effluent
Number of Samples	9	9	9
Mean	338,300	392,200	2,730
Standard Deviation	190,900	167,300	4,900
Minimum	53,300	210,200	660
Maximum	631,600	815,600	15,700

The total PBDE concentration in the NVIPS and SVIPS samples ranged from 53,300 to 815,600 pg/L. Effluent PBDE concentrations ranged from 660 to 15,700 pg/L. In Figure 2-7, the box-whisker plot shows the median, first and third quartile, and minimum and maximum PBDE values for the influent and effluent samples. Based on the average flows and concentrations of PBDEs at the NVIPS, SVIPS, and effluent locations, the Facility removed greater than 99 percent of the PBDE mass entering the Facility.

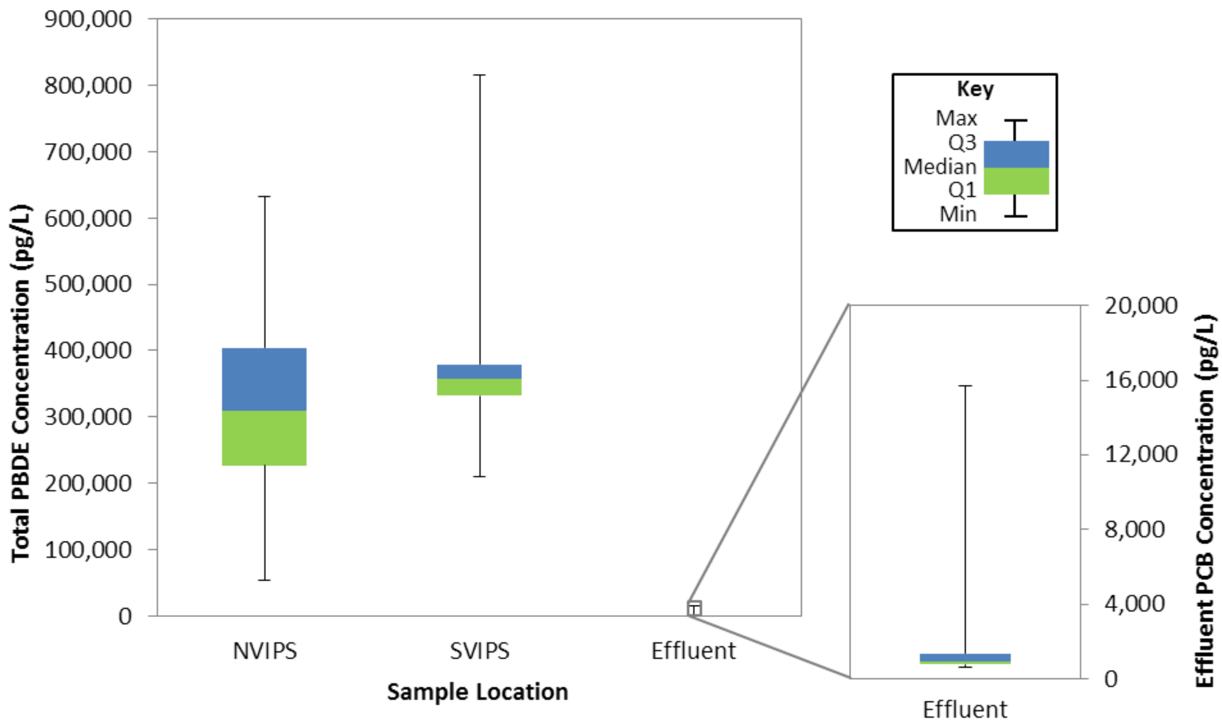

Figure 2-7. Box-whisker plot of total PBDE concentrations in influent trunk line and effluent samples

2.3.2 Collection System Track-Down Samples

The DMI basin was selected for further track-down based on the PCB concentrations measured in 2013–14 and reported in the 2014 Annual Report. As noted in section 2.1.2, there are multiple complicating factors in sampling subbasins including highly variable flows over a 24-hour period, traffic control requirements, and lack of power and security for automated equipment. Samples were taken as 40-minute composites at the approximate times listed in Table 2-7.

Table 2-7. Sampling Dates and Times for Track-Down Samples in 2014

Sampling Location	Date	Time	Date	Time
DMI MHA	6/23/2014	1:35 PM	12/8/2014	2:50 PM
DMI MHB	6/23/2014	12:32 PM	12/8/2014	1:30 PM
DMI MHC	6/24/2014	7:30 AM	12/9/2014	8:30 AM
DMI MHD	6/23/2014	3:15 PM	12/8/2014	11:48 AM
DMI MHE	8/12/2014	2:45 PM	10/20/2014	12:45 PM
DMI MHF	8/12/2014	1:00 PM	10/20/2014	8:40 AM
DMI MHG	8/13/2014	7:30 AM	10/20/2014	2:25 PM

DMI MH1, the manhole located at the outlet of the DMI basin, had an average PCB concentration of 20,090 pg/L in 2013. This was higher than the average concentrations measured at either influent pump station, or at the track-down locations upstream along the SVI and NVI.

The DMI basin splits near 28th Avenue, where one trunk line continues south along the Dishman-Mica Highway, and the other trunk line continues west. Sampling locations DMI MHA (west) and DMI MHB (south) cover each of these trunk lines.

Higher PCB concentrations were noted at DMI MHA on both sampling occasions. The average concentration at DMI MHA was approximately double that observed at DMI MHB. However, much of the difference is related to a high concentration in one sample collected at DMI MHA in June 2013 (33,000 pg/L).

Five more sampling locations were distributed throughout the DMI basin. These locations were intended to assess the importance of the year of housing construction to PCB observations. DMI MHC was located in a basin developed largely in the 1950s, DMI MHD was located in a basin developed largely in the 1970s, while the other three locations (DMI MHE, DMI MHF, and DMI MHG) were all located in basins developed in the past 10–20 years.

Data from the track-down sampling locations are summarized in Table 2-8 and Figure 2-8.

Table 2-8. Total PCB Concentrations (pg/L) and Statistics for Track-Down Samples in 2014

Statistics	DMI MHA	DMI MHB	DMI MHC	DMI MHD	DMI MHE	DMI MHF	DMI MHG
Sample 1	33,000	14,000	8,120	53,800	8,160	5,340	3,640
Sample 2	19,700	12,600	20,800	14,900	11,100	590	28,600
Average	26,300	13,300	14,500	34,400	9,600	2,970	16,100

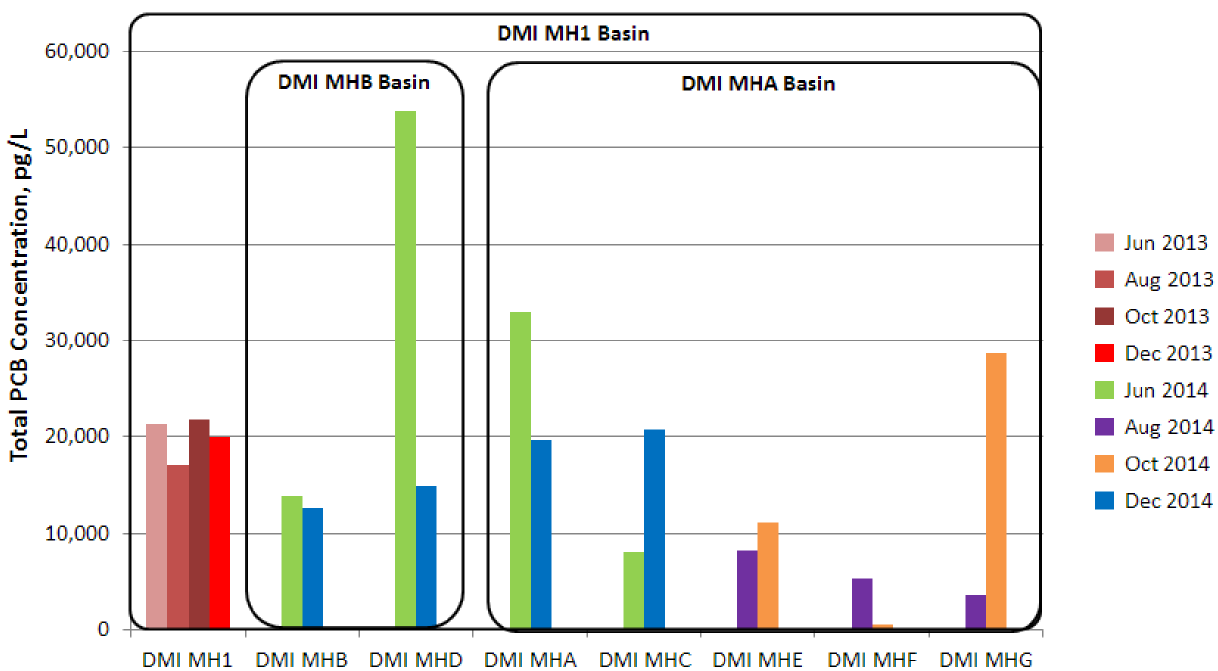

Figure 2-8. Total PCB concentrations at track-down locations within the DMI basin

The data at these locations (Figure 2-7) were difficult to compare, which may be related to the small number of observations (only two samples were taken at each location) at the time of this report's publication. DMI MHF, which covers a basin including new multifamily residential, as well as the trunk line to the Mica Landfill, had low PCB concentrations on both sampling events (5,340 and 590 pg/L). Relatively high PCB concentrations were noted during the June 2014 sampling event at DMI MHD (53,800 pg/L) and during the October 2014 sampling event at DMI MHG (28,600 pg/L).

The June 2014 loading at DMI MHD was not correlated with a high loading at downstream DMI MHA, which may indicate that the loading was of short duration. During the event, the wastewater sample at DMI MHD appeared unusually dark, with a relatively low pH and high solids (TSS) content (920 mg/L).There was low flow in the manhole during the event. The high solids loading may be associated with a flush of sediment because County maintenance crews have reported occasional grease plugging and subsequent flushing at that location. The relatively high PCB concentrations observed at DMI MHA, DMI MHD, and DMI MHG were noted only in one of the two samples taken at each site, limiting the conclusiveness of these data.

Given the limited number and duration of track-down samples, a correlation between the year of construction and the average PCB concentration in the downstream sewer could not be established. Aside from DMI MHF, which had consistently low PCB concentrations, none of the other subbasin sites demonstrated consistently noteworthy results. The DMI MHF subbasin has the highest proportion of new construction (only 4 percent homes built prior to 1980).

In summary, the track-down sampling conducted in Year 2 yielded the following results:

1. All sites were sampled two times during 2014, making it difficult to draw statistically relevant conclusions from the data. A third sampling event will be conducted at each of these sites, with results included in the 2016 Annual Report.
2. PCB concentrations at DMI MHA were consistently higher than those at DMI MHB.
3. PCB concentrations in the upstream basins demonstrated high variability compared to samples taken at the influent pump stations or the Year 1 track-down locations.
4. The site with the highest proportion of new construction had the lowest average PCB concentrations. Given the limited number and duration of track-down samples, a correlation between the year of construction and the average PCB concentration in the downstream sewer could not be established.

2.3.3 Pattern Analysis

PCBs and PBDEs are chemical groups comprising numerous individual congeners. Analyzing the pattern of congener concentrations within each sample can help identify relationships between samples and potential sources. This section presents pattern analysis for PCBs and PBDEs.

There are 209 PCB congeners, which can be sorted into homolog groups based on the number of chlorine atoms attached to the biphenyl ring. Congeners with a single chlorine atom are grouped into the monochlorobiphenyl homolog group (MoCB), congeners with two chlorine atoms are grouped into the dichlorobiphenyl homolog group (DiCB), and so on. The largest molecular weight congener is the decachlorobiphenyl homolog (DeCB) with ten chlorine atoms. Different PCB sources may comprise different levels of homolog groups. Analyzing the relative proportion of each homolog group within samples can demonstrate differences between the samples that may relate to potential different sources of PCBs.

Figure 2-9 presents the average proportion of each homolog group when compared to the average total PCB concentration for the influent trunk lines and effluent samples.

The homolog patterns for the NVIPS and SVIPS are similar to each other, while the Facility effluent appears to have a distinctly different homolog pattern compared to influent. NVIPS and SVIPS homolog patterns reflect a broad spectrum of all molecular weights of PCB congeners, and are mostly made up of tetra- through hexa-chlorinated biphenyl groups. The effluent contains primarily low-molecular weight PCB congeners (mono-chlorinated through tetra-chlorinated biphenyl groups), demonstrating the Facility's ability to filter out the higher molecular weight congeners that are present in the influent.

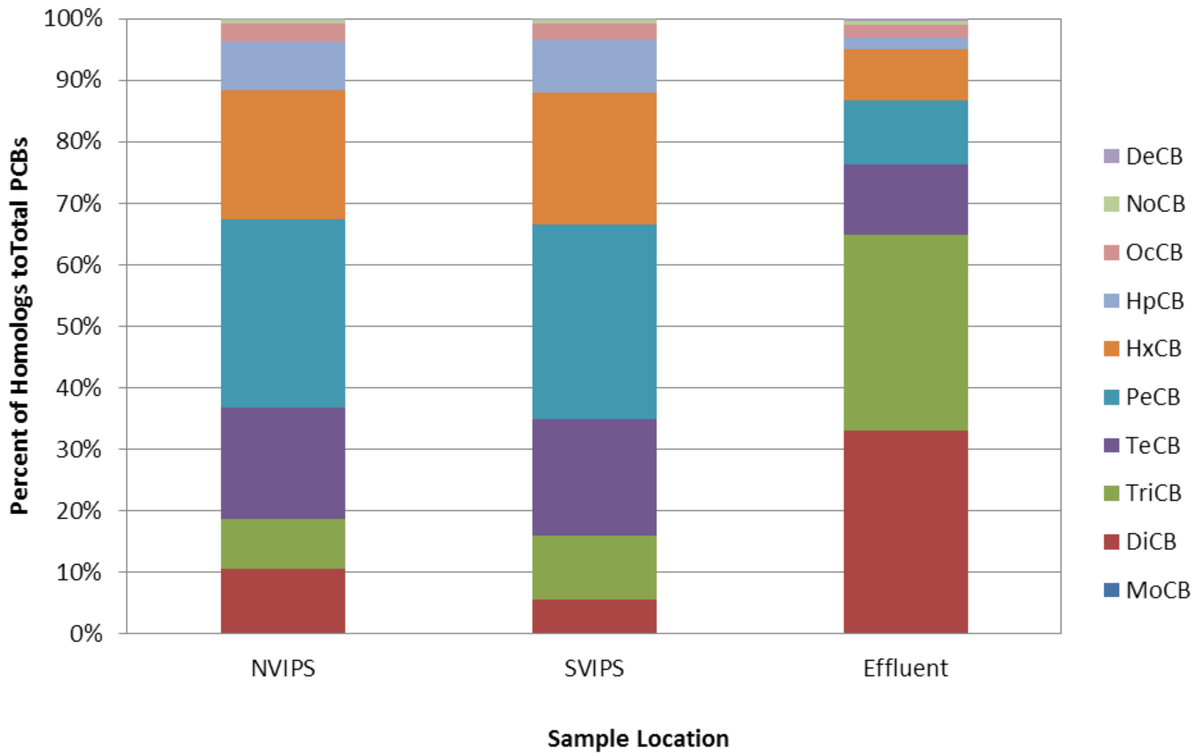

Figure 2-9. Comparison of PCB homolog composition for each sample type

The amount of each homolog was compared to the total PCB concentrations.

Figure 2-10 presents PCB homolog patterns for the track-down sampling locations. SVI MH1, NVI MH1 and DMI MH1 have very similar homolog proportions. The DMI MHB and DMI MHD, both in the DMI MHB subbasin, also have similar homolog proportions. More variability exists in the DMI MHA basin, which included five sampling locations. DMI MHE and DMI MHF have the highest proportion of low molecular weight congeners up to tetrachlorobiphenyls (TeCB) in that basin, much more than DMI MHA or DMI MHC. This variability in homolog pattern is evidence of different types of PCB sources in the sewershed.

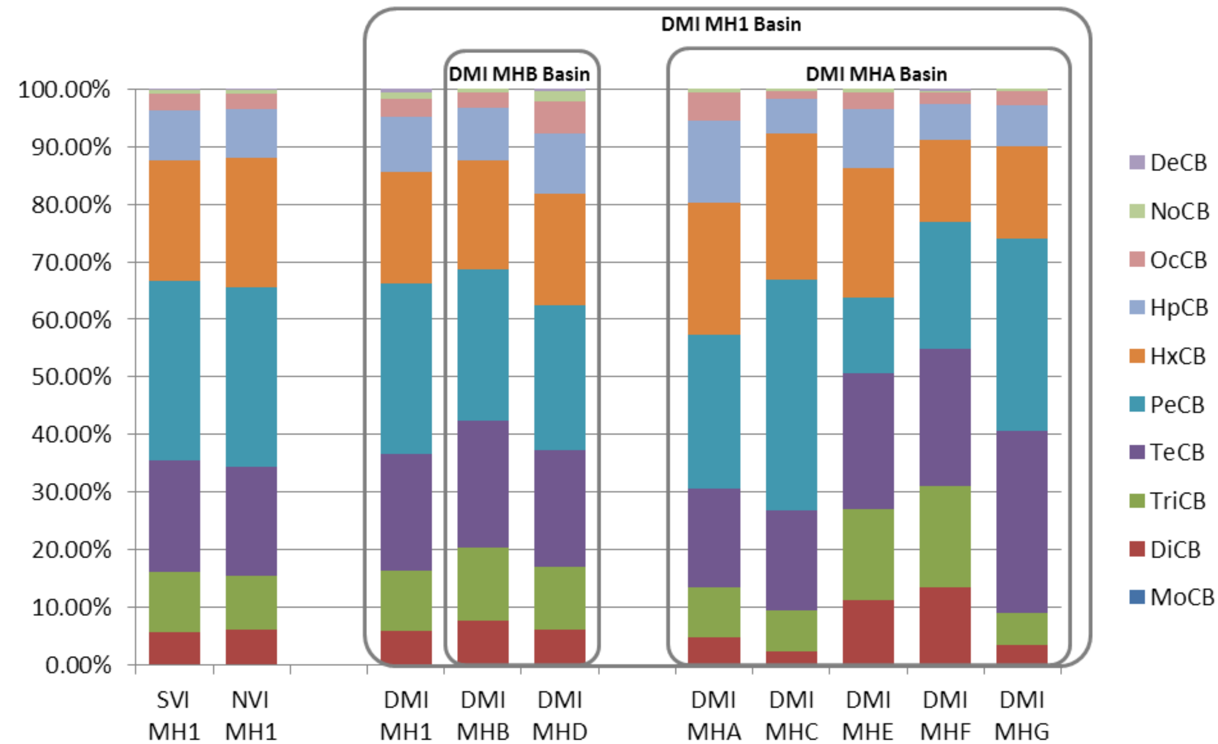

Figure 2-10. Comparison of PCB homolog composition for at track-down sampling locations

The amount of each homolog was compared to the total PCB concentrations.

Like PCBs, PBDEs may also be arranged into homolog groups. PBDEs are characterized by the number of bromine molecules attached to the diphenyl ether ring. Congeners with two bromine molecules compose the Dibromodiphenyl ether homolog group (DiBDE), congeners with three bromine molecules compose the Tribromodiphenyl ether homolog group (TriBDE), and so on. Figure 2-11 presents the composition of each homolog group when compared to the total brominated diphenyl ether concentration for the influent trunk lines, effluent, and track-down manholes. The percentages presented in Figure 2-10 are based on the average for each homolog group and the average total PBDE concentration for all of the data collected.

Tetrabromodiphenyl ether (TeBDE), pentabromodiphenyl ether (PeBDE), and decabromodiphenyl ether (DeBDE) compose the highest percentage of the influent trunk line samples. DeBDE is still produced in electronics, while the production of PeBDE has been phased out in the United States and most international markets (Ecology, 2006).

The effluent had high proportions of Nonabromodiphenyl ethers (NoBDE) and DeBDEs. However, this observation requires further discussion. The blank samples also typically registered relatively high concentrations of DeBDEs, specifically congener BDE-209. If the concentrations of PBDEs measured in the blanks are excluded, the majority of the effluent would be associated with the TeBDE and NoBDE homolog groups (specifically BDE-47, BDE-207, and BDE-208). However, congeners BDE-207 and BDE-208 were found only in two of the nine effluent samples. BDE-47 was found in all effluent samples, and this congener was not observed in high concentrations in the blanks.

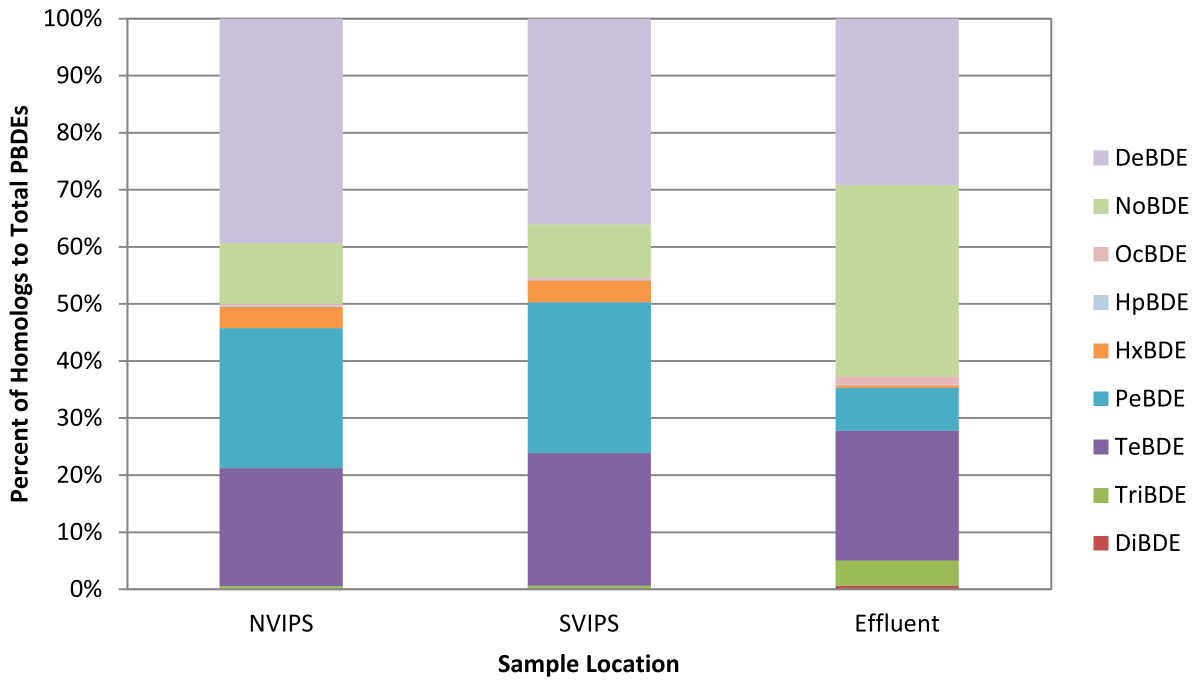

Figure 2-11. Comparison of PBDE homolog composition for each sample type

The amount of each homolog was compared to the total PBDE concentrations (excluding K flagged values).

The homolog group analysis demonstrates differences in homolog group levels in influent and track-down samples, but does not provide detailed evidence of potential PCB sources. To gain further insight into specific sources, differences between samples and sample locations can be analyzed at the congener level, using positive matrix factorization (PMF) as described in the following section.

2.3.4 Source Identification and Positive Matrix Factorization

The homolog evaluation was not able to discern potential sources. The County voluntarily performed an additional evaluation using Positive Matrix Factorization (PMF), an advanced source apportionment tool that has been used to identify PCB sources in water, sediment, and air. The PMF analysis was conducted to provide more definitive information on potential PCB and PBDE sources, even though this level of evaluation is not required by the Permit. This section describes the PMF analysis, which was performed by Dr. Lisa Rodenburg from Rutgers University.

2.3.4.1 PCB Positive Matrix Factorization

PMF is an advanced source apportionment tool developed by Paatero and Tapper (1994) that has been used to identify PCB sources in water, sediment, and air (Ding et al., 2013; Bzdusek et al., 2006a; Bzdusek et al., 2006b; Du et al., 2007; Du et al., 2008; Rodenburg et al., 2011; Qiu et al., 2012). The PMF2 software (YP-Tekniika KY Co., Helsinki, Finland) was used in this study.

PMF defines the sample matrix as a product of two unknown factor matrices with a residue matrix:

$$X = GF + E \qquad (1)$$

The sample matrix (*X*) is composed of *n* observed samples and *m* chemical species. *F* is a matrix of chemical profiles of *p* factors or sources. The *G* matrix describes the contribution of each factor to any given sample, while *E* is the matrix of residuals. The PMF solution, i.e., *G* and *F* matrices, are obtained by minimizing the objective function *Q* through the iterative algorithm:

$$Q = \sum_{i=1}^{n}\sum_{j=1}^{m}(e_{ij} / s_{ij})^{2} \qquad (2)$$

Q is the sum of the squares of the difference (i.e., e_{ij}) between the observations (*X*) and the model (*GF*), weighted by the measurement uncertainties (s_{ij}).

PMF analysis requires three input matrices. The concentration matrix contains the concentrations of the *m* chemical species (in this case, PCB congeners) in the *n* samples. None of the concentrations in this matrix can be zero, so a non-zero value must be estimated for any result that is missing or below the detection limit. The uncertainty matrix contains an estimate of uncertainty for each data point in the concentration matrix. Finally, the limits of detection (LOD) matrix contains the LOD for every data point.

In general, matrices used for factor analysis should not have more analytes (*m*) than samples (*n*). The data set contained 71 samples. including duplicates, the duplicates were treated as samples and 71 congeners were chosen for the PMF analysis. The 71 congeners were chosen based on their abundance in the Aroclors and in the data set, with care taken to retain congeners that are abundant in the effluent, even if they are not particularly abundant in the influent. This approach meant that low molecular weight congeners were retained in the data matrix at the expense of some high molecular weight congeners. The 71 congeners account for approximately 90 percent of all of the PCB mass in all samples, and 87 percent of the PCB mass in the effluent samples.

Concentration matrix: A unique blank correction method tailored to the PMF was used for this analysis. Concentrations were blank corrected by subtracting the average concentration in the blanks (travel, lab, and rinsate blanks) for each congener. These averages were calculated by setting non-detect values to zero and excluding blanks in which the sum of PCBs was greater than 1,000 pg/L. After blank correction, concentration values that were less than or equal to zero were defined as “below detection limit.” Values below the detection limit composed 373 out of 5,041 data points in the concentration matrix (7.4 percent). These values were replaced with one-half of the analytical detection limit on a congener basis.

LOD matrix: The LOD matrix used the congener- and sample-specific LOD as provided. In the small number of cases where the LOD was missing, the LOD was estimated based on similarity to other samples in the data matrix.

Uncertainty matrix: As in other studies (Du et al., 2008; Rodenburg et al., 2008; Rodenburg et al., 2010a), uncertainty was estimated from the surrogate recoveries. The standard deviation of the recoveries of each surrogate was calculated and used as the uncertainty for each congener quantified against that surrogate. The uncertainty for the values below the detection limit was three times the uncertainty of the detected concentrations (i.e., the [x,3x] uncertainty matrix was used).

2.3.4.2 Non-Aroclor PCB Sources

PCB-11 was measured at relatively high concentrations (compared to other congeners) in both the influent and effluent. PCB-11 is the single most abundant congener in the effluent. . This is true with or without blank correction (see above for details on blank correction). PCB-11 concentrations in the effluent average 25 ± 7 pg/L (all concentrations are after blank correction unless stated otherwise). Concentrations of PCB-11 are significantly higher in the NVIPS samples (1,734 ± 1,791 pg/L) than the SVIPS samples (441 ± 76 pg/L) according to the two-tailed t-test assuming unequal variances ($p < 0.05$).

PCB-11 is virtually absent in the Aroclors. It is thought to enter the environment primarily from the use of diarylide yellow and other pigments in printing on paper and textiles (Rodenburg, 2010b). PCB-11 has a low K_{ow} and low molecular weight. Compared to other congeners, PCB-11’s physical/chemical properties cause it to partition to a lesser extent to particles. This may explain why PCB-11 was found in the effluent at higher concentrations than other, less soluble congeners. When the duplicate NVIPS samples collected on December 17, 2013, are excluded, PCB-11 (3,3'-dichloro) is strongly correlated with PCB-35 (3,3',4-trichloro; R^2 = 0.73) and somewhat correlated with PCB-77 (3,3',4,4'-tetrachloro; R^2 = 0.27). These structurally related congeners have all been reported as trace contaminants in diarylide yellow pigments (Litten et al., 2002; Anezaki and Nakano, 2014).

Other than PCB-11, there is no evidence that non-Aroclor PCB sources are impacting the influent and/or effluent of this Facility. For example, in the Delaware River, production of $TiCl_4$ (a precursor to titanium dioxide [TiO_2]) led to the extensive contamination of the sediment of the Delaware River with PCBs 206, 208, and 209. Nothing of that kind is observed in the County data.

2.3.4.3 PCB PMF Factors Analysis

A major challenge of factor analysis is to choose the "correct" number of factors that adequately describe the data matrix without over- or under-fitting. In the present case, seven factors were isolated from the 71 x 71 data matrix. For comparison, the 38 x 38 data matrix analyzed in 2014 yielded six factors. The 2015 factors were similar to the 2014 factors.

The seven-factor PMF solution did an excellent job of reproducing the data. The correlation coefficient (R^2) for the modeled versus measured data was greater than 0.9 for 62 of the 71 congeners. It was above 0.8 for another three congeners. The congeners with lower R^2 values were: PCB-3 (R^2 = 0.64), PCB-5 (0.797), PCB-9 (0.69), PCB-27 (0.75), PCB-198 (0.65), and PCB-203 (0.68).

To determine whether any of the factors represented mixtures of Aroclors, a multiple linear regression was performed in which a congener pattern (excluding PCB-11) was calculated that represented a linear combination of the four main Aroclors:

$$C_f = aC_{1242} + bC_{1248} + cC_{1254} + dC_{1260} \quad (1)$$

where *C* is concentration of the resolved factor (*f*) or individual Aroclor and *a*, *b*, *c*, and *d* are partial regression coefficients, which were constrained to be positive. Correlation coefficients (R^2) between this best-fit composite Aroclor congener pattern and the factor congener pattern were calculated. The resolved factors were compared with the congener patterns of the Aroclors (Rushneck et al., 2004) in an attempt to identify them (Table 2-9). Each factor's best-fit was also compared to a combination of Aroclors (Table 2-10). All factors were reasonably well described as a combination of Aroclors, although the correlation is worst for Factors 1 and 5, suggesting that they have undergone the most weathering.

Table 2-9. Correlation Coefficients (R^2) between Factors and Single Aroclors

Factor	1016	1242	1248	1254	1260
F1	**0.73**	0.60	0.11	0.01	0.06
F2	0.16	0.34	**0.78**	0.32	0.02
F3	0.40	0.59	**0.75**	0.14	0.02
F4	0.01	0.03	0.15	**0.57**	0.32
F5	0.00	0.07	**0.53**	0.36	0.01
F6	0.04	0.00	0.10	**0.98**	0.12
F7	0.07	0.07	0.01	0.12	**0.84**

The R^2 value is the correlation coefficient for the best-fit Aroclor versus the actual congener pattern. Factors with lower R^2 values have probably undergone more weathering. Note PCB-11 is excluded from these correlations.

Table 2-10. Coefficients for the Best-fit Description of Each Factor as a Mixture of the Four Most Common Aroclors

Factor	1242	1248	1254	1260	R^2
F1	0.83	0.00	0.00	0.01	0.60
F2	0.07	0.25	0.12	0.00	0.88
F3	0.42	0.39	0.18	0.02	0.88
F4	0.22	0.10	0.39	0.27	0.79
F5	0.00	0.71	0.42	0.00	0.69
F6	0.01	0.00	0.97	0.02	0.98
F7	0.00	0.05	0.24	0.65	0.90

The R2 value is the correlation coefficient for the best-fit Aroclor combination versus the actual congener pattern. Factors with lower R2 values have probably undergone more weathering. Note PCB-11 is excluded from these correlations.

The fingerprints of the seven resolved factors are shown in Figures 2-11 through 2-15. Factors 1 and 2 resembled Aroclors only when PCB-11 was removed from the correlation. Each of the factors was at least somewhat similar to one of the Aroclors (i.e., R^2 greater than about 0.45). Factors 3, 6, and 7 appear to represent relatively fresh or unweathered Aroclors 1248, 1254, and 1260, respectively. Factors 4 and 5 were similar to Aroclors 1254 and 1248, respectively, but appear to have undergone more substantial weathering, as indicated by lower R^2 values.

Factor 1, which is dominant in the effluent but barely present in the influent, is similar to the individual Aroclors 1016 and 1242, but even when expressed as a sum of the four main Aroclors, this factor does not well resemble any of these formulations. It is likely that Factor 1 represents the dissolved-phase PCB concentration that is not removed during the wastewater treatment process (see Figure 2-12). In order to determine whether the congener pattern of Factor 1 (excluding PCB-11) is similar to any of the other Aroclors when the water/particle partitioning is taken into account, the congener patterns (i.e., the abundance of each congener) of the Aroclors were divided by the congener's octanol-water partition coefficient (Hansen et al., 1999). The new "dissolved" congener pattern was compared to the congener pattern of Factor 1. The R^2 values for the comparison of Factor 1 (without PCB-11) and the "dissolved" Aroclors 1016, 1242, and 1248 were all between 0.5 and 0.7. In addition, the concentration of Factor 1 in the effluent is relatively constant at 116 ± 14 pg/L. Taken together, these two lines of evidence suggest that Factor 1 represents the dissolved phase of a variety of low molecular weight Aroclor formulations, plus the dissolved fraction of PCB-11.

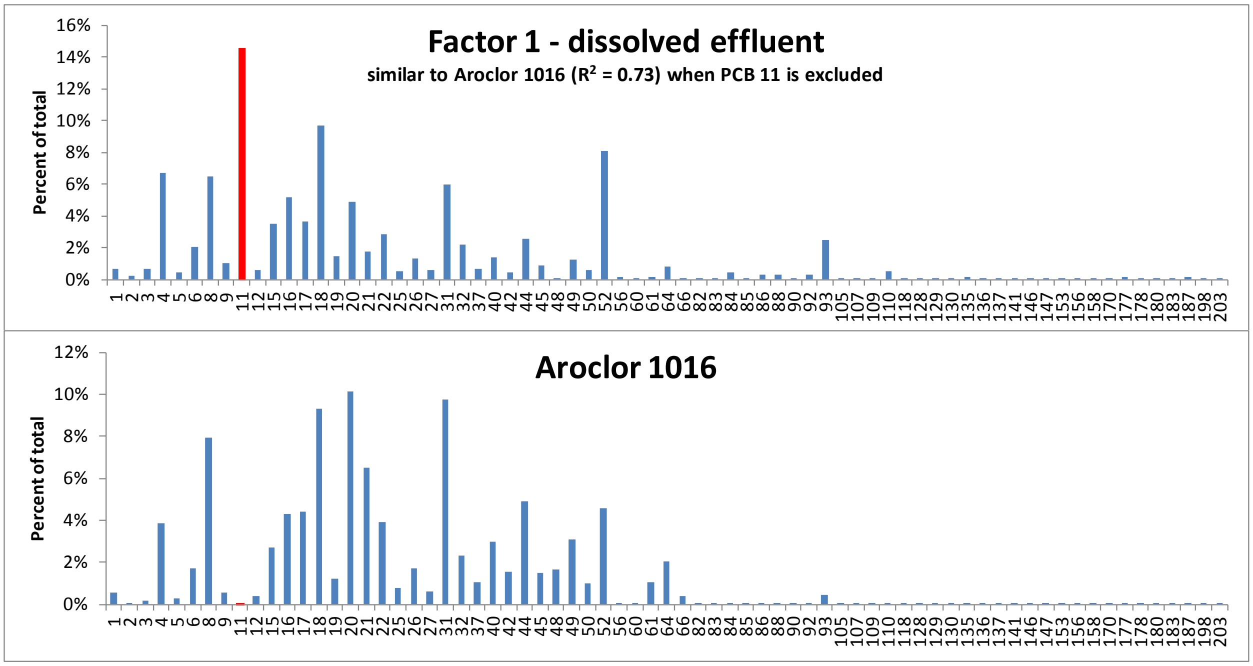

Figure 2-12. Fingerprint of Factor 1 compared to Aroclor 1016

Panel shows Factor 1 and each congener as percent of total mass in the data set.

Factor 2 is dominated by PCB-11 (Figure 2-13). When this congener is excluded, it resembles Aroclor 1248 (R^2 = 0.78). It is reasonably well described as a mixture of the four main Aroclors. As noted above, concentrations of this factor are significantly higher in NVIPS (1,845 ± 2,324 pg/L) than in SVIPS (589 ± 383 pg/L).

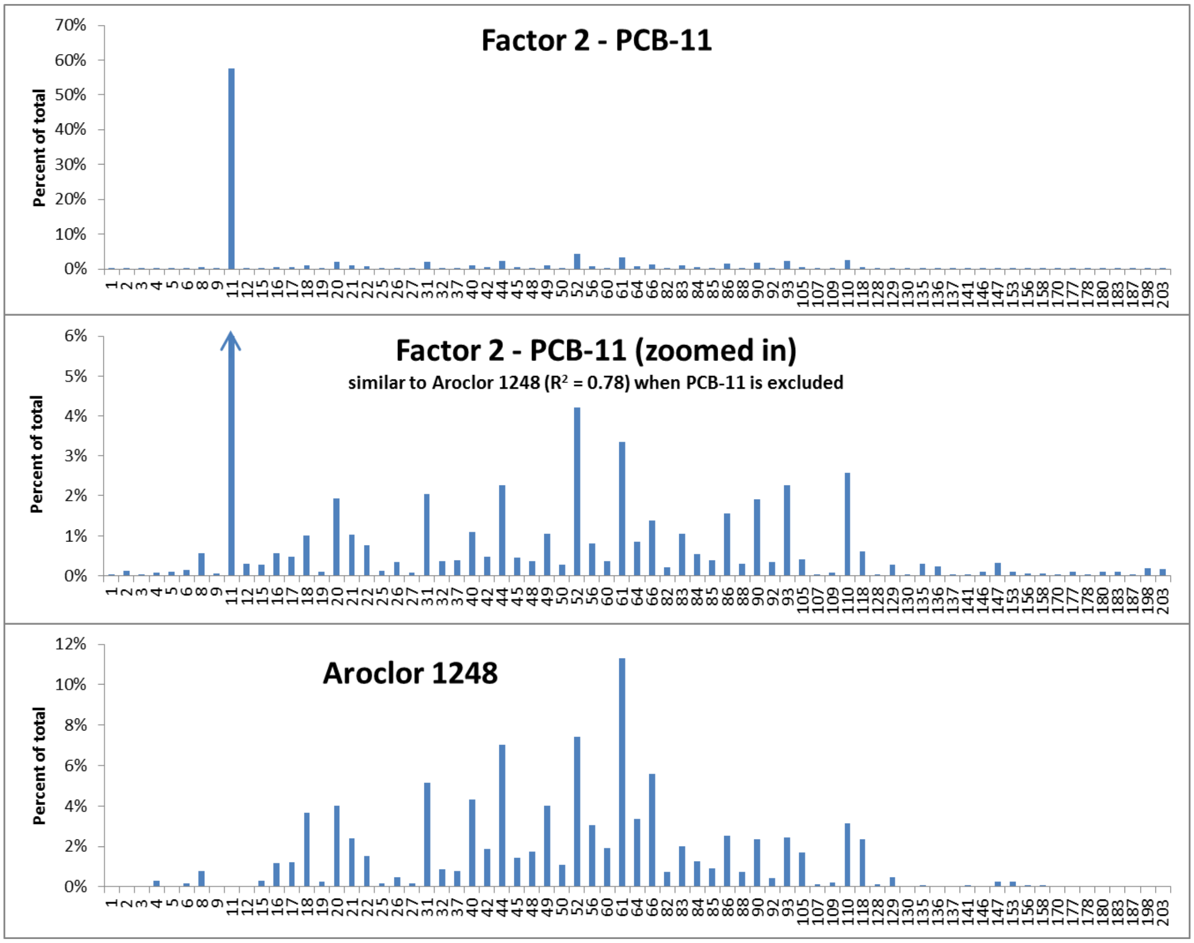

Figure 2-13. Fingerprint of Factor 2

Panel shows Factor 2 and each congener as percent of total mass in the data set. The bottom panel is the same fingerprint with the y-axis range modified to less than 6%.

Factor 3 is similar to Aroclor 1248 but, as Figure 2-14 shows, it contains a broader range of congeners at both the high and low MW ends of the spectrum. For this reason, Factor 3 is fairly well described as a mixture of the four main Aroclors. In contrast, Factor 5 also resembles Aroclor 1248, but it is “missing” congeners at both the high and low MW ends of the spectrum. It is similar to a mixture of Aroclors 1248 and 1254. Concentrations of Factor 3 are higher in SVIPS (3,268 ± 1,864 pg/L including track-down manholes, 2,827± 684 pg/L) than in NVIPS (1,815 ± 1,239 pg/L including track-down manhole samples, 1,854 ± 1,379 pg/L). Concentrations of Factor 5 are not different between NVIPS and SVIPS.

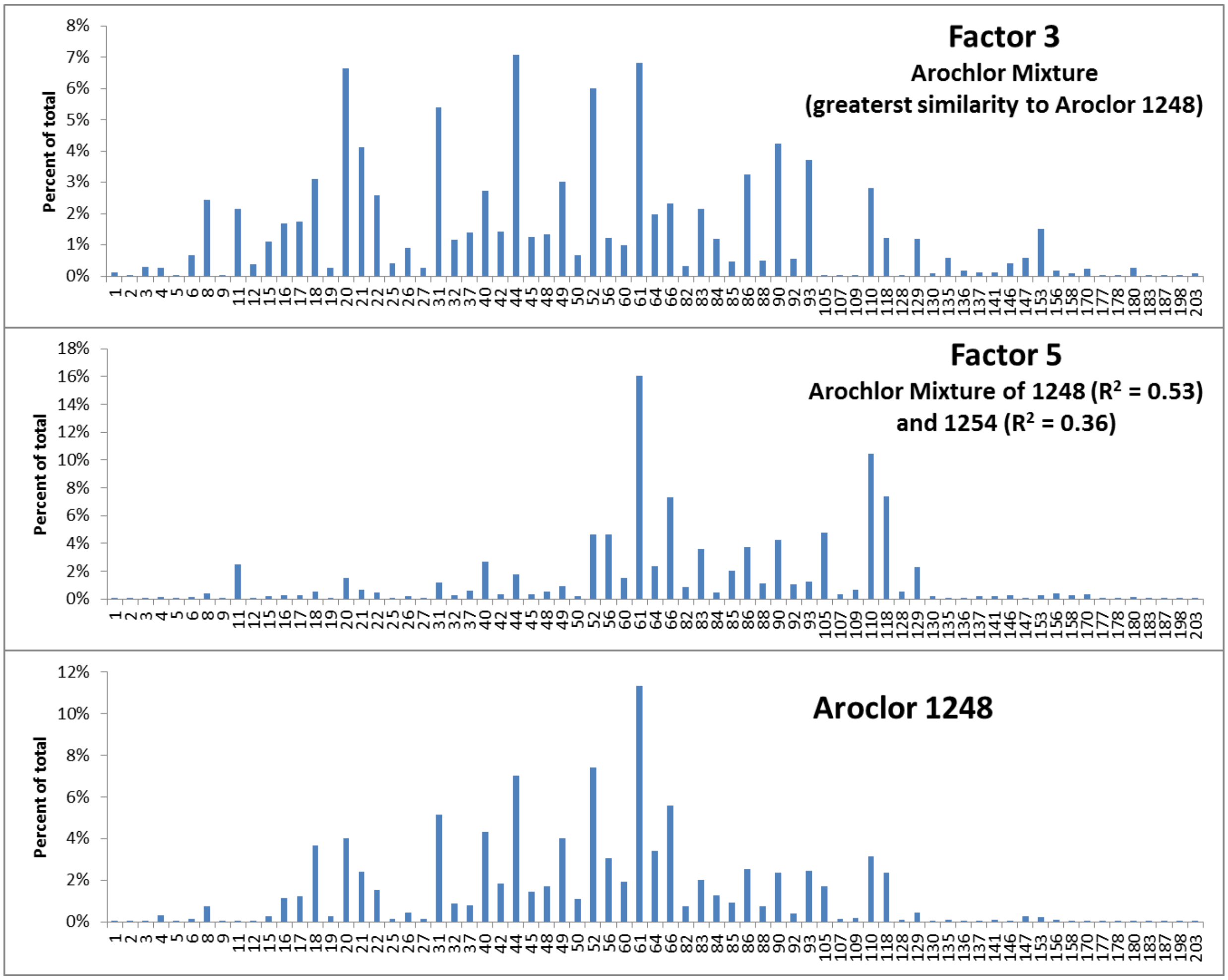

Figure 2-14. Fingerprints of Factors 3 and 5 compared to Aroclor 1248

Panel shows Factors 3 and 5, and each congener as percent of total mass in the data set.

Factor 4 resembles Aroclor 1254, but the correlation is not strong ($R^2 = 0.57$), and of all the factors, it is not well described as a mixture of Aroclors, indicating significant weathering. Concentrations of Factor 4 are not different between the NVIPS and SVIPS samples.

Factor 6 strongly resembles Aroclor 1254 ($R^2 = 0.98$). Such a strong resemblance implies virtually no weathering. Aroclor 1254 was the main Aroclor used in building materials such as caulk (Herrick et al., 2004). However, Aroclor 1254 was also used in a wide variety of other applications (Agency for Toxic Substances and Disease Registry [ATSDR], 2000). As noted in last year's report, this factor is particularly abundant in samples collected on August 20, 2013 at the NVIPS location. It is also abundant in the sample collected on December 9, 2014, at the DMI MHC location. Factors 4 and 6 are shown compared to Aroclor 1254 in Figure 2-15.

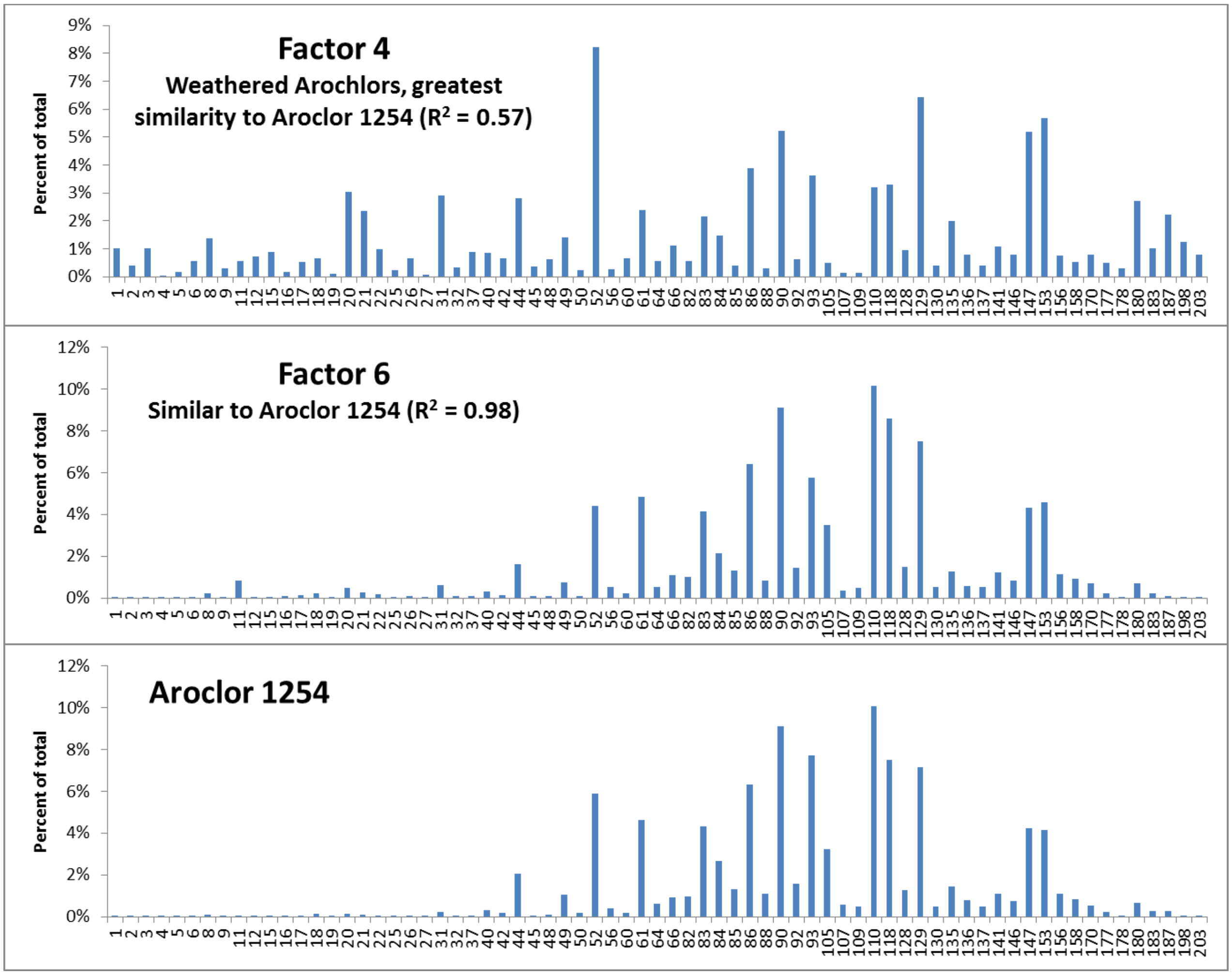

Figure 2-15. Fingerprints of Factors 4 and 6 compared to Aroclor 1254

Panel shows Factors 4 and 6, and each congener as percent of total mass in the data set.

Factor 7 somewhat resembles Aroclor 1260 (R^2 = 0.84), but contains more low molecular weight congeners (Figure 2-16). It is well described (R^2 = 0.90) as a mixture of Aroclors, especially Aroclors 1254 and 1260. Concentrations of Factor 7 are not different between NVIPS and SVIPS.

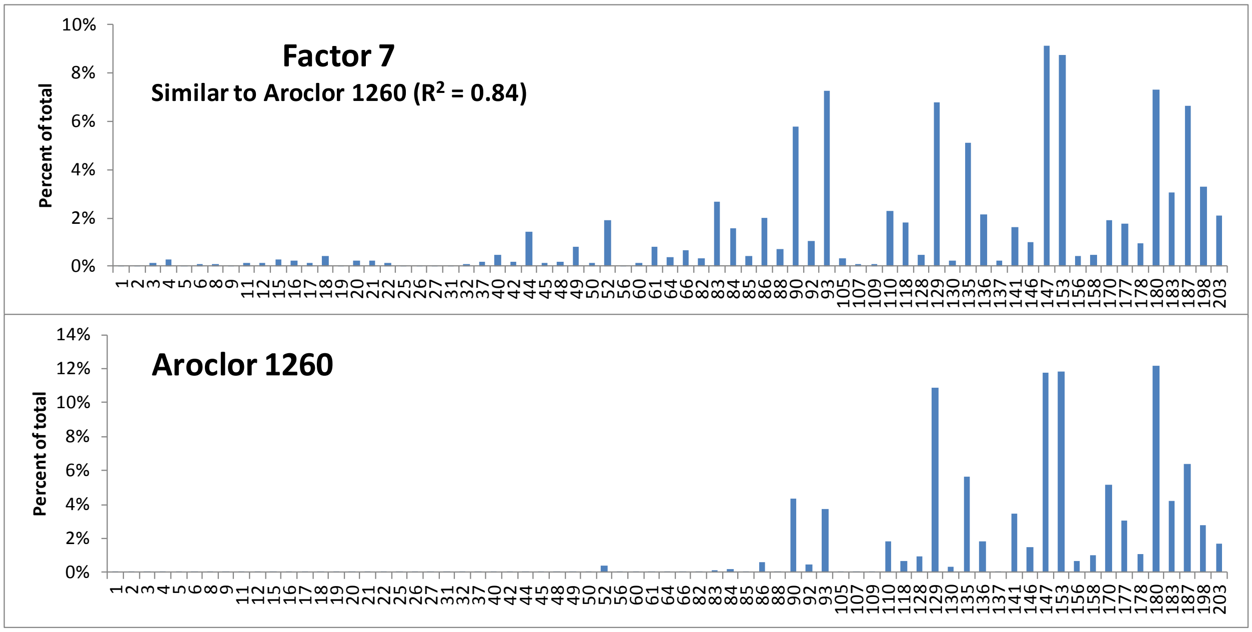

Figure 2-16. Fingerprint of Factor 7 compared to Aroclor 1260

Panel shows Factor 7 and each congener as percent of total mass in the data set.

The proportions of the seven factors in the influents (SVIPS and NVIPS) were similar to each other, but very different from the effluent. The following pie charts represent the average contribution of each factor to the total PCBs measured in selected samples. Figure 2-17 compares the factor profiles at the NVIPS and SVIPS. Factors 2 and 3 displayed significantly different concentrations in the NVIPS compared to the SVIPS samples. Concentrations of Factor 2 (which is dominated by PCB-11) were higher in the NVIPS samples, while concentrations of Factor 3 (which resembles Aroclor 1248) were higher in the SVIPS samples. This suggests that these two factors may be associated with specific contaminated locations, rather than regional background contamination. For this reason, these factors might be a priority for track-down. The Factor 3 concentration was noticeably elevated in the sample from DMI MHD collected on June 23, 2014.

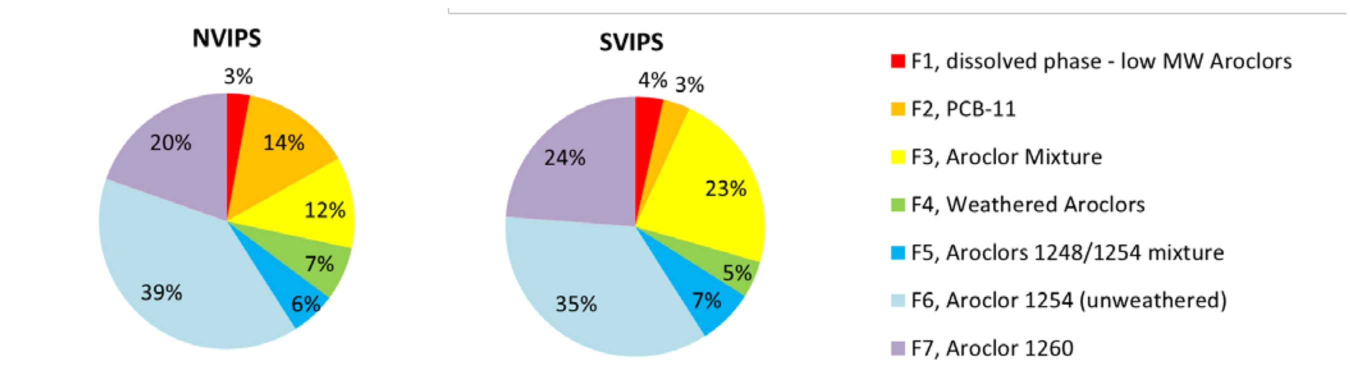

Figure 2-17. Contribution of each of the seven factors to the total PCB mass in the SVIPS and NVIPS

Figure 2-18 depicts the factor profiles in effluent samples. Factor 1, which correlates with dissolved phase low molecular weight Aroclors, is the most common factor. The other six factors are all present to varying degrees, with Factor 6 (unweathered Aroclor 1254) comprising the second-highest percentage. Factor 6 was the dominant factor at both influent locations.

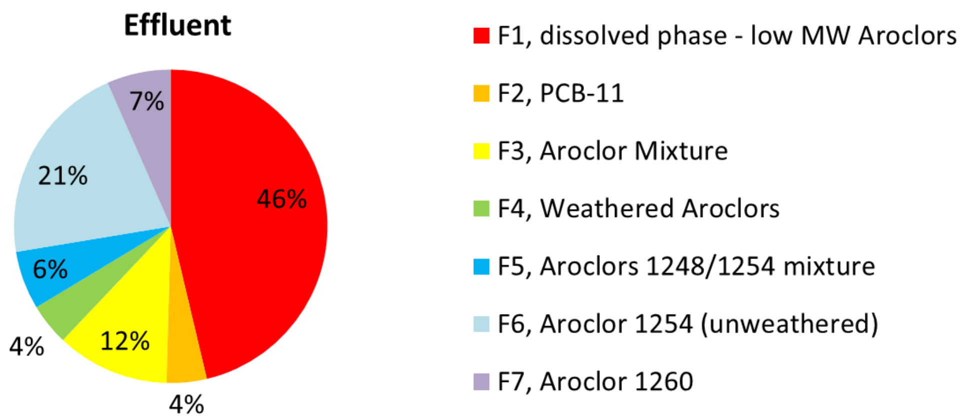

Figure 2-18. Contribution of each of the seven factors to the total PCB mass in the effluent

Figure 2-19 presents the factor profiles for the two highest total PCB concentrations observed to date: the August 2013 NVIPS sample (67,750 pg/L) and the June 2014 DMI MHD sample (53,900 pg/L). The August 2013 NVIPS sample is almost entirely comprised of Factors 6 and 7. Factor 6, which comprises 69 percent of the sample, correlates to a relatively pure (unweathered) profile of Aroclor 1254. This profile is consistent with an accidental point source discharge of one or two contaminated chemicals. In comparison, the June 2014 DMI MHD sample is much more varied, and resembles the overall profile observed at the downstream SVIPS and DMI MH1. A high TSS concentration was observed in this sample and this profile is consistent with a higher contamination due to the higher solids or sediment content.

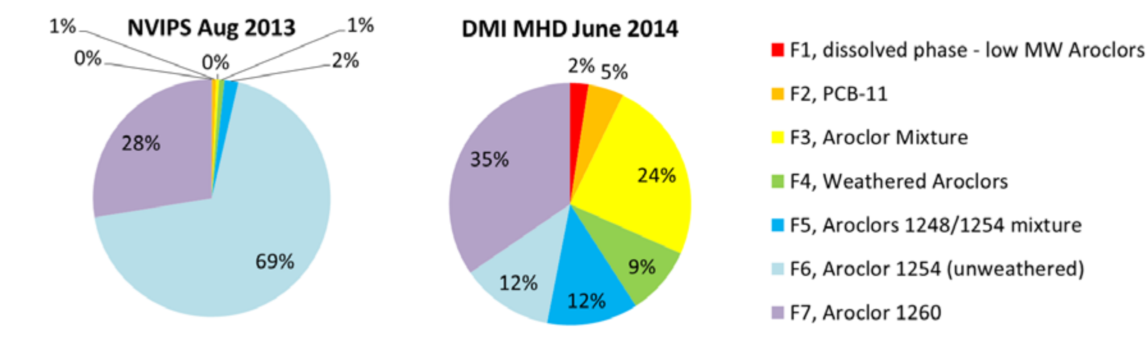

Figure 2-19. Contribution of each of the seven factors to the total PCB mass in the two most highly concentrated total PCB samples, to date

Figure 2-20 presents the factor profiles for the five track-down sampling locations in the DMI basin, which were selected on the basis of year of construction. Two samples from each DMI manhole location are presented in Figure 2-20. DMI-MHC, representing the oldest construction, shows a higher proportion of F6 (unweathered Aroclor 1254). Aroclor 1254 was commonly used in building materials, such as caulk and along with Aroclor 1260 were the main PCB mixtures used before 1950. DMI-MHD, representing homes built primarily in the 1960s and 1970s, has a profile similar to those observed at the influent pump stations and at the downstream DMI MH1. The three remaining sites, which represent newer developments, had varied profiles. DMI MHE had a high proportion of Factor 3, a mixture of four common Aroclors. DMI MHF, which represents the newest construction of all the sites, showed an even higher proportion of Factor 3, along with a relatively high proportion of Factor 2, which is associated with PCB-11. DMI MHG sampling results varied among the two samples taken. One sample from DMI MHG was dominated by Factor 5, which correlates to a mixture of Aroclors 1248 and 1254, with very little contribution from Factors 2 and 3. The DMI MHG profile is heavily influenced by the October 2014 event, with a total PCB concentration of 29,700 pg/L (compared to the August 2014 event which had a total PCB concentration of 3,670 pg/L). The October 2014 sample profile showed 66 percent Factor 5, and less than one percent of each of Factors 1, 2, 3, and 4.

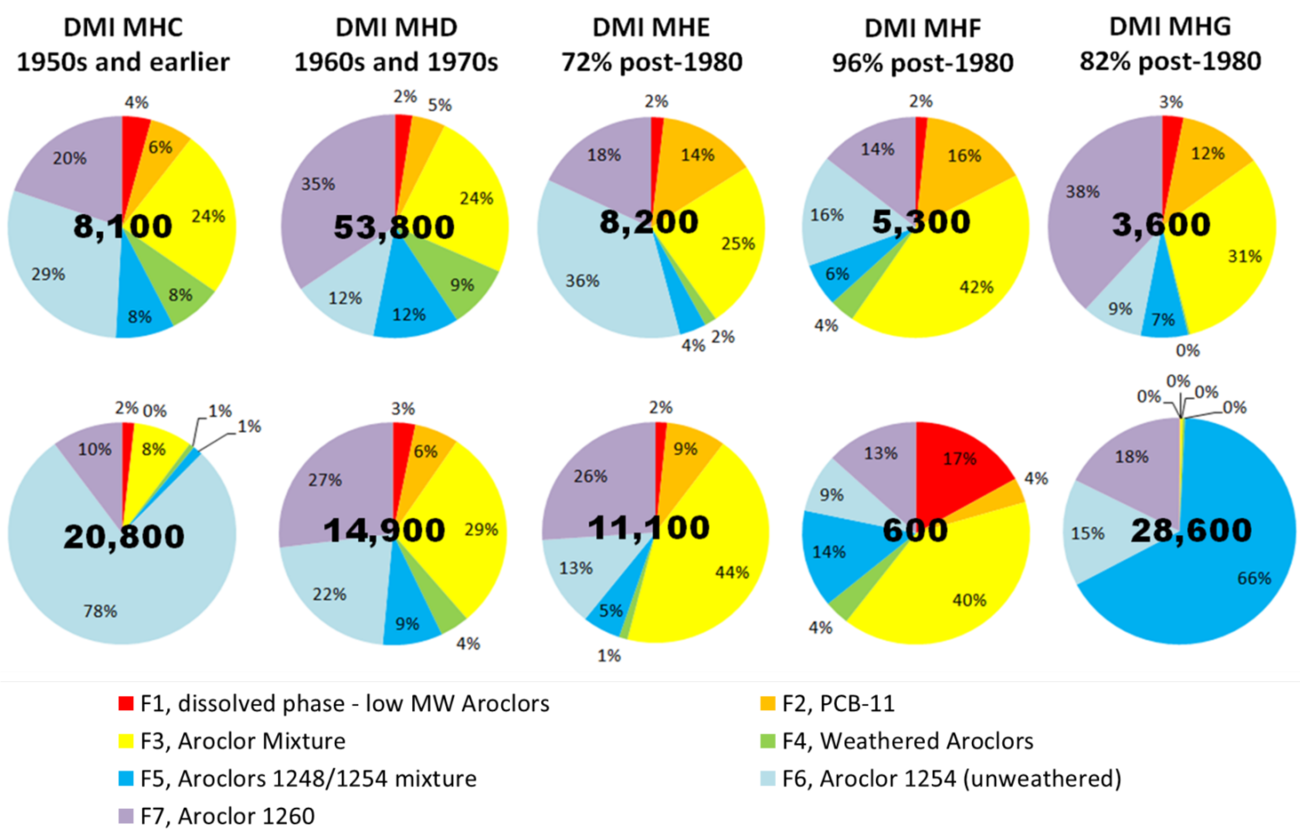

Figure 2-20. Contribution of each of the seven factors in the DMI subbasins

Note: the value bolded in black on each pie chart represents the total PCB concentration (pg/L) for each sample.

With only two samples per site in the 2014 DMI track-down, it is not possible to draw conclusions regarding the potential influence of year of construction. Impacts from individual or one-time point source discharges are amplified at sampling locations with small tributary areas. Events such as the October 2014 profile at DMI-MHG, dominated by 66 percent of Factor 5, and the December 2014 profile at DMI-MHC, which was 78 percent Factor 6, support this line of reasoning. Beyond that, the factor profiles suggest little correlation between the year of construction and the source of PCB contamination.

2.3.4.4 PCB PMF Summary and Conclusions

The PMF analysis yielded the following results and conclusions:

- The PMF analysis involved 71 congeners, totaling 90 percent of the total PCB mass across all samples.
- The seven-factor PMF solution did an excellent job of reproducing the data, based on congener correlation coefficients.
- Most of the factors are strongly correlated to Aroclors and Aroclor mixtures. The exception is Factor 2, which is mainly composed of PCB-11, which is often found in yellow dyes and pigments. Factor 2 was more prevalent at NVIPS than at SVIPS.
- Factor 1 comprised the majority of the effluent, and appears composed of dissolved-phase, low molecular weight Aroclors.
- Factor 6 appears similar to unweathered Aroclor 1254, which has been found in building materials such as caulk, and other applications. This factor was particularly abundant in the December 2014 sample at DMI MHC (20,900 pg/L total PCB concentration).
- Factor 3, which resembles a mixture of the four most common Aroclors, was much more prevalent in the SVIPS samples versus the NVIPS samples. It was also quite abundant in the June 2014 sample at DMI MHD (53,900 pg/L total PCB concentration).

2.3.4.5 PBDE Positive Matrix Factorization

PBDEs are produced and sold in three main types of formulations, the penta-, octa-, and deca-BDE formulations. Note that the name of the formulation does not necessarily correspond to the homologs of the BDEs that are present in the mixture. PeBDE is dominated by BDE-47, which is a TeBDE, as well as BDE-99 and BDE-100, which are both pentabromo congeners. Octa-BDE (OcBDE) contains primarily BDE-183 (hepta), although some octa formulations contain large amounts of BDE-206 and BDE-207 (nona), and BDE-209 (deca). DeBDE consists primarily of BDE-209.

The PBDE data set shows very little BDE-183; it is never more than 0.5 percent of the sum of BDEs in any sample. This may suggest that OcBDE was not used in significant quantities in this area.

Because BDEs in general have high octanol-water partition coefficients, they partition to the particulate matter in the water column to an even greater extent than PCBs. As a result, BDEs in general and especially the high molecular weight congeners are less likely to be found in the effluent because of the excellent solids removal of the Facility. Thus BDE-209 is undetectable in two of the nine effluent samples, despite its being the most abundant congener in many of the other samples (and in most environmental samples). Effluent BDE concentrations contain high proportions of TeBDEs, primarily BDE-47. BDE-47 is the dominant congener in the PeBDE commercial formulations, which include trade names such as DE-71 and 70-5DE, all sold under the name Bromkal.

BDE-28 and BDE-17 are also quite abundant in the effluent, composing up to 24 percent of the sum of BDEs. These two congeners are only very small contributors to the PeBDE technical mixtures. Bromkal DE-71 contains less than 0.1 percent BDE-17 and about 0.25 percent BDE-28 and BDE-33. Bromkal 70-5DE contains about 0.05 percent BDE-17 and 0.1 percent BDE-28. These two congeners are not detectable in the other commercial BDE formulations (La Guardia et al., 2006). Both of these congeners can be produced from the debromination of heavier BDE congeners. The photolysis of BDEs exhibits characteristic pathways and breakdown products (Wei et al., 2013; Fang et al., 2008; Sanchez-Prado et al., 2012; Sanchez-Prado et al., 2006). BDE-15 is a major photolysis product, with BDE-17 sometimes reported as a minor product (Wei et al., 2013; Sanchez-Prado et al., 2012). Several studies have noted that BDE-17 is a major product of microbial BDE debromination (Ding et al., 2013; La Guardia et al., 2007; Tokarz et al., 2008; Robrock et al., 2008). In contrast, Lee et al., 2011 studied the debromination of BDEs by a coculture consisting of Dehalococcoides and Desulfovibrio species, and found that debromination at the ortho position is preferred, with significant amounts of PBDE-15 formed.

Thus the abundance of BDE-17 and BDE-28 indicates that microbial debromination of BDEs is occurring in the system, most likely in the sewers (Rodenburg et al., 2010a and 2012a). The relative lack of BDE-15 suggests that photolysis is not important in this system.

PBDE PMF Analysis

The data set for PMF analysis included 27 of the 47 BDE congeners measured. The excluded congeners were below the detection limit in the majority of samples, so the data set included virtually 100 percent of the mass of all of the BDEs in the data set. As with the PCB PMF analysis, the BDE analysis was performed on blank corrected data and included the duplicates as separate samples. In the future when more samples are collected, duplicates can be excluded. The final matrix contained 27 congeners measured in 47 samples.

Concentration matrix: Values below detection limit composed 209 out of 1,269 data points in the concentration matrix (16 percent). These values were replaced with one-half of the detection limit. Blank correction was performed by subtracting the average concentration of each congener across all blanks from each sample.

LOD matrix: The LOD matrix used the congener- and sample-specific LOD as provided.

Uncertainty matrix: As in other studies (Du et al., 2008; Rodenburg et al., 2008; Rodenburg et al., 2010a), uncertainty was estimated from the surrogate recoveries. The standard deviation of the recoveries of each surrogate was calculated and used as the uncertainty for each congener quantified against that surrogate. For congeners that were quantified relative to more than one surrogate, the uncertainty was propagated for the average surrogate recovery (i.e., the uncertainty was the square root of the sum of the squared uncertainties of all surrogates used). The uncertainty for the values below the detection limit was three times the uncertainty of the detected concentrations (i.e., the [x,3x] uncertainty matrix was used).

PBDE PMF Results

Three factors were resolved from this data matrix. The three-factor model gave the best agreement between the nine seed runs (i.e., the relative standard deviation [RSD] of the G matrix was 1.4 percent) and the agreement between the modeled and measured concentrations was excellent. The correlation coefficient (R^2) for the measured vs. modeled concentrations was greater than 0.80 for 21 of the 27 congeners. The remaining congeners (BDEs 7, 8, 37, 71, 75, 199, and 183) had R^2 values greater than 0.85 when one to six of these outliers were removed from the correlation. The congener patterns for the three factors are shown in Figure 2-21.

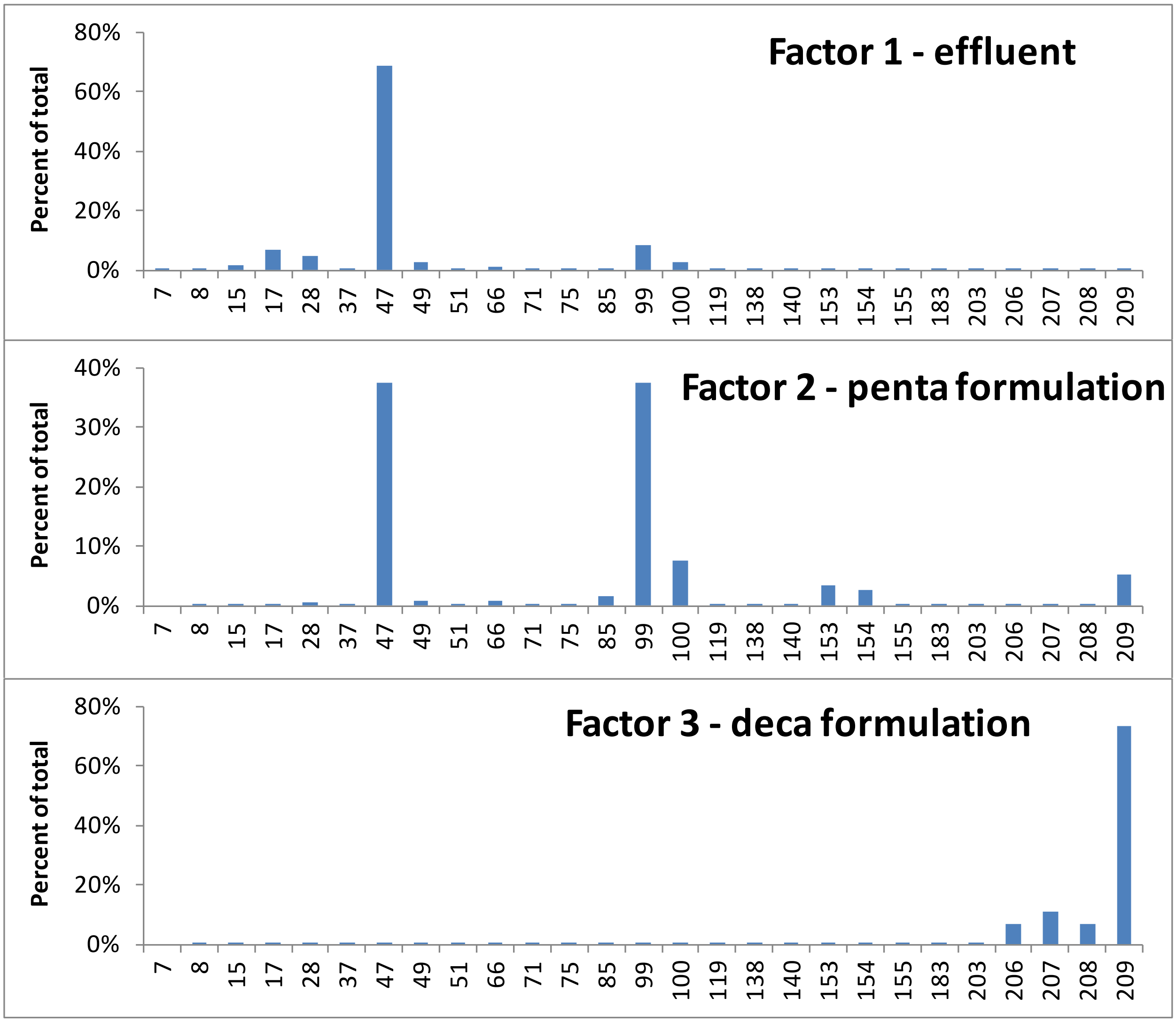

Figure 2-21. Fingerprints of the three resolved BDE factors

Numbers in parentheses are the percent contribution of each factor to the total mass in the data set.

Factor 1 does not strongly resemble any of the technical BDE formulations. Because it contains a relatively high amount (6.9 percent) of BDE-17 and the highest proportions of BDE-7 and BDE-8, it may represent debromination of higher molecular weight BDE congeners. It accounts for only 1 percent of the total mass in the data set, but it is the dominant factor in eight out of the nine effluent samples (Figure 2-19). In the effluent, concentrations of this factor are relatively constant averaging 689 ± 242 pg/L. In this sense, Factor BDE-1 is similar to Factor 1 of the PCB solution. Both appear to represent the dissolved phase. Factor 1 concentrations are significantly higher in SVIPS (4,714 ± 1,459 pg/L) than in NVIPS (2,679 ± 1,136 pg/L). This difference probably arises because Factor 2 is also higher in the SVIPS samples (see below) and Factor 1 represents the fraction of Factor 2 that partitions into the dissolved phase. This interpretation is supported by the fact that concentrations of Factor 1 are strongly correlated with concentrations of Factor 2 (R^2 = 0.78).

Factor 2 accounts for 62 percent of the mass in the NVIPS and SVIPS and represents the PeBDE formulations. Concentrations of this factor are significantly higher in SVIPS (273 ± 88 nanograms per liter [ng/L]) than in NVIPS (174 ± 53 ng/L). Note the change in units from pg/L to ng/L. Factor 2 is at low concentrations in the effluent and is removed by the Facility.

Factor 3 is dominated by high MW BDE congeners such as BDEs 206, 207, 208, and 209. It represents the deca-BDE formulation. Concentrations of this factor are not different between SVIPS and NVIPS. This factor is present only occasionally in the effluent, suggesting virtually complete removal

Figure 2-22 shows the contribution of each BDE factor compared to the total BDE mass of the NVIPS, SVIPS, and effluent samples. The PMF results suggest that the commercial PeBDE and DeBDE formulations are the dominant sources of BDEs to the influent.

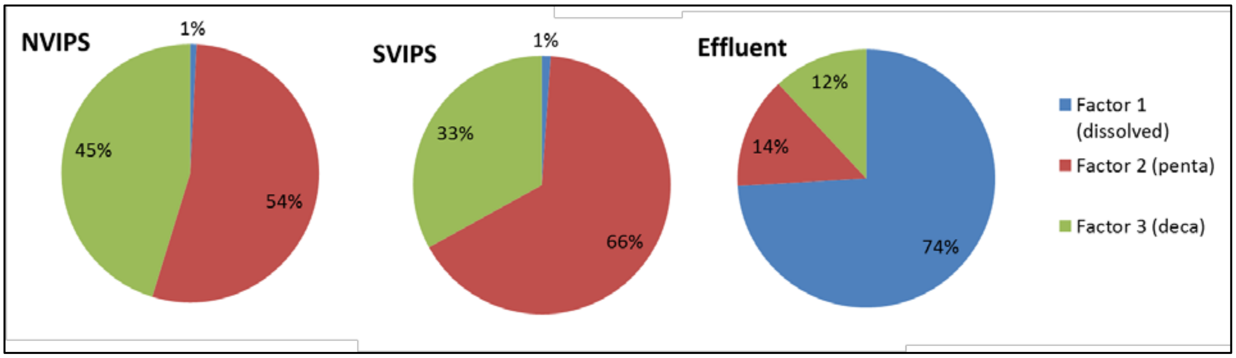

Figure 2-22. Contribution of each BDE factor to the total BDE mass in the NVIPS, SVIPS, and effluent samples

One effluent sample with high BDE-209 concentration was excluded.

PBDE PMF Conclusions

The BDE PMF accounted for nearly 100 percent of the PBDE mass found in the samples. The main source of PBDE is from commercial formulations, such as Bromkal. The 2014 results are similar to those of 2013; therefore, continued monitoring for PBDEs is unlikely to significantly improve the understanding of PBDE sources or management measures.

2.4 Source Assessment

This section discusses potential sources of PCB, Dioxin, and PBDE that could affect Spokane County's wastewater collection system. Potential PCB sources include legacy products, current products, and dispersed sources. These sources are described in the following sections.

Dioxin can be created as a by-product of certain industrial processes involving halogenated substances, such as herbicide or paper production. It can also be produced by combustion of municipal waste and other materials. As noted in Section 2.3, Dioxin has been detected only once in the samples collected to date, at a concentration close to the detection limit.

PBDEs have been used as flame retardants in a variety of household products. Because they are not chemically bound to plastic, foam, fabrics, and other products in which they are used, PBDEs can leach out of those products. There are no water quality or fish tissue standards for PBDEs. The manufacture and import of PeBDEs and OcBDEs were banned in the United States in 2004. The County is not aware of any industrial sources of PBDE within its service area. Ecology (2012) found that wastewater samples from new residential areas contained higher PBDE concentrations than wastewater samples collected from industrial or older residential areas in the Liberty Lake, Washington, study area. Based on the Liberty Lake pilot study, Ecology recommended that efforts to reduce PBDEs in wastewater focus on education of residents and businesses associated with residential work, such as carpet cleaners, laundromats, furniture shops, and re-upholsterers (Fernandez, 2012).

2.4.1 Legacy Products

PCBs are man-made compounds with no natural sources. PCBs were commercially produced in the United States as standard mixtures bearing the brand name Aroclor (Belton et al., 2007). Aroclors were produced from about 1929 until 1979, when EPA banned PCB manufacturing, distribution, and use. Because of the long service life of many PCB-containing items and the use of PCBs in some durable products, Aroclors are still found in some equipment and materials currently in use (Munoz, 2007).

Aroclors were used in a wide range of products, as summarized in Table 2-11 below. Specific Aroclors are defined by a four-digit number. The first two digits refer to the number of carbon atoms in the phenyl ring (for PCBs, this number is 12). The second two digits refer to the percentage of chlorine by mass in the mixture, except for Aroclor 1016, which has 12 carbon atoms but 42 percent chlorine by mass.

Table 2-11. Common Uses of Aroclors

Common uses	Aroclor						
	1016	1221	1232	1242	1248	1254	1260
Adhesives			✓				
Capacitors	✓	✓				✓	
Carbonless copy paper				✓			
Chlorinated rubber						✓	
Cutting oils						✓	
Dedusting agents						✓	✓
Epoxy resins		✓			✓		
Ethylene vinyl acetate						✓	
Gas transmission turbines		✓		✓			
Heat transfer				✓			
Hydraulic fluid			✓	✓	✓	✓	✓
Inks						✓	
Pesticide extenders						✓	
Polyester resin							✓
Polystyrene		✓					
Polyvinyl acetate		✓	✓	✓			
Polyvinyl chloride					✓	✓	✓
Rubber		✓	✓	✓	✓		
Sealants and caulking compounds						✓	
Styrene-butadiene co-polymers						✓	
Synthetic resins						✓	
Transformers				✓		✓	✓
Vacuum pumps					✓	✓	
Varnish							✓
Wax extenders				✓			

Sources: Nagpal (1992), ATSDR (2000).

Table 2-11 indicates the wide range of historical application of Aroclor products. The three Aroclors found in the samples could have originated from sources such as electrical transformers, capacitors, hydraulic fluids, rubber products, varnishes, and a variety of other products. Some of these products can be found in commercial or residential areas as well as industrial areas.

A land use map for the Facility's service area is presented in Figure 2-23. While there are areas of industrial use, at present the data are insufficient to link any of these areas with toxics entering the County's sanitary sewer system.

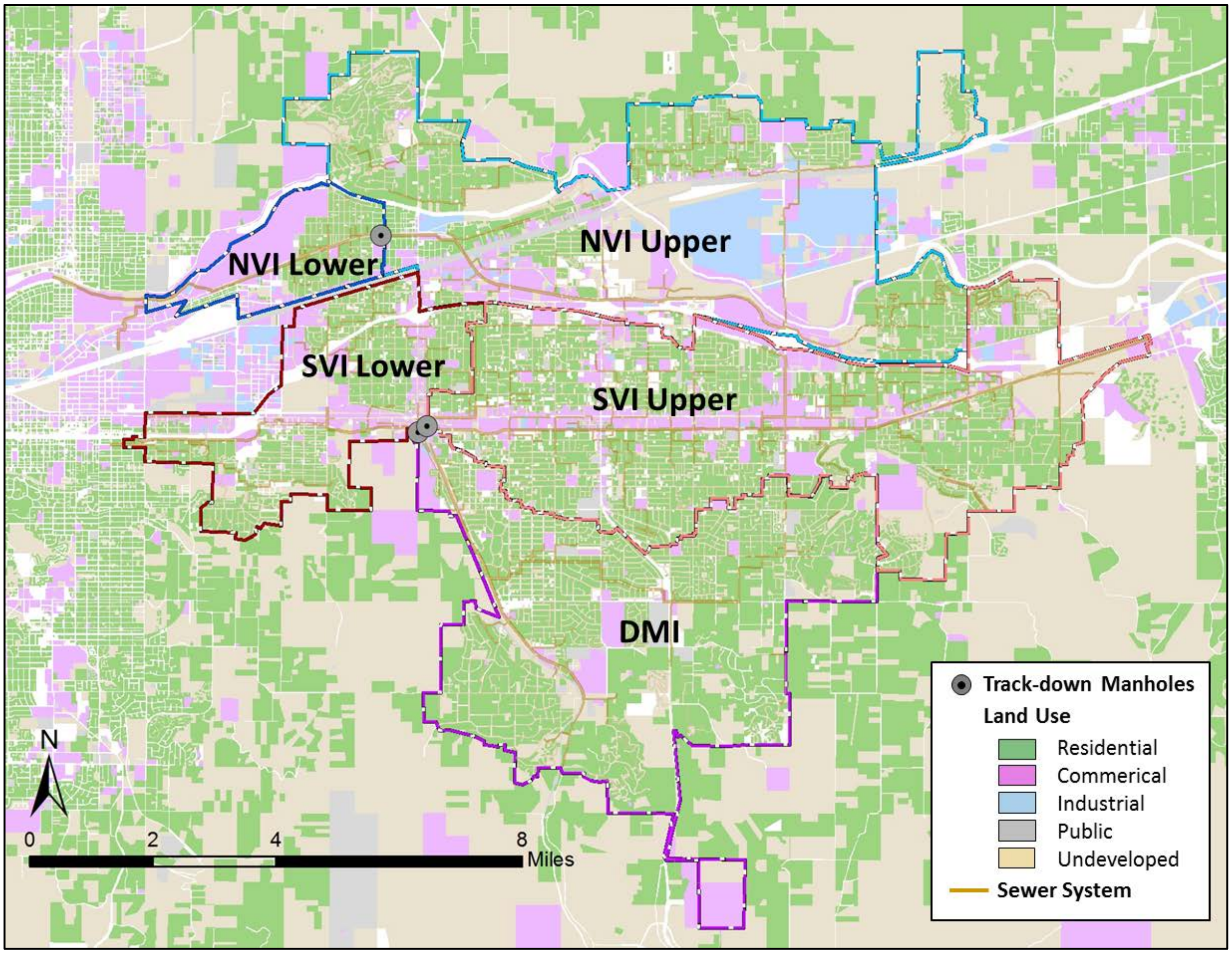

Figure 2-23. Land use in Facility service area

2.4.2 Current Products

Chemical processes involving carbon, chlorine, and high temperatures can inadvertently produce PCBs as by-products. For example, synthesis of diarylide yellow pigment, titanium dioxide white pigment, and silicone rubber tubing have the potential to generate PCB by-products (Rodenburg, 2012b). More than 200 chemical processes can generate PCBs as by-products (Munoz, 2007). The Toxic Substances Control Act (TSCA) allows concentrations of 5 to 50 parts per million (ppm) as manufacturing by-products.

2.4.3 Dispersed Sources

PCBs can enter the air through volatilization and combustion and be deposited on land or water via precipitation or dry deposition (NJDEP, 2009). Precipitation can contain significant concentrations of PCBs (Franz and Eisenreich, 1993; Gregor and Gummer, 1989; Los Alamos National Laboratory, 2012; Offenberg and Baker, 1997). PCBs in precipitation could enter the sewer system via stormwater inflow or groundwater infiltration. PCBs in dry deposition could enter the sewer system via hand-washing, washing of fruits and vegetables, laundry, or other domestic activities.

PCBs can be present in fatty fish and other foods. Some of the ingested PCBs are excreted in fecal matter (Juan et al., 2002; Harrad et al., 2003).

2.4.4 Potential Pathways

PCBs from the potential sources listed above could enter the County's collection system in a variety of ways:

- wastewater discharge from residential, commercial, or industrial land uses
- storm flow runoff that enters the wastewater system via cross-connections or leaky manholes
- groundwater that enters the wastewater system via cracks or leaks

The County's sewer system is relatively new (much of the pipe is less than 10–20 years old) and constructed in accordance with modern sewer codes designed to minimize inflow and infiltration. As a result, flows in the two influent trunk lines do not increase very much during wet weather. Flow and rainfall data were compared for 2012. On the days with the nine largest precipitation events (0.5 to 1.2 inches per day), the observed increase in flow to the Facility ranged from 1 to 11 percent. Larger flow increases were sometimes observed on days without rainfall. These flow and rainfall data suggest that stormwater runoff and groundwater infiltration volumes are relatively minor and are probably minor pathways for PCBs to enter the County's wastewater collection system.

2.4.5 Source Assessment Summary

No specific sources of toxic constituents were identified in 2014. While relatively high PCB concentrations were noted at several track-down sampling locations, those findings were not consistent over the two sampling events this year. As one moves upstream within the collection system toward a PCB source, one would expect the PCB concentration to increase as the sewage flow decreases. The DMI basin comprises approximately 10,000 parcels. Subbasin DMI MHD, which observed the highest PCB concentration recorded in 2014 (53,900 pg/L), comprises approximately 500 parcels. In order to account for the difference in PCB concentrations between the DMI basin (20,375 pg/L) and the other 2013 track-down locations (12,630 pg/L at NVI MH1 and 15,425 pg/L at SVI MH1), the DMI MHD subbasin would need to generate an average PCB concentration of over 120,000 pg/L on a consistent basis. This was not observed, nor was it observed in any of the other track-down subbasins within the DMI sewer basin. The evidence suggests that PCB contamination is more generalized, with a large number of small sources, rather than a small number of large sources, contributing to the influent loading from this basin.

If PCB contamination is from a large number of small sources, a reasonable approach to source assessment would be to group the County customers and assess whether certain groups are discharging disproportionately large amounts of PCBs in the sewage. With the 2014 track-down sampling, customers have been grouped according to the year of structure construction. The basis of this grouping was the supposition that structures built prior to PCB regulations in the late 1970s could discharge relatively more PCB contaminants through leaching from pipe and caulking material, or collection from paint, dust, and other surfaces through the collection and disposal of washwater. With one or two sampling events per track-down location completed to date, the data are inconclusive. The basin with the smallest proportion of older (pre-1980) construction has demonstrated very low levels of PCB contamination (average concentration of 3,940 pg/L at DMI MHF). However, relatively high concentrations have been observed in one basin dominated by homes built in the 1960s and 1970s (53,900 at DMI MHD) as well as in one basin dominated by homes built in the 1980s and 1990s (29,700 pg/L at DMI MHG).

Further track-down efforts will be directed at both stepwise track-down and customer grouping, with an emphasis on customer grouping based on the results observed to date.

The PMF and congener analysis showed that PCB-11 and four of the Aroclors (1242, 1248, 1254, and 1260) compose the bulk of the influent. PCB-11 is found as a manufacturing by-product in diarylide yellow and other pigments used in printing on paper and textiles (Rodenburg, 2011). The abundance of PCB-11 may be linked to dispersed sources (such as household laundries) or active sources. Examples of active sources could include paper and printing industries, textile and apparel manufacturers, paint manufacturers, chemical manufacturers, or manufacturing of miscellaneous materials where dyes or pigments may be used. Figure 2-24 presents a map of all industries in the service area that fit into these categories. The prevalence of such industries is similar in the SVI and NVI basins, with few such industries located in the DMI basin. The four printing locations within the DMI basin are all home-based businesses, and are unlikely to represent major sources of PCB contamination. The upcoming track-down effort will include directed sampling of areas with higher densities of such customers.

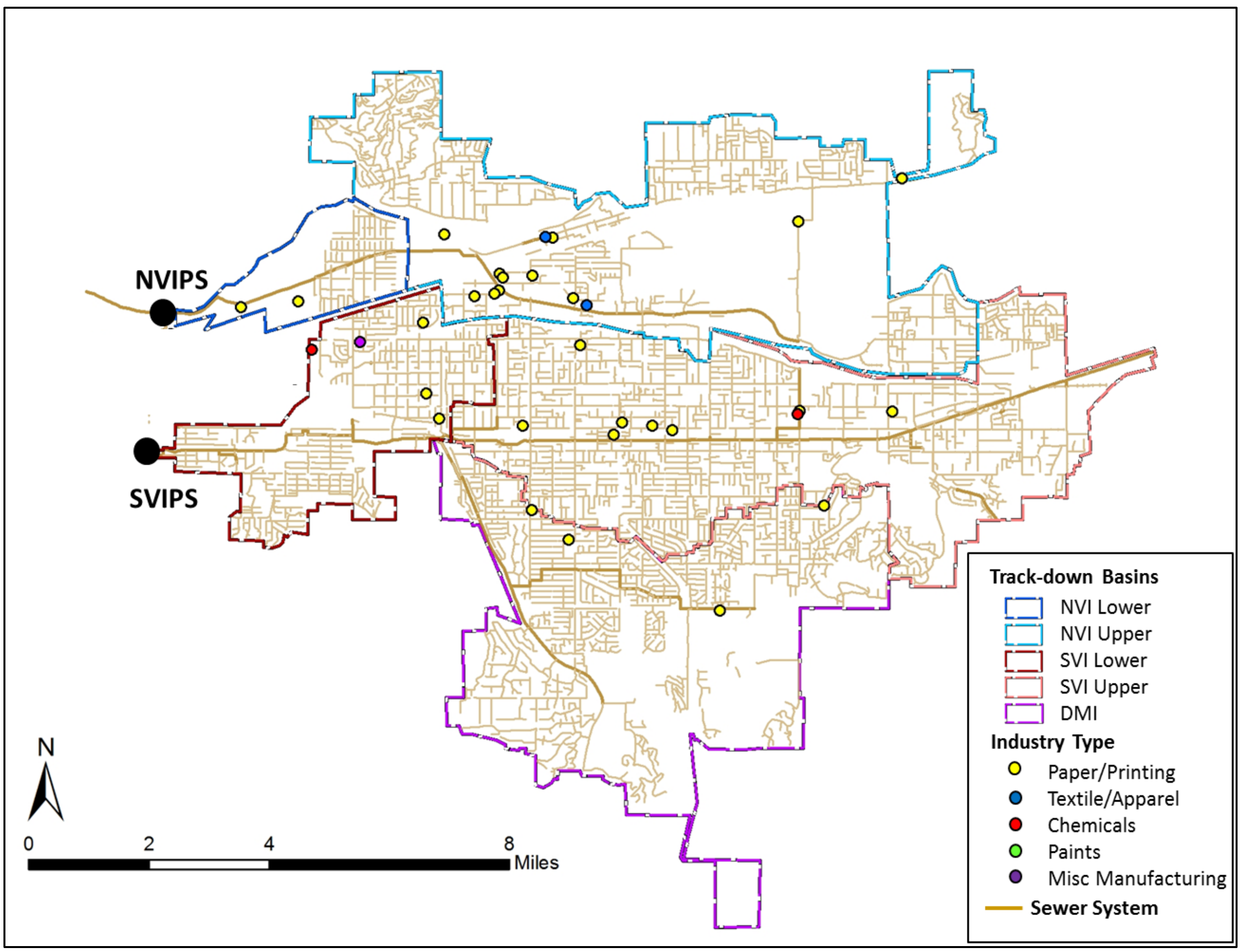

Figure 2-24. Industries that may use or produce dye or pigment

Ongoing collection system track-down sampling suggests that multiple small sources, rather than few large sources, are responsible for the bulk of PCB contamination in the influent. The Toxics Management Action Plan, presented in Section 3 of this Report, describes how Spokane County intends to move forward during the next 2 years to investigate, identify, and mitigate sources of pollutants.

Section 3

Toxics Management Action Plan

This section describes Spokane County's proposed Toxics Management Action Plan for reducing toxics entering the County's wastewater collection system. The County's 4-year plan includes the activities listed below:

1. Source investigation and identification
2. Remediation and/or mitigation of individual sources
3. Application of best management practices (BMPs) to all County sewer customers
4. Application of pretreatment regulations to industrial users

Section 3.1 describes the overall approach. Sections 3.2 through 3.4 describe the proposed activities for the remainder of the Permit term. Toxics Management Action Plans prepared for each subsequent year will be refined based on the increasing body of knowledge.

3.1 4-Year Program Approach

As discussed in Section 2 above, the pollutants targeted in this Toxics Management Action Plan could enter the sewer either via active disposal or passive transport.

<u>Sources of active disposal of toxic compounds of concern could include:</u>

- Industrial, commercial, and residential sites where products or equipment manufactured before 1979 that contain PCBs are still in use, such as older mechanical machinery, electrical equipment and components, and construction material content such as paints and caulking.
- Industrial, commercial, and residential sites with products containing inadvertently produced or unregulated levels of PCBs, such as inks, dyes, soaps, and cleaners from foreign as well as domestic manufacturers. As noted above, TSCA allows concentrations of 5 to 50 ppm as manufacturing by-products.
- Industrial sites where active manufacturing processes are inadvertently generating PCBs below the TSCA limits.

<u>Sources of passive entry of pollutants into the sewer via stormwater runoff, inflow, or infiltration could include</u>:

- locations where legacy products or equipment are still in use and exposed to rainfall or runoff: industrial sites, commercial locations, and private residences
- locations where legacy products have been discarded or disposed-of: vacant lots, open spaces, landfills, and junk yards
- locations where legacy products have been used in the past, and where leakage or spills may have taken place: industrial sites, commercial locations, private residences, vacant lots, and open spaces
- locations where products containing inadvertently produced or unregulated levels of pollutants are used, stored, disposed, or otherwise exposed to rainfall or runoff: industrial sites, commercial locations, and private residences
- locations where pollutants conveyed in the atmosphere or rainfall could enter sewers via inflow or infiltration

Based on the data collected to date, Aroclors 1242, 1248, 1252, and 1260, as well as PCB-11, appear to be potential sources of PCBs to the Facility. As noted in Table 2-11 above, these Aroclors were used in a wide range of commercial products before PCB production was banned in 1979. PCB-11 is virtually absent in Aroclor products, but occurs as a manufacturing by-product in diarylide yellow and other pigments in printing on paper and textiles. Notably, PCB-11 was the most abundant congener found in the effluent samples. It is possible that the most substantive long-term action to reduce PCB-11 loads may be an industry-wide product reformulation on a national or international scale, rather than local source control actions.

The data collected to date suggest that commercial formulations, such as Bromkal, may be important sources of PBDEs to the Facility (see Section 2.3.4.5). Industry-wide product reformulation may be the most effective long-term action to reduce PBDE loads to the Facility.

The County's toxics management program takes a systematic approach to source identification, with an investigative emphasis on tracking down sources of toxic compounds through sampling, and identification of potential products and activities through chemical fingerprinting. Other activities will be directed at remediation and/or mitigation of identified individual sources, and application of BMPs throughout the community.

3.1.1 Source Investigation and Identification

The 4-year approach to source investigation and identification is summarized on Figure 3-1. This approach features a track-down sampling program and chemical fingerprint analysis that is described in detail in the next two sections. This approach was first introduced in the 2013 Annual Toxics Management Report and the implementation of this continued approach is described in this section.

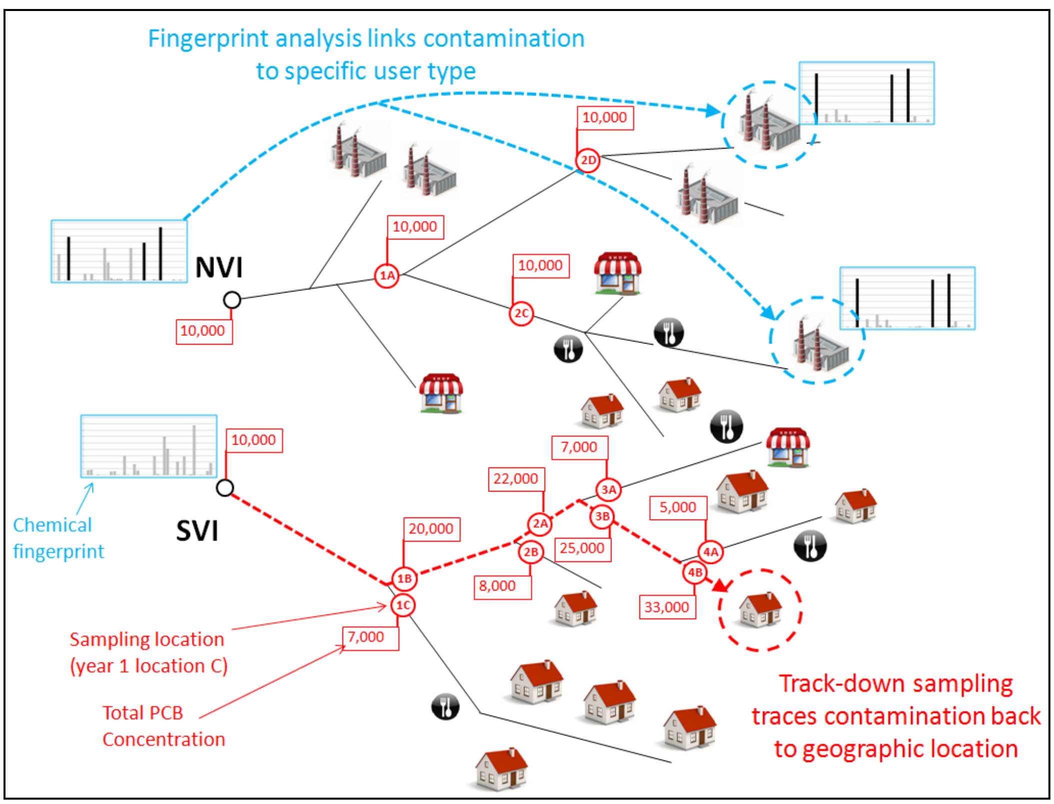

Figure 3-1. Approach to source investigation and identification

Locations, concentrations, and fingerprints on figure are conceptual and have no relation to actual data.

3.1.1.1 Track-Down Sampling

In addition to the ongoing sampling at the NVIPS and SVIPS, the County will collect samples at locations upstream in each interceptor. Each year, sampling locations will move farther upstream and investigate certain hypotheses to help identify potential sources of toxics (Figure 3-1). By tracing relative concentrations upstream and evaluating specific hypotheses related to user type or land use, the program aims to track down sources of toxic compounds and to inform public education programs.

Track-down sampling results will be evaluated during preparation of each annual report. Sampling parameters, locations, and frequency maybe adjusted based on the results.

The track-down sampling was first implemented in 2013. The 2013 sampling divided the service area into five basins. The 2013 track-down sampling focused on PCBs and PBDEs because Dioxin had been detected in only one influent sample since October 2012.

In 2014, track-down sampling was focused on PCBs in the DMI basin. PBDE track-down sampling was completed in 2013, as the PMF analysis accounted for nearly 100 percent of the mass. Section 3.2.2 describes the proposed 2015 track-down sampling.

At this time, the County envisions that 2015 track-down sampling will focus on PCBs in the NVI basin, as discussed in Section 3.3 below.

3.1.1.2 Chemical Fingerprinting and Positive Matrix Factorization

PCBs and PBDEs are groups of chemicals comprising hundreds of individual congeners. By comparing the relative concentrations of congeners in samples against legacy products and other pollutant-containing products, it may be possible to identify specific sources. For example, if samples taken at the NVIPS show a consistent pattern that relates to a specific product or industry, this would allow the targeting of specific sites for further assessment. The fingerprinting analysis could potentially lead to identification of individual sources, as depicted on Figure 3-1. It could also help focus application of BMPs if, for example, the fingerprint analysis indicated that a common construction material, such as paint or caulking, was a likely source.

Chemical fingerprinting was continued for this 2015 Annual Toxics Management Report following the initial analysis in the 2014 Annual Toxics Management Report. The PMF data for PCBs suggest a combination of legacy sources (Aroclors 1016, 1242, 1248, 1252, and 1260) and PCB-11, which is associated with pigments, and is the single most abundant congener in the effluent. The PMF results for PBDEs accounted for nearly 100 percent of the mass and suggest that commercial formulations such as Bromkal are contributing PBDEs to the Facility.

3.1.2 Remediation and/or Mitigation of Individual Sources

If the track-down sampling program or chemical fingerprinting identifies potential individual sources, the County will sample wastewater discharge from the potential source area. If the focused sampling confirms that the source area wastewater PCB concentrations are substantially elevated compared to the NVIPS or SVIPS sample concentrations, the County will notify the property owner about the issue and provide guidance for the property owner to remediate or mitigate the source (depending on the nature of the source [e.g., active process, passive runoff, soil contamination etc.]). Guidance will be based on standards provided by appropriate regulatory agencies and in coordination with the SRRTTF. This may involve educating the property owner about legacy sources (e.g., products containing Aroclors manufactured before 1979), as well as current products that can contain inadvertently produced PCBs (e.g., yellow pigment). Engagement with property owners may be done under the County's Industrial Pretreatment Program and related ordinances (Spokane County Code [SCC] 8.03A) for industrial sources and/or via the County's sewer ordinance (SCC 8.03) for domestic and commercial sources.

3.1.3 Application of Best Management Practices

The County used the track-down sampling and PMF results to help refine and focus its toxic management activities proposed in this Report for upcoming work.

Spokane County's accomplishments during 2014 included public education, participation in the SRRTTF, and other activities as follows:

- Public education on toxics management: Public education is a critical component of the County's ongoing efforts to reduce toxic pollutant loadings to the Facility. The County is an active participant in the SRRTTF and is developing a targeted, regional public education program in coordination with the SRRTTF. In 2014, the County began a targeted, multimedia public outreach program for residential and commercial/industrial sewer customers. The program identifies commonly used products known to contain PCBs and informs customers about the existing health advisories, effects of PCBs on public health, and measures that they can take to reduce PCB releases to the environment. The education program also promotes proper handling and disposal practices of materials that are known to contain PCBs. Information has been disseminated via various mailings and utilities billings inserts, the Spokane County Utilities Web site, and public events at the Spokane County Water Resource Center. Product-specific information is limited but is developed and disseminated when appropriate and reliable information is available. The following specific activities were accomplished by Spokane County in the past year:
  - Hired a water resources communications specialist to implement outreach and education and to participate on the SRRTTF
  - Updated County web presence to include PCB information
  - Developed and mailed a PCB primer to all County wastewater treatment customers, both commercial/industrial and residential (about 40,000 customers)
  - Developed a PCB informational poster for display in the Water Resource Center and other venues
  - Coordinated an Open House event at the Water Resource Center, including PCB information, in November 2014
  - Coordinated a meeting with other regional municipal wastewater treatment entities to discuss coordinated and consistent outreach to commercial and pretreatment customers
  - Prepared and sent a letter to County pretreatment customers requesting individual meetings to provide PCB information
  - Presented at several area conferences regarding the results thus far of the track-down sampling and treatment efficiency
  - Provided input to the Washington Legislature regarding the Toxics Management Act
  - Provided in-kind and financial support to the local EnviroStars program, a local source control/waste minimization program aimed at businesses
  - Provided financial support for PCB monitoring and education by the SRRTTF.
- Played an active role in the SRRTTF including financial support for administrative and technical tasks
- Supported industry-wide reformulation of products that can contain elevated concentrations of PCB-11 (e.g., diarylide yellow and other pigments used in printing and textiles), as well as commercial products that contain elevated PBDE concentrations (e.g., Bromkal).
- Elimination of older, County-owned, mechanical and electrical machinery: The County removed all known PCB-containing light ballasts and transformers from County-owned facilities in 1993 and 1995. The County Facilities Department will continue to remove and dispose of the remaining PCB-

containing materials and equipment as they are encountered. These materials are profiled and disposed of during annual hazardous waste identification and disposal activities.

- Regional clearinghouse: The County continued to contribute data on observed PCB concentrations and patterns from the County's monitoring program to the SRRTTF's regional clearinghouse. The County data, in combination with data submitted by others, will increase understanding of the potential sources of PCBs in the region and help focus regional management efforts.
- Procurement policies: The County supported the SRRTTF in identifying commercial products that could contain inadvertently produced PCBs. This past year the County passed a revised procurement practices ordinance that allows for PCB testing of products and preferential purchasing of non-PCB equivalents within cost controls, similar to the City of Spokane and State of Washington. The newly passed purchasing ordinance now allows the County to minimize purchase of PCB-containing products.

3.2 Toxics Management Action Plan for 2015

This section summarizes the sampling and analysis to be conducted from April 2015 through March 2016. The purpose of proposed actions for 2015 includes continued compliance with the Permit and continued systematic analysis and track-down of toxics in subbasins of the Facility's sewersheds. Actions to be conducted prior to the next annual report include the following:

- Continued sampling of the two influent trunk lines (NVIPS and SVIPS) and the Facility effluent per the terms of the Permit
- Year 3 of track-down sampling in the NVI collection system for PCBs only
- Continued chemical fingerprinting analysis
- Conducting initial source control measures

These actions were chosen as next steps in the continued systematic analysis and track-down approach and are described further in the following sections.

3.2.1 Continued Sampling at Influent Trunk Lines and Facility Effluent

NPDES-mandated sampling of the NVIPS, SVIPS, and Facility effluent will continue per the terms of the Permit. By the publication of the April 2016 annual report, the following data will have been collected during the period of study:

- 20 samples of PCB and Dioxin data at each influent trunk line (i.e., NVIPS and SVIPS), for a total of 80 samples
- 13 samples of PCB, Dioxin, and PBDE data at the Facility effluent, for a total of 39 samples
- 13 samples of PBDE at the NVIPS and SVIPS, for a total of 26 samples
- QA/QC samples per the approved QAPP

The additional data should allow for an assessment of variability over time. Continuing fingerprinting analysis of the PCB and PBDE congener data will also be performed in order to assess similarities and differences in the PCB makeup of the wastewater in each influent trunk line. These analyses may assist with point source identification and continuing track-down analysis. They may also provide guidance with respect to application of BMPs or industrial pretreatment regulations.

3.2.2 Year 3 of Track-Down Sampling (2015)

The County evaluated the first 2 years of track-down results in order to develop its strategy for future track-down sampling. The 2013 sampling plan focused on manholes upstream of the NVIPS and SVIPS locations, NVI MH1, SVI MH1, and DMI MH1.

The following bullets summarize the findings from the 2013 track-down sampling:

- PCB concentrations were higher at the DMI track-down location (DMI MH1) than at either of the other two track-down locations (SVI MH1 or NVI MH1) or at the SVIPS.
- PCB concentrations at the NVIPS appeared higher than those observed at NVI MH1, suggesting potential PCB sources between these two locations.
- The PCB PMF results identified six factors. The PMF was able to account for about 60 percent of the mass of PCBs.
- PBDE concentrations were more varied than PCB concentrations, and the differences between sites were less notable.
- The PMF results for PBDEs suggest dispersed sources related to commercial products that are still in widespread use. The PMF was able to account for nearly 100 percent of the PBDE mass.
- Based on the 2013 results, the County focusedits 2014 track-down sampling on PCBs in the DMI basin in 2014. The following bullets summarize the findings from the 2014 track-down sampling.The PCB PMF results identified seven factors. The PMF was able to account for about 90 percent of the mass of PCBs.
- Most of the factors are strongly correlated to Aroclors and Aroclor mixtures. The exception is Factor 2, which is mainly composed of PCB-11, which is often found in yellow dyes and pigments. Factor 2 was more prevalent at NVIPS than at SVIPS.
- Upstream sampling within the DMI noted relatively high variability in PCB concentrations over time and space, but the limited number of sampling events limits the statistical relevance of the findings. None of the track-down locations registered PCB concentrations high enough to independently account for the relatively high average concentration noted at the DMI MH1 in 2013. Rather, the high concentration appears more likely the result of moderately elevated concentrations from multiple sources.
- Track-down sampling efforts aimed to differentiate PCB contamination by the age of construction within the DMI subbasins. While the lowest overall concentrations were observed in the basin most dominated by new construction, no statistically relevant trend was observed in the other basins given the limited data.

Based on the 2013 and 2014 results, year 3 track-down sampling will wrap up analysis of the DMI basin and then focus on the NVI basin. Track-down sampling will have three directives:

1. Confirm the diffuse nature of PCBs in the DMI subbasins. The 2014 sampling developed a limited dataset for the DMI subbasins. A further round of sampling in these subbasins will be completed to support the evidence that PCBs are ubiquitous at relatively low levels in the DMI subbasins.
2. Sample the NVI Lower basin—the basin located between the NVIPS and NVI MH1. In 2013, PCB concentrations were consistently higher at the NVIPS than at the upstream NVI MH1, suggesting a relatively higher contribution of PCBs between the two sampling locations. Notably, the highest PCB concentration noted to date (67,600 pg/L) was noted at NVIPS, during an event where the PCB concentration at the upstream NVI MH1 was only 16,000 pg/L.
3. An attempt to discern relationships between customer type and average PCB concentration. The NVI basin has a relatively large industrial customer component. Track-down efforts will focus on industrial and light industrial zones. The data may be compared against residential sampling in the DMI basin in 2014 to determine whether the user class may be applied as an indicator or predictor of PCB contamination in the sewage. As part of this effort, areas with multiple textile and paper industries will be investigated throughout the NVI basin (Figure 2-24).

In line with these efforts, six potential sites have been identified for track-down sampling within the NVI basin (Figure 3-2). Two of these sites are located in the NVI Lower basin (NVI L-MHA and NVI L-MHB), while the others are located in the NVI Upper basin.

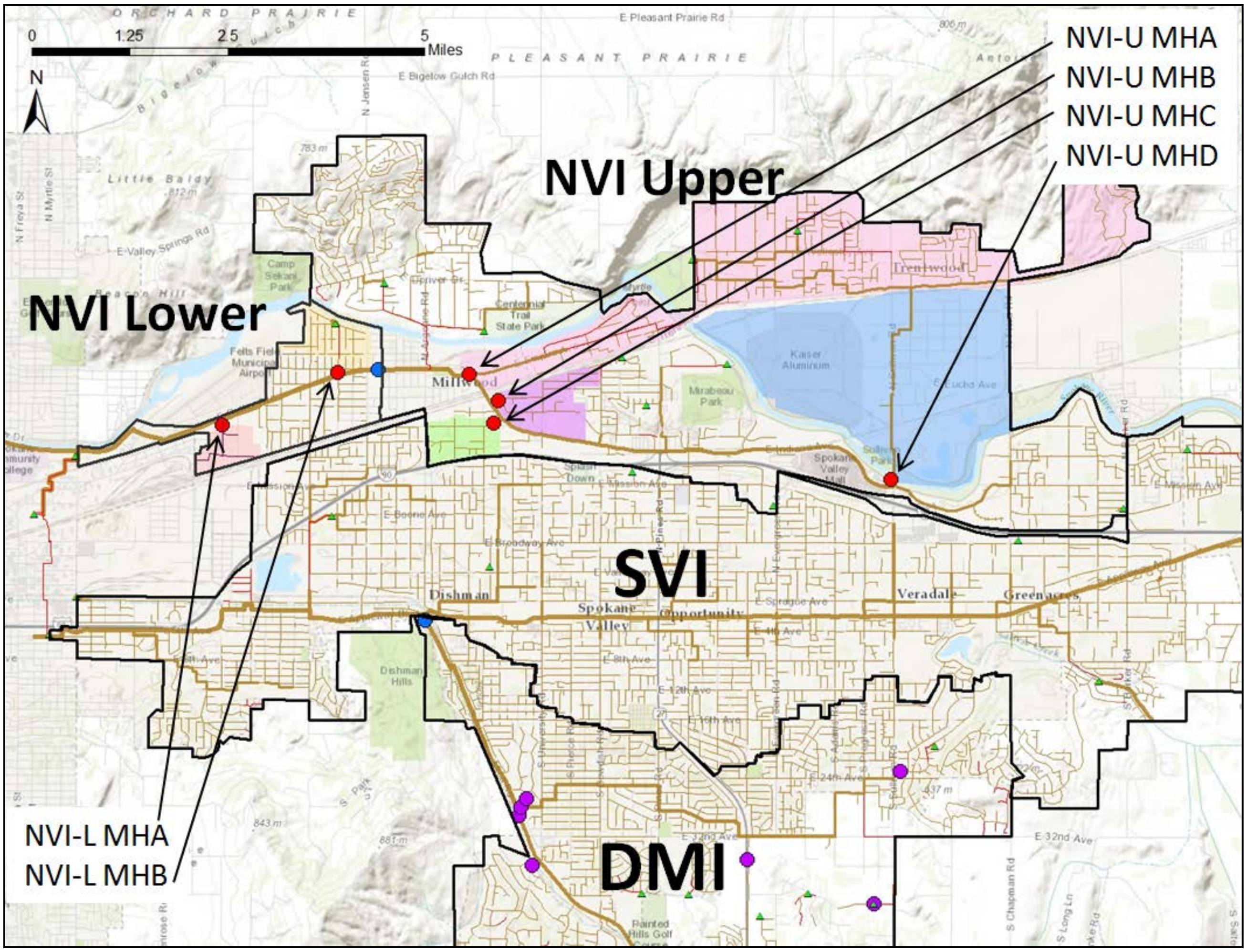

Figure 3-2. Potential sampling locations for track-down analysis for 2014

Based on field conditions, the number of sites sampled and the locations may be adjusted. The 2014 track-down sampling locations will be described in further detail in the 2015 revised QAPP. Additionally, an adaptive monitoring approach will be used based on the results from the sampling analysis to determine how many subsequent samples are taken at each proposed manhole location.

The QAPP will be amended to reflect the new track-down sampling approach. QA/QC samples will be collected in accordance with the approved QAPP. Each sample will be tested for PCBs. This sampling will allow for these upstream samples to be compared to the samples collected from the two influent trunk lines (i.e., at the NVIPS and SVIPS).

Track-down sampling will be evaluated during preparation of each annual report. Sampling locations and frequency may be adjusted based on the results.

3.2.3 Chemical Fingerprinting Analysis

Chemical fingerprinting analysis will be expanded to include the Year 3 (2015) track-down sampling locations. With each year, the database of results will increase, and the accuracy of the fingerprinting analysis will improve. With an increased number of sampling locations, the fingerprinting analysis may help to establish relationships between sources of toxics and specific locations within the collection system, and specific user characteristics.

3.2.4 Source Control Measures

The County will continue to apply the BMPs summarized in Section 3.1.3. These actions include active participation in the SRRTTF, development of a targeted public education program, ongoing removal of PCB-containing equipment and machinery, and revision of County procurement practices. Depending upon the results of chemical fingerprinting and track-down analysis, initial source control measures may extend to individual source remediation and/or mitigation, if individual sources are identified.

The County plans to expand its public education program. Planned education activities for 2015 include:

- Spring and fall open houses at the Water Resource Center
- Increase collaboration with non-dischargers to disseminate toxics management information (e.g., Spokane Riverkeeper)Provide updates as warranted to wastewater treatment customers regarding new and useful PCB information that can provide consumer guidance
- Updates to PCB information on the County website
- Meet with pretreatment customers to review latest information on PCBs
- Presentations at area conferences and to citizen groups
- Provide input to the Legislature regarding impending legislation regarding PCBs
- Continue in-kind and financial support to the local EnviroStars program

Additionally, Spokane County plans to:

- Support industry-wide reformulation of products that can contain elevated concentrations of PCB-11 as well as commercial products that contain elevated PBDE concentrations (e.g., Bromkal)
- Continue to contribute data on PCB concentrations and sources to the SRRTTF's regional clearinghouse to help increase understanding of the potential sources and to help regional management efforts
- Continue to play an active role in the SRRTTF including financial support for administrative and technical tasks
- Continue to support the SRRTTF in identifying commercial products that could contain inadvertently produced PCBs
- Continue to review the County wastewater customer database in light of the ongoing chemical fingerprinting analysis, and perform follow-up actions as appropriate.

3.3 Toxics Management Action Plan for 2016

In March and April 2016, the County will evaluate the results of the NVIPS and SVIPS sampling and track-down sampling conducted during 2015. The evaluation will look for differences in PCB concentrations related to land use and year of construction to discern potential sources. Chemical fingerprinting analyses will continue and expand to identify the types of products that could account for the observed PCB patterns. The analytical data and evaluation of potential sources will be presented in the April 2016 Annual Toxics Management Report.

At this time, it is envisioned that the 2016 track-down sampling will focus on the SVI sewersheds.

The April 2016 Toxics Management Action Plan will describe the proposed track-down sampling, source investigations, and focused control measures to be implemented in 2016 (if sources are identified). The County will update the QAPP as needed to guide the track-down sampling and source investigations.

The April 2016 Toxics Management Action Plan will also update the County's proposed BMPs for reducing use of products that could contain PCBs. The County will work with the SRRTTF to refine these BMPs and develop new BMPs based on the lessons learned during 2015.

3.4 Annual Toxics Management Report for 2016

The County will prepare the April 2016 Annual Toxics Management Report to summarize the County's toxic source control program, actions completed, BMPs implemented, and source identification results. In addition, the 2016 document will include a summary of all of the toxics sampling and laboratory results completed by the County under the current NPDES Permit.

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Section 4

References

Agency for Toxic Substances and Disease Registry (ATSDR). 2000. Toxicological Profile for Polychlorinated Biphenyls (PCBs). U.S. Department of Health and Human Services, Public Health Service, Atlanta, Ga.

Anezaki, K. and Nakano, T. 2014. Concentration levels and congener profiles of polychlorinated biphenyls, pentachlorobenzene, and hexachlorobenzene in commercial pigments. *Environmental Science and Pollution Research 21* (2), 998–1009.

Belton, T., J. Botts, L. Lippincott, and E. Stevenson. 2007. An Industrial Ecology Approach to PCB Source Trackdown in Camden City, New Jersey. Pages 61–96 in "Optimizing Contaminant Trackdown: Focusing on Wastewater Treatment Plants and Related Systems – A Compendium for Practitioners of Contaminant Trackdown Efforts," New York Academy of Sciences.

Bzdusek, P., Christensen, E., Lee, C., Pakdeesusuk, U., and Freedman, D. 2006a. PCB Congeners and Dechlorination in Sediments of Lake Hartwell, South Carolina, Determined from Cores Collected in 1987 and 1998. *Environ. Sci. Technol. 40*, 109–119.

Bzdusek, P.A., Lu, J., Christensen, E.R., 2006b. PCB Congeners and Dechlorination in Sediment of Sheboygan River, Wisconsin, Determined by Matrix Factorization. Environ. Sci. Technol. 40, 120–129.

Ding, C., Chow, W. L., and He, J. Z. 2013. Isolation of Acetobacterium sp Strain AG, Which Reductively Debrominates Octa- and Pentabrominated Diphenyl Ether Technical Mixtures. *Appl Environ Microbiol 79*, (4), 1110–1117.

Du, S., Belton, T., and Rodenburg, L. 2008. Source Apportionment of PCBs in the Tidal Delaware River. *Environ. Sci. Technol.* 42: 4044–4051.

Du, S., Rodenburg, L.A., 2007. Source Identification of Atmospheric PCBs in Philadelphia/Camden Using Positive Matrix Factorization Followed by the Potential Source Contribution Function. Atmospheric Environment 41, 8596–8608.

Ecology, 2012. Liberty Lake Source Trace Study Regarding PCB, PBDE, Metals and Dioxin/Furan. Washington State Department of Ecology Publication No. 10-04-027. 2010, revised 2012.

Ecology. 2006. Polybrominated Diphenyl Ether (PBDE) Chemical Action Plan: Final Plan. Washington State.

Fang, L., Huang, J., Yu, G., and Wang, L. 2008. Photochemical degradation of six polybrominated diphenyl ether congeners under ultraviolet irradiation in hexane. *Chemosphere* 71 (2): 258–267.

Fernandez, Arianne. 2012. Liberty Lake Source Trace Study Regarding PCB, PBDE, Metals, and Dioxin/Furan: A Pilot Project for Spokane Basin Source Tracing. *Ecology* Publication No. 10-04-027.

Franz, T.P. and Eisenreich, S.J., 1993. Wet deposition of polychlorinated biphenyls to Green Bay, Lake Michigan. *Chemosphere* 26(10): 1767–1788.

Gregor, D.J. and Gummer, W.D., 1989. Evidence of atmospheric transport and deposition of organochlorine pesticides and polychlorinated biphenyls in Canadian Arctic snow. Environ. Sci. Technol., 23(5): 561–565.

Hansen, B.G., Paya-Perez, A.B., Rahman, M., Larsen, B.R., 1999. QSARs for KOW and KOC of PCB congeners: A critical examination of data, assumptions and statistical approaches. Chemosphere 39, 2209–2228.

Harrad, S., Y. Wang, S. Sandaradura, and A. Leeds, 2003. Human dietary intake and excretion of dioxin-like compounds. J. Environmental Monitoring 5(2): 224–228.

Herrick, R.F., McClean, M.D., Meeker, J.D., Baxter, L.K., Waymouth, G.A., 2004. An unrecognized source of PCB contamination in schools and other buildings. Envir. Heal. Persp. 112, 1051–1053.

Juan, C.Y., G.O. Thomas, A.J. Sweetman, and K.C. Jones. 2002. An input-output balance study for PCBs in humans. *Envron. Int.* 28(3): 203–214.

La Guardia, M., Hale, R., and Harvey, E. **2007.** Evidence of debromination of decabromodiphenyl ether (BDE-209) in biota from a wastewater receiving stream. *Environ. Sci. Technol. 41* (19): 6663–6670.

La Guardia, M., Hale, R., and Harvey, E. **2006**. Detailed polybrominated diphenyl ether (PBDE) congener composition of the widely used penta-, octa-, and deca-PBDE technical flame-retardant mixtures. *Environ. Sci. Technol. 40* (20): 6247–6254.

Lee, L., Ding, C., Yang, K., and He, J. **2011**. Complete Debromination of Tetra- and Penta-Brominated Diphenyl Ethers by a Coculture Consisting of Dehalococcoides and Desulfovibrio Species. *Environ. Sci. Technol*. 45 (19): 8475–8482.

Litten, S., Fowler, B., and Luszniak, D. **2002**. Identification of a novel PCB source through analysis of 209 PCB congeners by US EPA modified method 1668. *Chemosphere 46*: 1457–1459.

Los Alamos National Laboratory, **2012**. Polychlorinated Biphenyls in Precipitation and Stormwater within the Upper Rio Grande Watershed. *LA-UR-12-1081*, Los Alamos, N.M.

Lubliner, Brandi, **2009**. Palouse River Watershed PCB and Dieldrin Monitoring, 2007-2008. Washington State Department of Ecology Publication No. 09-03-004.

Munoz, G. **2007**. Processes that Inadvertently Produce PCBs. Pages 208–233 in "Optimizing Contaminant Trackdown: Focusing on Wastewater Treatment Plants and Related Systems—A Compendium for Practitioners of Contaminant Trackdown Efforts," New York Academy of Sciences.

Nagpal, N.K., Ph.D. **1992.** Water Quality Criteria for Polychlorinated Biphenyls. Ministry of Environment, Lands, and Parks, Province of British of Columbia. http://wlapwww.gov.bc.ca/wat/wq/BCguidelines/pcbs/index.html

New Jersey Department of Environmental Protection, **2009**. Atmospheric Deposition: PCBs, PAHs, Organochlorine Pesticides, and Heavy Metals. *Environmental Trends Report*, NJDEP Office of Science.

Offenberg, J.H. and Baker, J.E., **1997**. Polychlorinated Biphenyls in Chicago Precipitation: Enhanced Wet Deposition to Near-Shore Lake Michigan. *Environ. Sci. Technol.* 31(5): 1534–1538.

Paatero, P. and Tapper, U. **1994**. Positive Matrix Factorization: a Non-negative Factor Model with Optimal Utilization of Error Estimates of Data Values. *Environmetrics 5*, 111–126.

Qiu, M., Chen, X., Deng, D., Guo, J., Sun, G., Mai, B., and Xu, M. **2012**. Effects of electron donors on anaerobic microbial debromination of polybrominated diphenyl ethers (PBDEs). *Biodegradation* 23, (3), 351–361.

Robrock, K., Korytar, P., and Alvarez-Cohen, L. **2008**. Pathways for the anaerobic microbial debromination of polybrominated diphenyl ethers. *Environ. Sci. Technol.* 42 (8): 2845–2852.

Rodenburg, L., Du, S., Lui, H., Guo, J., Oseagulu, N., and Fennell, D. **2012a.** Evidence for Dechlorination of Polychlorinated Biphenyls and Polychlorinated Dibenzo-p-Dioxins and -Furans in Wastewater Collection Systems in the New York Metropolitan Area. *Environ. Sci. Technol.46*: 6612–6620.

Rodenburg, **2012b**. Inadvertent PCB Production and Its Impact on Water Quality. PowerPoint presentation. Spokane River Regional Toxics Task Force.

Rodenburg, L., Du, S., Xiao, B., and Fennell, D. **2011**. Source Apportionment of Polychlorinated Biphenyls in the New York/New Jersey Harbor. Chemosphere 83, 792–798.

Rodenburg, L., Du, S., Fennell, D., and Cavallo, G. **2010a**. Evidence for Widespread Dechlorination of Polychlorinated Biphenyls in Groundwater, Landfills, and Wastewater Collection Systems. *Environ. Sci. Technol. 44*, 7534–7540.

Rodenburg, L. A.; Guo, J.; Du, S.; Cavallo, G. J. **2010b**. Evidence for Unique and Ubiquitous Environmental Sources of 3,3'-dichlorobiphenyl (PCB 11). *Environ. Sci. Technol. 44*, 2816–2821.

Rodenburg, L., Fennell, D., Du, S., and Xiao, B. **2008**. Source apportionment of organic contaminants in the NY/NJ Harbor Estuary; Final Report to the Hudson River Foundation, Grant # 010/05A: New York, N.Y.

Rushneck, D., Beliveau, A., Fowler, B., Hamilton, C., Hoover, D., Kaye, K., Berg, M., Smith, T., Telliard, W., Roman, H., Ruder, E., and Ryan, L. **2004**. Concentrations of dioxin-like PCB congeners in unweathered Aroclors by HRGC/HRMS using EPA Method 1668A. *Chemosphere* 54, 79–87.

Sanchez-Prado, L., Kalafata, K., Risticevic, S., Pawliszyn, J., Lores, M., Llompart, M., Kalogerakis, N., and Psillakis, E. 2012. Ice photolysis of 2,2 ',4,4 ',6-pentabromodiphenyl ether (BDE-100): Laboratory investigations using solid phase microextraction. *Analytica Chimica Acta* 742: 90–96.

Sanchez-Prado, L., Lores, M., Llompart, M., Garcia-Jares, C., Bayona, J., and Cela, R., 2006. Natural sunlight and sun simulator photolysis studies of tetra- to hexa-brominated diphenyl ethers in water using solid-phase microextraction. *Journal of Chromatography A 1124*: 157–166.

Spokane, City of, 2014. City of Spokane Quality Assurance Project Plan (QAPP) for NPDES Permit Required Study of PCBs, PBDEs, and 2,3,7,8 TCDD.. City of Spokane Wastewater Management Department.

Tokarz, J., Ahn, M., Leng, J., Filley, T., and Nies, L. 2008. Reductive debromination of polybrominated diphenyl ethers in anaerobic sediment and a biomimetic system. *Environ. Sci. Technol. 42* (4): 1157–1164.

Wei, H., Zou, Y., Li, A., Christensen, E., and Rockne, K. 2013. Photolytic debromination pathway of polybrominated diphenyl ethers in hexane by sunlight. *Environ. Pollut 174*: 194–200.

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Appendix A: Quality Control Comment/Action Records

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Quality Control
Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Polychlorinated Biphenyl (PCB)
Laboratory report checked by: Valerie Fuchs

Batch Date: 3/14/2014
Batch ID: WG46535
Check Date: 4/14/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Quality Control

Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Polychlorinated Biphenyl (PCB)
Laboratory report checked by: Valerie Fuchs

Batch Date: 5/21/2014
Batch ID: WG47248
Check Date: 5/28/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
Revised 21-May-14: 1. Revised the EDD to include omitted Homologue Totals and TEQ data. Please discard previously submitted data and accept this data as final. 2. Data are considered final. 3. Data are not blank corrected.	No action necessary.
4. A disturbance of the mass ion used to monitor instrument performance (lock-mass) greater than method specifications was observed in sample 'SVIPS PCB' (AXYS ID:L21382-7) near the retention time corresponding to PCB 197/200 and in the Laboratory Blank (AXYS ID: WG47248-102) near the retention time corresponding to PCB 2 and these targets have been flagged with a 'G'. PCB 197/200 and PCB 2 are not major contributors to the total concentration of PCB in these samples, respectively, and data are not considered significantly affected.	None of the G-flagged data account for more than 2% percent of the total PCB concentration reported for the respective sample. The data are accepted, but G flags will be retained for future reference.

Quality Control
Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services — Batch Date: 7/24/2014
Laboratory analysis type: Polychlorinated Biphenyl (PCB) — Batch ID: WG47904
Laboratory report checked by: Valerie Fuchs — Check Date: 8/6/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

The total concentrations of the duplicate (split) sample were within 12% of each other, meeting the QAPP requirement of equal to or less than 50% relative percent difference.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	No action necessary.
3. The recovery of different 13C-labelled PCB congeners in different samples did not meet the method criteria; these compounds are flagged with a 'V'. As the isotope dilution method of quantification produces data that are recovery corrected, the slight variances from the method acceptance criteria are deemed not to affect the quantification of the analytes.	TBD. SVIPS and the Lab Blank both had 77% passing; all other samples were greater than 95%. The spiked matrix had 87% passing. All of the V-flagged congeners were below the 25% recovery acceptance limit. Most were between 20-25%. Congeners with recovery less than 20% are as follows: for the lab blank 104L was 18% and 155L was 16.3%. For DMI-MHA, 155L was 18.2% and 209L was 18.5%. The data are accepted, but V flags will be retained.

Quality Control
Comment/Action Record

CLIENT:	County of Spokane, WA
PROJECT NAME:	Spokane County PCB Study
PROJECT NUMBER:	142892

Laboratory report prepared by: AXYS Analytical Services — Batch Date: 9/24/2014
Laboratory analysis type: Polychlorinated Biphenyl (PCB) — Batch ID: WG48374
Laboratory report checked by: Valerie Fuchs — Check Date: 9/29/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.
3. A disturbance of the mass ion used to monitor instrument performance (lock-mass) greater than method specifications was observed in samples near the retention time corresponding to some targets and quantification standards and have been flagged with a 'G'.	21 congeners from 5 samples (SVIPS, NVIPS, DMI-MHE, DMI-MHF, DMI-MHG) are flagged with a 'G'. The total mass of G-flagged congeners is less than 5% of the total sample mass for all samples. The data are accepted, but G flags will be retained.

Quality Control

Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Polychlorinated Biphenyl (PCB)
Laboratory report checked by: Valerie Fuchs

Batch Date: 11/20/2014
Batch ID: WG49261
Check Date: 11/25/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Additional comment: The effluent rinsate blank did not meet QA/QC requirements and the backup was analyzed in December 2014. Data for the effluent rinsate backup was included in the December 2014 laboratory report.

Brown AND Caldwell

Quality Control
Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Polychlorinated Biphenyl (PCB)
Laboratory report checked by: Valerie Fuchs

Batch Date: 1/09/2015
Batch ID: WG49800
Check Date: 1/22/2015

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

The total concentrations of the duplicate (split) sample were within 17% of each other, meeting the QAPP requirement of equal to or less than 50% relative percent difference.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final 2. Data are not blank corrected.	None.
3. Relative Retention Times (RRTs) corresponding to PCB 170 in sample Travel Blank PCB (AXYS ID L22546-1), PCB 123 in sample NVIPS PCB (AXYS ID L22546-3), PCB131, 132, 133, 134/143, 139/140, 144,145,147/149 and 148 for sample SVIPS PCB (AXYS ID: L21314-4) are outside the RRT QC limits provided in Form 4A for the short-list calibration verification and Form 3A for the long-list calibration (data filename: PB5C_005 S: 1 for both forms). These compounds were determined to be present by visual inspection and comparing to the calibration chromatogram pattern. Data are not considered affected.	Concentrations of affected congeners are relatively low; RRT is not considered to be significant.

Quality Control
Comment/Action Record

CLIENT:	County of Spokane, WA
PROJECT NAME:	Spokane County PCB Study
PROJECT NUMBER:	142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Dioxin/Furan
Laboratory report checked by: Valerie Fuchs

Batch Date: 3/13/2014
Batch ID: WG46537
Check Date: 3/26/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.
3. The recovery of 13C-labeled-2,3,7,8-TCDD in sample Travel Blank TCDD (AXYS ID L21009-2) is slightly outside the method acceptance criteria; this compound has been flagged with a 'V'. As the isotope dilution method of quantification produces data that are recovery corrected, the slight variances from the method acceptance criteria are deemed not to affect the quantification of these analytes. Percent surrogate recoveries are used as general method performance indicator only.	Recovery of 13C-labeled-2,3,7,8-TCDD was 36% (target 35%); does not appear to be outside of acceptance criteria. This congener is not flagged in the data file. 37CL-labeled-2,3,7,8-TCDD is flagged with V but also does not appear to be outside of acceptance criteria. The data are accepted but V flags are retained.

Quality Control
Comment/Action Record

CLIENT:	County of Spokane, WA
PROJECT NAME:	Spokane County PCB Study
PROJECT NUMBER:	142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Dioxin/Furan
Laboratory report checked by: Valerie Fuchs

Batch Date: 5/20/2014
Batch ID: WG47244
Check Date: 5/28/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Quality Control
Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Dioxin/Furan
Laboratory report checked by: Valerie Fuchs

Batch Date: 7/15/2014
Batch ID: WG47905
Check Date: 8/7/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Brown AND Caldwell

Quality Control

Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Dioxin/Furan
Laboratory report checked by: Valerie Fuchs

Batch Date: 10/30/2014
Batch ID: WG48981
Check Date: 12/19/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Additional comment: On September 24, 2014, AXYS notified BC that the TCDD samples did not pass AXYS QA/QC requirements, and recommended analyzing the backup. The data provided in the 2015 Annual Toxics Management Report is for the TCDD backup samples.

Quality Control
Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Dioxin/Furan
Laboratory report checked by: Valerie Fuchs

Batch Date: 11/19/2014
Batch ID: WG49184
Check Date: 11/25/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Brown AND Caldwell

Quality Control
Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services
Laboratory analysis type: Dioxin/Furan
Laboratory report checked by: Valerie Fuchs

Batch Date: 1/07/17
Batch ID: WG49801
Check Date: 1/22/2015

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data and data quality checks met the requirements of the QAPP.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Quality Control
Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services — Batch Date: 3/05/2014
Laboratory analysis type: Polybrominated Diphenylether (PBDE) — Batch ID: WG46538
Laboratory report checked by: Valerie Fuchs — Check Date: 4/14/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data were deemed usable for the intended purposes of this study.

The total concentrations of the duplicate (split) sample were within 16% of each other, meeting the QAPP requirement of equal to or less than 50% relative percent difference.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Quality Control

Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services — Batch Date: 5/20/2014
Laboratory analysis type: Polybrominated Diphenylether (PBDE) — Batch ID: WG47245
Laboratory report checked by: Valerie Fuchs — Check Date: 5/28/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data were deemed usable for the intended purposes of this study.

The total concentrations of the duplicate (split) sample were within 5% of each other, meeting the QAPP requirement of equal to or less than 50% relative percent difference.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Quality Control
Comment/Action Record

CLIENT: County of Spokane, WA
PROJECT NAME: Spokane County PCB Study
PROJECT NUMBER: 142892

Laboratory report prepared by: AXYS Analytical Services — Batch Date: 9/22/2014
Laboratory analysis type: Polybrominated Diphenylether (PBDE) — Batch ID: WG48416
Laboratory report checked by: Valerie Fuchs — Check Date: 9/29/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data were deemed usable for the intended purposes of this study.

The total concentrations of the duplicate (split) sample were within 5% of each other, meeting the QAPP requirement of equal to or less than 50% relative percent difference.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected. Data are not blank corrected. Sample data should be evaluated with consideration of analyte levels in the Lab Blank (AXYS ID WG48416-101).	None.

Quality Control

Comment/Action Record

CLIENT:	County of Spokane, WA
PROJECT NAME:	Spokane County PCB Study
PROJECT NUMBER:	142892

Laboratory report prepared by: AXYS Analytical Services | Batch Date: 11/22/2014
Laboratory analysis type: Polybrominated Diphenylether (PBDE) | Batch ID: WG49260
Laboratory report checked by: Valerie Fuchs | Check Date: 12/05/2014

DESCRIPTION:
QA/QC was performed on the AXYS laboratory data based on the measurement quality objectives detailed in the QAPP. All data were deemed usable for the intended purposes of this study.

The total concentrations of the duplicate (split) sample were within 5% of each other, meeting the QAPP requirement of equal to or less than 50% relative percent difference.

Laboratory check/spiked samples were within the percent recovery range required in the QAPP.

ADDITIONAL REMARKS / COMMENTS:

AXYS Comments	BC Response
1. Data are considered final. 2. Data are not blank corrected.	None.

Appendix B: Laboratory Results from AXYS and Anatek

Submitted electronically

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Draft response to downstream waters comments

Comments paraphrased:

Comments from tribes, enviro groups, public: The new HHC will not protect the consumption uses of downstream tribal waters, usual and accustomed waters, and waters shared with other states.

Comments from EPA: explain how narrative provision protects downstream waters - provide rationale detailing how use of a narrative downstream protection criterion alone will protect Oregon's more stringent water quality standards.

Also from EPA:

> *"...most of Washington's rivers are in the Columbia River basin and are, therefore, upstream of Oregon's portion of the Columbia River. In addition, the Columbia River creates most ofthe Washington-Oregon border. Since approximately 90% ofWA's proposed human health criteria are higher than Oregon's EPA-approved criteria for the same pollutants, the EPA strongly encourages Ecology to consider adopting numeric criteria (either in addition to or instead of narrative criteria) that ensure the attainment and maintenance of Oregon's downstream WQS, or to provide additional rationale detailing how the use of a narrative downstream protection criterion alone will protect Oregon's more stringent WQS. For waters flowing into Oregon, criteria that are equally stringent or more stringent than Oregon's human health criteria would better ensure the attainment and maintenance of Oregon's downstream WQS consistent with 40 CFR 131.10(b). This aligns with the EPA's previous statements regarding a desire for regional consistency in human health criteria among Region 10 states."*

RESPONSE STARTS BELOW

Responses to comments on protection of downstream waters are addressed in the discussion below:

What are the requirements on downstream waters protection that are in the federal water quality standards regulation (40CFR131)?

The federal regulations specify how states are to address downstream waters in development of state water quality standards. These two requirements are found in 40 CFR 131.10 as follows:

> *"Subpart B—Establishment of Water Quality Standards*
> *§ 131.10 Designation of uses.*
> *(b) In designating uses of a water body and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters."*

These requirements are broken out as:

- ...the State shall take into consideration the water quality standards of downstream waters
- ...the State... shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.

These two specific requirements of states are addressed more fully below.

Has Ecology fulfilled the federal requirements? Yes, as explained in 1 and 2 below.

1. ...the State shall take into consideration the water quality standards of downstream waters

Washington formally took into consideration the water quality standards of downstream waters by (1) placing language requiring protection of downstream waters in the draft rule and (2) by considering all public comments that were received during the public comment period, regarding downstream waters protection, as the final rule was developed.

2. ...the State... shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.

Rule narrative language in WAC 173-201A ensures that Washington's water quality standards provide for attainment and maintenance of the water quality standards of downstream waters as follows (relevant section in boldface):

Washington water quality standard from WAC 173-201A-260 that provides for attainment and maintenance of the water quality standards of downstream waters	What does this language mean?
New language: WAC 173-201A-240 Toxic substances. (b) Human health protection. The following provisions *apply to the human health criteria in Table 240. All waters shall maintain a level of water quality when entering downstream waters that provides for the attainment and maintenance of the water quality standards of those downstream waters, including the waters of another state.*	This language explicitly requires upstream water quality to provide for attainment and maintenance of downstream water quality standards. This language was taken from EPA's *Templates for Narrative Downstream Protection Criteria in State Water Quality Standards* (EPA 2014, 820-F-14-002) at http://water.epa.gov/scitech/swguidance/standards/narrative.cfm .
WAC 173-201A-260 Natural conditions and other water quality criteria and applications. (3) Procedures for applying water quality criteria. *In applying the appropriate water quality*	This language allows for case-by-case establishment of additional requirements to fully support designated and existing uses.

criteria for a water body, the department will use the following procedure: *(a) The department will establish water quality requirements for water bodies, in addition* *to those specifically listed in this chapter, on a case-specific basis where determined* *necessary to provide full support for designated and existing uses.*	
WAC 173-201A-260 Natural conditions and other water quality criteria and applications. (3) Procedures for applying water quality criteria. *In applying the appropriate water quality* *criteria for a water body, the department will use the following procedure:* *(b) Upstream actions must be conducted in manners that meet downstream water body* *criteria....*	This language directs that upstream actions (such as discharges into waters) must be conducted in a manner to meet downstream criteria.

Does Ecology's approach align with federal guidance and federal precedent?

Federal Guidance: Ecology did not follow the approach to downstream waters protection that is the focus of the EPA 2014 guidance FAQ. The language in EPA's downstream guidance FAQ, which is not a rule and is thus not binding on states, addresses the uses and criteria sections of the water quality standards (and acknowledges the antidegradation section), but does not mention or take into account the General Provisions portions of the standards, described in EPA's Water Quality Standards Handbook (Chapter 1: General Provisions (40 CFR 131.1-131.6; http://water.epa.gov/scitech/swguidance/standards/handbook/chapter01.cfm) as follows:

> *"WQS consist of the following elements:*
>
> - *Designated use or uses such as "supporting aquatic life" or "recreation" (which are described in Chapter 2 of this Handbook).*
> - *Water quality criteria necessary to protect the designated uses (which are described in Chapter 3 of this Handbook).*
> - *Antidegradation requirements (which are described in Chapter 4 of this Handbook).*
> - *General policies affecting the application and implementation of WQS that states and authorized tribes may include at their discretion (e.g., mixing zone, variance, and critical low-flow policies, which are described in Chapter 5 of this Handbook)."*

The downstream waters protection approach that is used in the Washington standards (language in table above) is best described by language developed by EPA (2004; http://water.epa.gov/scitech/swguidance/standards/upload/Sierra-Club-Petition-Response-signed-2004-06-25.pdf) in its decision on how to address a settlement agreement petition: *"Decision on petition for rulemaking to publish water quality standards for the Mississippi and Missouri Rivers within Arkansas, Illinois,* *Iowa, Kansas, Kentucky, Missouri, Nebraska and Tennessee."* The language from that document addresses a situation where, because of issues surrounding downstream waters protection, EPA was petitioned by the Ozark Chapter of the Sierra Club to *"publish water quality standards for the Mississippi and Missouri Rivers within the petition area states. Such standards should be: 1) Consistent among the states on each river, such that no state impairs the ability of any other affected state (whether across-stream or downstream) to achieve its water quality standards; and..."* (EPA 2014).

EPA's response to that petition includes:

> *Protection of Downstream Uses*
> *The federal regulations state, "In designating uses of a water body and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters." 40 C.F.R. §131.10(b).* ***The regulations do not compel states to adopt the same criteria and uses, nor do they suggest that this is the only way a state can meet these requirements. The water quality program is structured to provide states with flexibility to determine the best way to meet their obligations under § 131.10(b).***
>
> *Under the NPDES permitting regulations, no permit may be issued "when the imposition of conditions cannot ensure compliance with applicable water quality requirements of all affected States[.]" 40 C.F.R. §122.4(d). To obtain approval of a state NPDES program, the CWA requires the state to have the authority to notify other affected states of applications for permits and provide an opportunity for a hearing. CWA section 402(b)(3). Further, the state must allow any state whose waters may be affected by the discharge to submit recommendations. If the permitting state rejects the recommendations, it must notify the affected state and EPA Administrator. CWA section 402(b)(5). Where EPA determines the permitting state rejected the recommendations for inadequate reasons, EPA may exercise its discretionary authority to object to the permit. If the objection is not resolved, EPA may issue a federal permit. 40 C.F.R. §123.44(c)(2).*
> *(Page 4, EPA 2004)*

In this response EPA states that the federal regulations do not compel states to adopt the same criteria and uses, or even suggest that this is the only way a state can meet the requirements to protect downstream waters, and that the federal water quality program is structured to provide states with flexibility to determine the best way to meet their obligations under § 131.10(b). The Washington water quality standards contain the combination of a direct statement on downstream protection (new proposed language), an allowance for additional requirements, and requirements for upstream actions implemented under various CWA permitting programs.

What about the general comment that water quality standards upstream should be as stringent as the downstream standards in order to protect downstream uses, especially with regard to the risk levels used in criteria calculations?

This is best responded to by language developed by EPA (2004; http://water.epa.gov/scitech/swguidance/standards/upload/Sierra-Club-Petition-Response-signed-2004-06-25.pdf) in its decision on how to address a settlement agreement petition: *"Decision on petition for rulemaking to publish water quality standards for the Mississippi and Missouri Rivers within Arkansas, Illinois, Iowa, Kansas, Kentucky, Missouri, Nebraska and Tennessee."* The language from that document addresses a situation where, because of issues surrounding downstream waters protection, EPA was petitioned by the Ozark Chapter of the Sierra Club to *"publish water quality standards for the Mississippi and Missouri Rivers within the petition area states. Such standards should be: 1) Consistent among the states on each river, such that no state impairs the ability of any other affected state (whether across-stream or downstream) to achieve its water quality standards; and..."* (EPA 2014).

The states along the Mississippi River have differing risk levels (PCB example given):

> *"EPA acknowledges there are variations in the numeric PCB criteria adopted by the petition states. There are four legitimate reasons why the numeric PCB criteria vary within the petition area:...*
>
> *...(3) As discussed in the "Statutory and Regulatory Background" section, EPA publishes section 304(a) criteria based on a 10–6 risk level for carcinogens; states may select a specific risk level based on their own risk management decisions. EPA believes that adoption of criteria within a risk level of 10–6 (one in a million incremental risk for cancer) or 10–5 (one in one hundred thousand incremental risk for cancer) represents an acceptable range of risk management discretion for states and tribes.[24] Within the petition states, each state adopts criteria to protect human health based on risk management decisions. Iowa, Arkansas, Tennessee, and Nebraska have adopted PCB criteria based on a 10-5 risk level; Illinois, Kentucky and Missouri have adopted PCB criteria based on a 10-6 risk level; and Kansas chose to adopt a PCB criterion to protect human health at a 10-7 risk level.*
>
> *[24] U.S. Environmental Protection Agency. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Office of Water. Washington, D.C. EPA-822-B-00-004. <http://www.epa.gov/waterscience/humanhealth/method> October 2000."*
>
> *(Pages 17-18, EPA 2004)*

The human health criteria differed among states for a number of valid reasons, among them the differing risk levels. EPA language for PCBs is below:

> *"As discussed above, Iowa and Missouri adopted a numeric PCB criterion to protect human health based on the toxicity information available in IRIS that was updated in 1989. With regard to the Sierra Club's specific concern about Iowa's PCB criterion as compared to Missouri's criterion, EPA found that Iowa's criterion is an order of magnitude greater than Missouri's because Iowa has chosen to protect human health at a 10-5 risk level while Missouri protects human health at a 10-6 risk level. With regard to the Sierra Club's specific concern about Nebraska's PCB criterion as compared to Missouri, EPA found that Nebraska adopted a numeric PCB criterion to protect human health based on EPA's section 304(a) criteria recommendations published in 1999 (Missouri used the updated 1999 IRIS data), but chose a 10-5 risk level. As a result, Nebraska's PCB criterion is greater than Missouri's criterion."*
>
> *(Page 18, EPA 2004)*

These differences in criteria were not found to be cause for EPA to promulgate consistent criteria across the states:

"...the regulations do not compel states to adopt the same criteria and uses in order to provide for attainment and maintenance of downstream water quality standards (40 C.F.R. §131.10(b)), nor do the regulations suggest that this is the only way a state can meet the requirements under § 131.10(b). The water quality program is structured to provide states with flexibility to determine the best way to protect their designated uses and meet their obligations under § 131.10(b)."

(Page 19, EPA 2004)

How does Ecology protect downstream uses as it implements the water quality standards?

Ecology implements the standards in its permitting and certification processes, as well as in its Water Clean-up (Total Maximum Daily Load) program. The requirements for downstream protection (as per WAC 173-201A-260) apply to all criteria, including toxic and conventional pollutants. An example for each are below.

Example 1 – NPDES permit – Human health criteria pollutants (XXX Have Vince fill in table)	
NPDES permit reissuance	Weyerhaeuser permit and number and date
Receiving water (shared with Oregon)	Columbia River
Human health criteria pollutants found in discharge	PCBs
Reasonable potential determination	
Effluent limits	
Verification that Oregon standards would be met	

Example 2 – TMDL – conventional pollutants (nutrients)	
TMDL	*Spokane River and Lake Spokane Dissolved Oxygen Total Maximum Daily Load: Water Quality Improvement Report* (2007, as revised in 2010)
Receiving water	Discharges to Spokane River. Downstream impacts occurring in Long lake
Conventional pollutants found in point and non-point source discharges	Nutrients causing downstream dissolved oxygen depletion
Basis of allowable loading of phosphorus and nitrogen	The allowable loads to the Spokane River were based on meeting the dissolved oxygen criteria in downstream Long Lake
Effluent limits	Based on meeting the load allocations in the TMDL
Verification that downstream standards will be met	The TMDL and effluent limits are based on meeting dissolved oxygen standards in Long Lake. Effectiveness monitoring will verify improvements in water quality over time.

Environ Monit Assess
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ORIGINAL ARTICLE

Contaminant exposure in outmigrant juvenile salmon from Pacific Northwest estuaries of the United States[1]

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Abstract To better understand the dynamics of contaminant uptake in outmigrant juvenile salmon in the Pacific Northwest, concentrations of polychlorinated biphenyls (PCBs), DDTs, polycylic aromatic hydrocarbons (PAHs) and organochlorine pesticides were measured in tissues and prey of juvenile chinook and coho salmon from several estuaries and hatcheries in the US Pacific Northwest. PCBs, DDTs, and PAHs were found in tissues (whole bodies or bile) and stomach contents of chinook and coho salmon sampled from all estuaries, as well as in chinook salmon from hatcheries. Organochlorine pesticides were detected less frequently. Of the two species sampled, chinook salmon had the highest whole body contaminant concentrations, typically 2–5 times higher than coho salmon from the same sites. In comparison to estuarine chinook salmon, body burdens of PCBs and DDTs in hatchery chinook were relatively high, in part because of the high lipid content of the hatchery fish. Concentrations of PCBs were highest in chinook salmon from the Duwamish Estuary, the Columbia River and Yaquina Bay, exceeding the NOAA Fisheries' estimated threshold for adverse health effects of 2400 ng/g lipid. Concentrations of DDTs were especially high in juvenile chinook salmon from the Columbia River and Nisqually Estuary; concentrations of PAH metabolites in bile were highest in chinook salmon from the Duwamish Estuary and Grays Harbor. Juvenile chinook salmon are likely absorbing some contaminants during estuarine residence through their prey, as PCBs, PAHs, and DDTs were consistently present in stomach contents, at concentrations significantly correlated with contaminant body burdens in fish from the same sites.

Keywords Chinook salmon · Coho salmon · Contaminants · PAHs · PCBs · DDTs · Pesticides · Washington · Oregon · Estuary

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1 Introduction

Estuaries are important habitats for salmon during the juvenile stage of their life cycle, when they make the transition from freshwater to the ocean (Healey, 1982). Estuaries provide outmigrating juvenile salmon with a refuge from predators, a rich food supply that supports rapid growth, and appropriate conditions for the physiological adaptation to saltwater (Dorcey *et al.*, 1978; Simenstad *et al.*, 1982). However, urban and industrial development may impair the quality of estuarine habitats. Estuaries located near urban centers often receive inputs of toxic contaminants from municipal and industrial activities (Brown *et al.*, 1998; USEPA,

[1] Environmental Monitoring and Assessment

1997), which may be taken up by juvenile salmon and their prey. Because juvenile salmon are in a period of rapid development, and undergoing many physiological changes during their residence in estuarine environments, they may be especially vulnerable to the deleterious effects of toxic chemicals.

The well-documented presence of chemically contaminated sediments in Puget Sound urban estuaries (e.g., Malins *et al*., 1982) prompted a series of studies to examine the degree to which juvenile salmon were exposed to toxic chemicals during estuarine residence (McCain *et al*., 1990; Varanasi *et al*., 1993; Stein *et al*., 1995; Stehr *et al*., 2000). Juvenile salmon (primarily chinook and coho, *Onchorhynchus tshawytscha* and *O. kisutch)* were sampled from several urban and non-urban estuaries in Puget Sound including the Green River/Duwamish Estuary system in Seattle, the Puyallup River/Hylebos Waterway system in Tacoma, and the more rural Snohomish River and Nisqually River Estuaries. Juvenile chinook salmon from hatcheries associated with sampled estuaries were also collected and whole bodies and stomach contents were analyzed for chemical concentrations. Results of these surveys showed that outmigrating juvenile chinook salmon from the Duwamish and Hylebos Waterways exhibited consistent evidence of exposure to contaminants. Juvenile chinook salmon from the Snohomish Estuary, which has some urban development, also appeared to be exposed to contaminants, but to a much lesser degree than salmon from the Duwamish and Hylebos Waterways. In addition, when held in tanks with flow-through seawater for a period of several months, juvenile salmon from the Duwamish Estuary exhibited reduced growth and reduced disease resistance when compared to salmon from either the Green River Hatchery (the primary source of salmon for the Duwamish Estuary) or to salmon from the nonurban Nisqually system (Arkoosh *et al*., 1998; Casillas *et al*., 1995). Similar effects were observed for juvenile salmon from the Hylebos Waterway (Arkoosh *et al*., 2001; Casillas *et al*., 1998). Chemical contaminant exposure in the estuary appeared to place additional stresses on juvenile chinook salmon that could affect their long-term health and survival as they enter the marine environment.

To increase our knowledge of concentrations of chemical contaminants in outmigrant salmon in the Pacific Northwest, we carried out an expanded study from 1996–2001 in which juvenile coho and chinook salmon were collected for contaminant analyses from a number estuaries in Washington and Oregon. Classified by the overall level of development and channel alteration in each estuary (Cortright *et al*., 1987), the sampling areas included: five deep draft estuaries, with the maximum level channel alteration and urban development (Duwamish Estuary, Columbia River, Grays Harbor, Yaquina Bay, and Coos Bay); two shallow draft estuaries with less extensive channel alteration and some urban and industrial development (Tillamook Bay and Coquille River), four conservation estuaries, where channel alteration is minimal and development is limited (Skokomish Estuary, Nisqually Estuary, Willapa Bay and Alsea Bay); and two natural estuaries, which are largely undeveloped for residential, commercial or industrial uses (Elk River and Salmon River). Predominantly wild fish were collected in the estuaries, although some fish of hatchery origin may have been sampled due to incomplete marking of hatchery fish. Juvenile chinook salmon were also sampled from regional hatcheries to evaluate contaminant uptake during rearing but prior to release. Our results indicate that exposure to chemical contaminants is widespread in outmigrant juvenile chinook and coho salmon, and concentrations in tissues of chinook salmon from several estuaries are high enough to pose a potential threat to their health and survival.

2 Materials and methods

2.1 Collecting juvenile salmon

Juvenile, subyearling chinook salmon were collected from a number of Washington and Oregon estuaries over a 6-year period (1996–2001; Fig. 1; Table 1). The Washington estuaries included: Skokomish and Nisqually Estuaries; Duwamish Estuary, and Grays Harbor and Willapa Bay. The Oregon estuaries included the Columbia, Salmon, Coquille, and Elk Rivers; and Yaquina, Alsea, and Coos Bays. Juvenile coho were also collected from Grays Harbor and Willapa, Yaquina, Alsea, and Coos Bays during 1998 (Fig. 1; Table 1). Due to the pattern of salmon movement in the estuaries, we generally sampled on early morning outgoing tides. Salmon were caught with a beach seine net 36.6 meters in length. The wings of

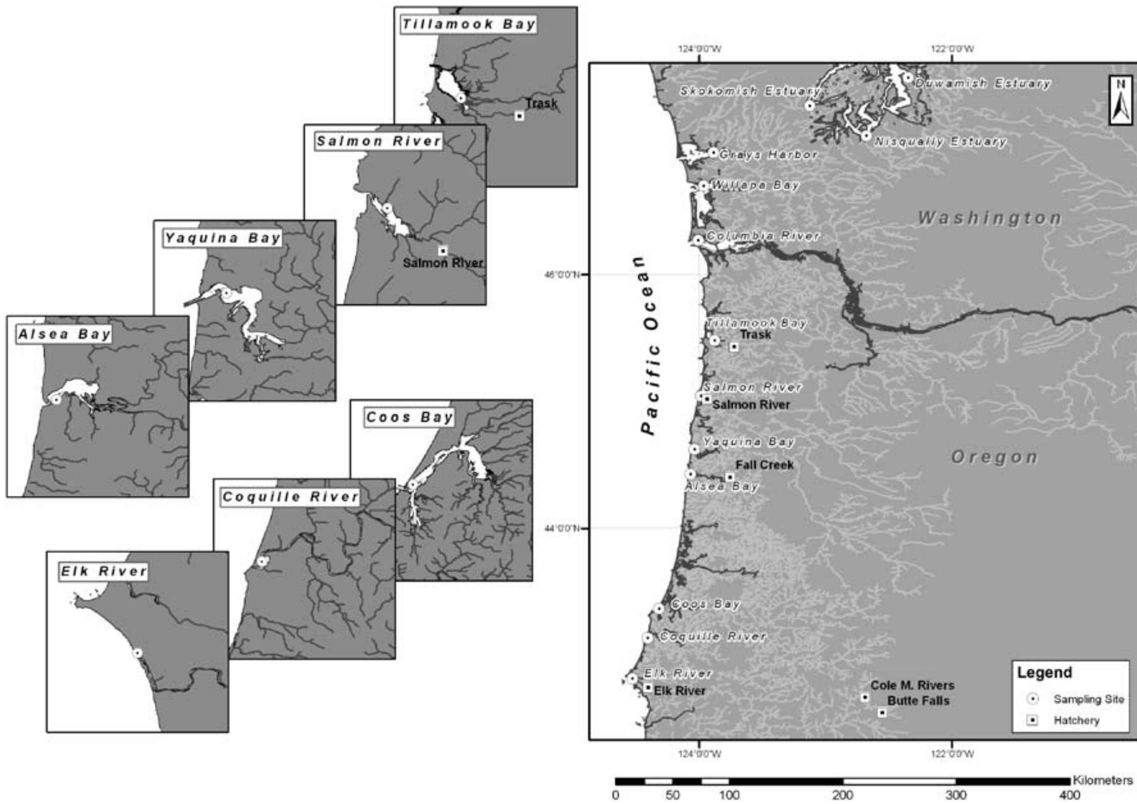

Fig. 1 Locations of hatcheries and estuaries where juvenile coho and chinook salmon were collected

the net were 18 meters long by 2.3 meters deep with 0.6 cm mesh.

Appropriate sampling permits were obtained from the National Marine Fisheries Service (NMFS), and the Oregon and Washington Departments of Fish & Wildlife prior to sampling. To ensure sampling of wild fish instead of hatchery-reared fish we attempted to collect fish from field sites prior to releases from hatcheries or other programs (such as the Salmon and Trout Enhancement Program or STEP). Although a few finclipped hatchery fish were collected and sampled, we did not include these fish in our analyses. Once target salmonids were removed from the net they were placed in insulated aerated tanks and transported live to the nearest laboratory, either the Hatfield Marine Science Center in Newport, Oregon; the University of Oregon's Oregon Institute of Marine Biology in Charleston, Oregon; the U.S. Fish and Wildlife's Olympia Fish Health Center in Olympia, Washington, the Point Adams Field Station in Hammond, Oregon or the Northwest Fisheries Science Center in Seattle, Washington, where they were necropsied within a few hours of collection. Juvenile chinook salmon were also obtained directly from several hatcheries (Fall Creek, Butte Falls, Cole M. Rivers, Elk River, Salmon River, and Trask; see Fig. 1 for locations) to evaluate contaminant uptake during hatchery rearing. Juvenile hatchery coho salmon were not available for sampling at the time of the survey.

Fish to be necropsied were measured (to the nearest mm) and weighed (to the nearest 0.1 g), then sacrificed by a blow to the head. Bile and stomach contents were removed, and composites of 10–15 fish each were generated. Whole gutted bodies from 10 fish were also collected and composited. Bile and stomach contents samples were frozen and stored at −80 °C and whole body samples were frozen and stored at −20 °C until chemical analyses were performed. Sampling sites, dates, and sample types collected are listed in Table 1. Because of limitations associated with fish availability and tissue requirements for analysis, not all samples types could be collected each year from all sites.

Table 1 Sites sampled in Washington and Oregon for juvenile salmonids. Sites were classified by estuary type according to Cortright *et al*. (1987). N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary NS = not sampled; CH = chinook sampled; CO = coho sampled. wb = whole body sampled; b = bile sampled; s = stomach contents sampled

	1996	1997	1998	1999	2000	2001
WA						
Skokomish Estuary (C)	NS	NS	CH (wb,b)	CH (wb,b)	CH (b)	NS
Duwamish Estuary (D)	NS	NS	CH (wb,b)	CH (wb,b,s)	NS	NS
Nisqually Estuary (C)	NS	NS	CH (wb,b,s)	CH (wb,b,s)	NS	NS
Grays Harbor (D)	NS	NS	CH (wb,b.s) CO (wb,b,s)	CH (wb,b,s)	NS	NS
Willapa Bay (C)	NS	NS	CH (wb,b,s) CO (wb,b,s)	CH (wb,b,s)	NS	NS
Columbia River (D)	NS	NS	CH (wb,s)	CH (wb,b,s)	CH(b,s)	CH (b)
OR						
Salmon River (N)	CH (wb)	NS	CH (b)	CH (wb,s)	CH (wb,s)	CH (wb,s)
Yaquina Bay (D)	NS	NS	CH (wb,b,s) CO (wb,b,s)	CH (wb,b,s)	CH (wb,s)	CH (b) CO (wb,s)
Alsea Bay (C)	CH (wb,b)	NS	CH (wb,s) CO (wb,b,s)	CH (wb,b,s)	CH (wb,b,s)	CH (wb,b,s) CO (wb,s)
Coos Bay (D)	CH (wb)	NS	CH (wb,b,s) CO (wb,b,s)	CH (wb,b,s)	CH (wb,s)	NS
Coquille River (S)	CH (wb)	NS	NS	NS	NS	NS
Elk River (N)	CH (wb)	NS	CH (wb,b.s)	NS	CH (wb,s)	CH (wb,b,s)
Salmon River Hatchery	CH (wb)	NS	NS	NS	NS	NS
Fall Creek Hatchery	CH (wb)	NS	NS	NS	NS	NS
Trask Hatchery	CH (wb)	NS	NS	NS	NS	NS
Butte Falls Hatchery	CH (wb)	NS	NS	NS	NS	NS
Cole M. Rivers Hatchery	CH (wb)	NS	NS	NS	NS	NS
Elk River Hatchery	CH (wb)	NS	CH (wb,s)	NS	NS	NS

2.2 Sample analyses

2.2.1 Organochlorine and aromatic hydrocarbon analyses of composite whole body and stomach content samples

Samples in this study were analyzed using a performance-based measurement system (Telliard, 1999), described in detail by Sloan *et al*. (1993) and updated in Sloan *et al*. (2005). Briefly, after the addition of surrogate standards, samples of up to 3 g were extracted with dichloromethane either by homogenizing in the presence of sodium sulfate (Sloan *et al*., 1993) or utilizing accelerated solvent extraction (Sloan *et al*., 2005). For composite whole body samples, a portion of the extract was taken for gravimetric lipid determination. The portion of the extract to be analyzed underwent initial cleanup by filtering through silica gel and neutral alumina, followed by the addition of a recovery standard to determine the fraction of the total extract analyzed. After further sample cleanup using high-performance liquid chromatography with size-exclusion chromatography, the sample fraction containing organochlorines (OCs) and 2–6 ring aromatic hydrocarbons was collected. The fraction was reduced in volume, a GC standard was added, and the sample was analyzed using high-resolution gas chromatography coupled with electron capture detection (samples analyzed for OCs 1996–1998; Sloan *et al*., 1993) or mass spectrometry with selected-ion monitoring (samples analyzed for OCs 1999–2001; Sloan *et al*., 2005) with 5–10 levels of calibration standards. Concentrations of aromatic hydrocarbons (stomach contents samples only) were analyzed in all sampling years by high-resolution gas chromatography with mass spectrometry using selected ion monitoring and 5–6 levels of calibration standards. Quality assurance measures included analysis of a certified reference material and a laboratory blank with each batch of samples. Performance criteria were met for all samples and sample batches.

Analyses for OCs included individual PCB (polychlorinated biphenyl) congeners, DDTs, chlordanes, lindane, aldrin, dieldrin and mirex. PCBs measured over all years included a standard list of 17 congeners (IUPAC numbers 18, 28, 44, 52, 95, 101, 105, 118, 128, 138, 153, 170, 180, 187, 195, 206, and 209). Total PCBs was calculated by summing the concentrations of these individual congeners and multiplying the result by two. This formula provides a good estimate of the total PCBs in a typical environmental sample of sediments or animals feeding on lower trophic levels, where a mixture of Aroclors 1254 and 1260 is the predominant pattern (Lauenstein *et al.*, 1993). Summed DDTs (ΣDDTs) levels were calculated by summing the concentrations of *o,p′*- and *p,p′*-DDD, *o,p′*- and *p,p′*-DDE, and *o,p′*- and *p,p′*-DDT. Summed chlordanes (ΣCHLDs) were calculated by summing the concentrations of heptachlor, heptachlor epoxide, γ-chlordane, α-chlordane, oxychlordane, *cis*-nonachlor, *trans*-nonachlor and nonachlor III. Summed low molecular weight aromatic hydrocarbons (ΣLAHs) were determined by adding the concentrations of biphenyl, naphthalene, 1-methylnaphthalene, 2-methylnaphthalene, 2,6-dimethylnapthalene, acenaphthene, fluorene, phenanthrene; 1-methylphenanthrene, and anthracene. Summed high molecular weight aromatic hydrocarbons (ΣHAHs) were calculated by adding the concentrations of fluoranthene, pyrene, benz[a]anthracene, chrysene, benzo[a]pyrene, benzo[e]pyrene, perylene, dibenz[a,h]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, indenopyrene, and benzo[ghi]perylene. Summed total aromatic hydrocarbons (ΣAHs) were calculated by adding ΣHAHs and ΣLAHs.

2.2.2 *PAH metabolites in bile*

Composite samples of bile were analyzed by high-performance liquid chromatography with fluorescence detection (HPLC/uvf) for aromatic hydrocarbon (AH) metabolites as described in Krahn *et al.* (1986). In brief, bile was injected directly onto a C18 reverse-phase column (Phenomenex Synergi Hydro) and eluted with a linear gradient from 100% water (containing a trace amount of acetic acid) to 100% methanol at a flow of 1.0 mL/min. Chromatograms were recorded at the following wavelength pairs: 1) 260/380 nm where several 3–4 ring compounds (e.g., phenanthrene) fluoresce and 2) 380/430 nm where 4–5 ring compounds (e.g., benzo[a]pyrene) fluoresce. Peaks eluting after 5 minutes were integrated and the areas of these peaks were summed. The concentrations of fluorescent AHs in bile were determined using phenanthrene (PHN) and benzo[a]pyrene (BaP) as external standards and converting the fluorescence response of bile to phenanthrene (ng PHN equivalents/g bile), and benzo[a]pyrene (ng BaP equivalents/g bile) equivalents. Bile metabolites fluorescing at phenanthrene wavelengths were considered an indicator of exposure to low molecular weight PAHs, while metabolites fluorescing at benzo[a]pyrene (BaP) wavelengths were considered as an indicator of exposure to high molecular weight PAHs.

2.2.3 *Statistical methods*

Statistical analyses were conducted with the Statview©statistical software package (SAS Institute, Inc., Cary, NC, USA). Temporal and intersite differences in tissue, stomach contents, and bile contaminant concentrations were determined by ANOVA. Data were log-transformed as necessary to achieve a normal distribution. The significance level for all analyses was set at $\alpha = 0.05$.

3 Results

3.1 Lipid content in whole bodies

Lipid content (as total extractable organics) in bodies of chinook salmon collected from the estuaries varied from 0.8% in fish from Tillamook Bay to 3.5% in fish from Coquille River, with an average concentration of 2.4% (Fig. 2; Table 2). Lipid levels in juvenile coho salmon were slightly lower, with an average concentration of 1.2% (Fig. 2; Table 2), but not significantly different than levels in estuarine chinook salmon (ANOVA, $p = 0.08$). Lipid concentrations in hatchery chinook salmon were significantly higher than in estuary chinook (ANOVA, $p = 0.001$), with an average concentration of 7.9% (Fig. 2; Table 2). The number of samples collected (typically one composite per site or hatchery) was too small for intersite or interhatchery differences to be meaningfully evaluated,

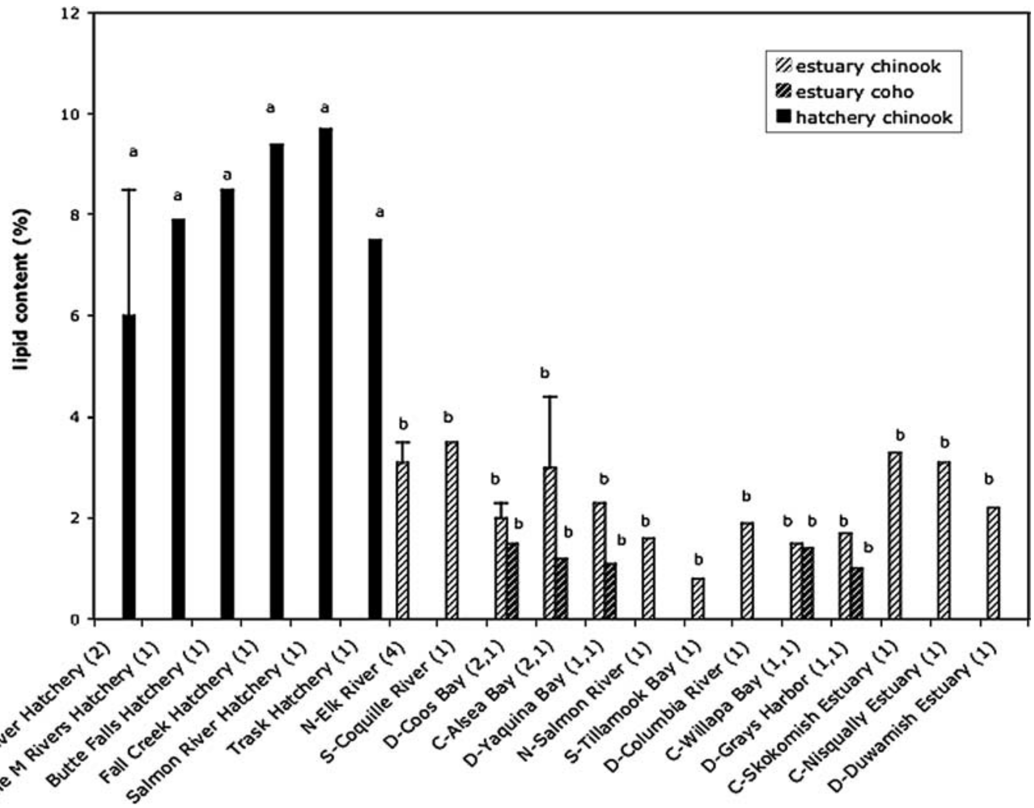

Fig. 2 Mean lipid content (%, as total extractable organics, ± SE) in whole bodies of chinook and coho salmon from Pacific Northwest estuaries and juvenile chinook salmon from associated hatcheries. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$)

but concentrations tended to be fairly uniform within the sampling groups (i.e, estuarine chinook, estuarine coho, and hatchery chinook).

3.2 Organochlorine contaminants in whole bodies

Concentrations of PCBs in whole bodies of estuarine chinook salmon (Fig. 3, Tables 2 and 3) were quite variable, ranging from ∼500 ng/g lipid weight (lw) in salmon from Elk River and Coquille Estuaries to 3100 ng/g lw in salmon from the Duwamish Estuary in Seattle (or from 3.6 ng/g wet weight (ww) at Salmon River to 103 ng/g ww at Duwamish). The lowest concentrations of PCBs were found in chinook salmon from Elk River Estuary, Coquille River, Alsea Bay Estuary, Salmon River, and Tillamook Bay; wet weight PCB concentrations were less than 20 ng/g ww at all these sites, and lipid weight PCB concentrations were below 600 ng/g lw in chinook from Elk River Estuary, Coquille River, and Tillamook. The highest PCB concentrations (2500–3100 ng/g lw or 45–103 ng/g ww) were found in salmon from Yaquina Bay, the Columbia River, and the Duwamish Estuary.

Concentrations of PCBs in juvenile coho salmon (Fig. 3, Tables 2 and 3) tended to be lower than those in chinook salmon. At sites where both species were collected, the mean PCB concentration overall was significantly lower in coho than in chinook on both a lipid weight and wet weight basis (1030 vs. 1650 ng/g lw, $p = 0.018$; 10 vs. 30 ng/g ww; $p = 0.0026$). No significant differences were observed in PCB concentrations in coho salmon from different sampling sites, but the number of samples was very small.

The mean concentration of PCBs in juvenile chinook salmon from hatcheries (Fig. 3, Tables 2 and 3) was relatively low on a lipid weight basis (620 ng/g lw),

Table 2 Contaminant concentration mean values (± SE), ranges, and sites where high and low values were observed in juvenile chinook and coho salmon from Pacific Northwest estuaries and juvenile chinook salmon from Pacific Northwest hatcheries. Values with different superscripts are significantly different (ANOVA, $p = 0.05$) in estuarine chinook, estuarine coho, and hatchery chinook

	Estuaries		Hatcheries
	Chinook	Coho	Chinook
% lipid	2.4 ± 0.2 (n = 19)[a] 0.8–3.5.% Tillamook–Coquille	1.2 ± 0.1 (n = 5)[a] 1.1–1.5% Grays Hbr.-Coos	7.9 ± 0.8 (n = 7)[b] 6–9.7%[1] Elk–Salmon
Body PCBs (ng/g wet wt)	27 ± 4 (n = 65)[a] 3.6–103 Salmon–Duwamish	9.7 ± 1.6 (n = 9)[b] 6–16 Alsea–Grays Hbr.	46 ± 3 (n = 7)[c] 39–59 Trask–Salmon
Body PCBs (ng/g lipid)	1650 ± 190 (n = 19)[a] 516–3099 Elk R.–Duwamish	1030 ± 230 (n = 5)[a] 470–1564 Willapa-Grays Hbr.	620 ± 50 (n = 7)[b] 521–760 Fall Cr.–Elk
Body DDTs (ng/g wet wt)	13 ± 2 (n = 65)[a] 0.5–41 Tillamook–Columbia.	1.7 ± 0.3 (9)[b] 0.9–3.4 Willapa-Grays Hbr.	34 ± 3 (7)[c] 27–45 Trask–Salmon
Body DDTs (ng/g lipid)	550 + 120 (n = 19) 62–2280 Tillamook–Columbia	140 + 50 (n = 5) 66–333 Willapa-Grays Hbr.	436 + 234 (n = 7) 354–507 Trask–Elk
Whole body DDT/PCB ratio	0.63 ± 0.06 (n = 65)[a] 0.10–1.1 Tillamook–Salmon	0.21 ± 0.03 (n = 9)[b] 0.13–0.26 Coos-Alsea	0.72 ± 0.03 (n = 7)[a] 0.68–0.75 Elk/Trask–Salmon
FACs-BaP (ng/g bile)	364 ± 96 (n = 47) 108–1925 Alsea–Duwamish	218 ± 26 (n = 10) 136–298 Yaquina–Grays Hbr.	ND
FACs-PHN (ng/g bile)	44600 ± 15900 (n = 47) 9270–359000 Nisqually-Duwamish	17600 ± 2040 (n = 10) 12900–25400 Yaquina–Coos Bay	ND
Stomach contents PCBs (ng/g wet wt)	18.6 ± 5.7 (n = 35) 4.5–200 Salmon–Duwamish	11.6 ± 2.5 (n = 9) 5.4–22 Alsea–Grays Hbr.	13 (n = 1) Elk
Stomach contents DDTs (ng/g wet wt)	8.3 ± 2.9 (n = 35) 0.6–45 Elk.–Grays Hbr.	1.5 ± 0.4 (n = 9) 0.9–2.3 Alsea–Grays Hbr.	4.5 (n = 1) Elk
Stomach contents ΣLAHs (ng/g wet wt)	415 ± 235 (n = 35)[a] 12–8000 Elk-Duwamish	40 ± 19 (n = 9)[b] 10–69 Coos Bay-Alsea Bay	28 (n = 1)[b] Elk
Stomach contents ΣHAHs (ng/g wet wt)	594 ± 353 (n = 35)[a] 1.3–6300 Elk/Salmon-Willapa	5.4 ± 1.7 (n = 35)[b] 1.3–10 Coos Bay–Grays Hbr.	5 (n = 1)[b] Elk

comparable to concentrations observed in estuary chinook and coho salmon from rural estuaries (e.g., Elk River, Coquille River, Alsea Bay). On a wet weight basis, however, the mean PCB concentration in hatchery chinook was quite high (47 ng/g ww), comparable to concentrations in moderately to heavily urbanized estuaries (Table 3).

Concentrations of ΣDDTs in estuarine chinook salmon bodies ranged from 62 ng/g lw at Tillamook Bay to 2280 ng/g lw in the Columbia River (or from below 0.5 ng/g ww in fish from Tillamook Bay to 41 ng/g ww in fish from the Columbia River) (Fig. 4, Tables 2 and 3), with a mean concentration of 550 ng/g lw or 13 n/g ww (Fig. 4; Tables 2 and 3). Concentrations

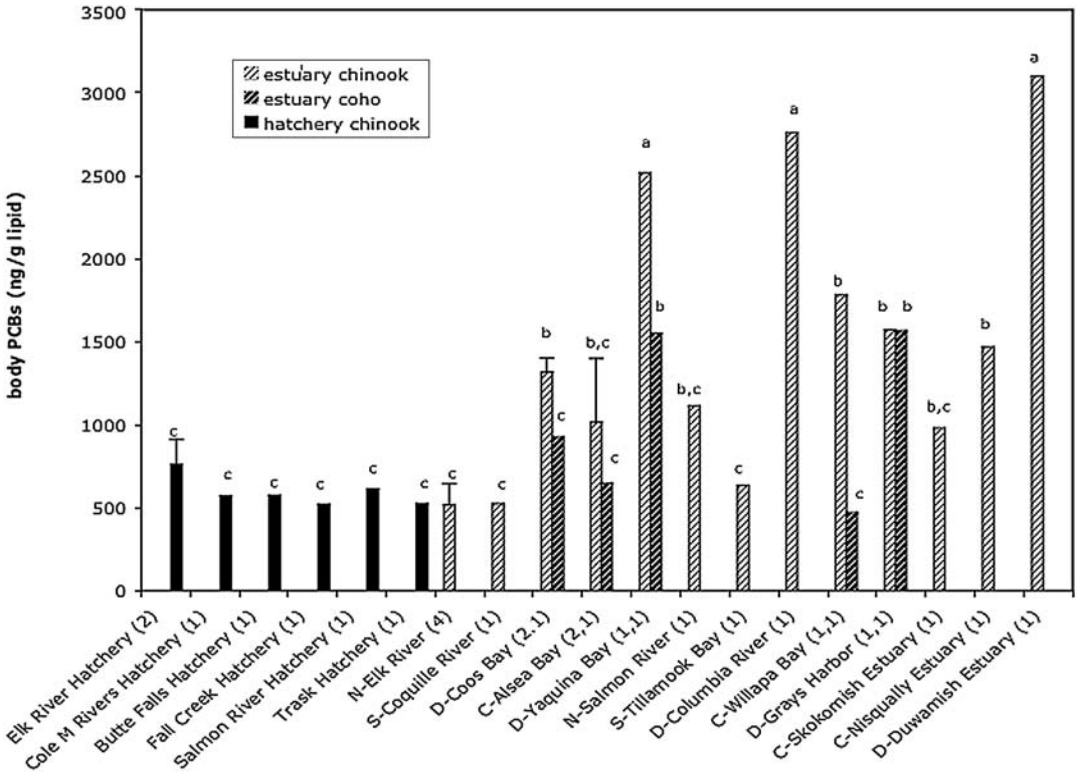

Fig. 3 Mean concentrations of ΣPCBs (ng/g lipid, ± SE) in whole bodies of juvenile chinook and coho salmon from Pacific Northwest Estuaries and juvenile chinook salmon from associated hatcheries. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$)

of ΣDDTs were low in fish from Tillamook Bay, Alsea Bay, and Elk River on both a wet wt and lipid wt basis (below 250 ng/g lw and 5 ng/g ww); at Coquille River lipid wt DDT concentrations were comparable but wet wt concentrations were higher, while the reverse was true for chinook from Salmon River. Concentrations of ΣDDTs were relatively high (over 1000 ng/g lw or 25 ng/g ww) in fish from the Nisqually, Duwamish, and Columbia River Estuaries. Fish with the highest ΣDDT concentrations were from the Columbia River, where levels were over 2200 ng/g lw or 40 ng/g ww.

In juvenile coho salmon, the maximum ΣDDT concentration was 333 ng/g lw or 3.4 n/g ww in fish from Grays Harbor (Fig. 4; Tables 2 and 3), while the mean concentration was 140 ng/g lw or 1.7 ng/g ww. When coho and chinook salmon collected from the same sites were compared, ΣDDT concentrations were much lower in coho salmon (1.7 ± 0.3 ng/g ww vs. 8.8 ng/g ww, $p = 0.0026$; or 137 ng/g lw vs. 551 ± 95 ng/g lw, $p \leq 0.001$).

On a wet weight basis, concentrations of ΣDDTs in whole bodies of juvenile Chinook collected from the hatcheries were fairly high, with the mean concentrations for all hatcheries significantly above the mean concentrations measured in estuarine chinook and coho (Tables 2 and 3). However, because of the high lipid content of the hatchery fish, their whole body ΣDDT concentrations on a lipid weight basis were more moderate (400–500 ng/g lw), and did not differ significantly from mean concentrations in estuarine salmon (Fig. 4; Tables 2 and 3).

Of the six DDTs measured in salmon whole bodies, *p,p′*-DDE predominated in whole bodies of both coho and chinook salmon from all estuaries and hatcheries sampled, accounting for 75–100% of DDTs measured (Fig. 5; Table 3). The second most prominent DDT was *p,p′*-DDD; it accounted for 10–20% of DDTs measured in chinook and coho salmon from most sites. Additionally, *p,p′*-DDT was present at several sites, accounting for 3–6% of total DDTs in chinook salmon

Table 3 Mean concentrations (± SE) in ng/g, wet wt of ΣPCBs, ΣDDTs, and DDT isomers in whole bodies of juvenile chinook and coho salmon collected from Pacific Northwest estuaries and juvenile chinook salmon from Pacific Northwest hatcheries. Compounds were measured by GC/ECD in samples collected from 1996–1998 and by GC/MS in samples collected from 1999–2001. Values with different letter superscripts are significantly different (ANOVA, $p \leq 0.05$)

Site	ΣPCBs	ΣDDTs	*o,p′*-DDD	*o,p′*-DDE	*o,p′*-DDT	*p,p′*DDD	*p,p′*-DDE	*p,p′*-DDT
Estuary chinook								
Columbia River (6)	50 ± 14[b]	41 ± 3[a]	0.6 ± 0.1[a]	0.27 ± 0.0[a]	0.71 ± 0.15[a]	6.2 ± 0.64[a]	31 ± 2.3[a]	2.4 ± 0.6[a]
Alsea Bay (8)	11 ± 3[c]	2.4 ± 0.5[d]	<DL[b]	0.05 ± 0.05[b]	<DL[c]	0.32 ± 0.25[b]	2.8 ± 0.8[c]	0.11 ± 0.09[b]
Elk River (2)	9.9 ± 3.9[c]	4.7 ± 2.6[d]	0.04 ± 0.03[b]	<DL[b]	0.02 ± 0.03[c]	0.5 ± 0.4[b]	4.1 ± 2.1[c]	0.21 ± 0.15[b]
Grays Harbor (3)	27 ± 8[b,c]	11.3 ± 4[c]	0.07 ± 0.07[b]	<DL[b]	<DL[c]	1.1 ± 0.6[b]	9.9 ± 3.3[b]	0.1 ± 0.1[b]
Salmon River (11)	3.6 ± 1.6[c]	1.9 ± 0.5[d]	<DL[b]	<DL[b]	<DL[c]	0.16 ± 0.09[b]	1.7 ± 0.4[c]	0.11 ± 0.06[b]
Skokomish Estuary (3)	29 ± 2[b,c]	19.9 ± 1.5[b]	0.08 ± 0.08[b]	<DL[b]	0.05 ± 0.05[c]	1.9 ± 0.15[b]	17.3 ± 1.2[b]	0.27 ± 0.18[b]
Willapa Bay (3)	24[b,c]	12.3 ± 0.4[c]	<DLb	<DL[b]	<DL[c]	0.62 ± 0.14[b]	11.2 ± 0.7[b]	0.14 ± 0.14[b]
Yaquina Bay (7)	46 ± 1[b]	7.8 ± 2.2[d]	<DL[b]	<DL[b]	0.07 ± 0.07[b]	0.48 ± 0.11[b]	6.8 ± 1.8[b]	0.41 ± 0.14[b]
Coos Bay (3)	22 ± 3[b,c]	10.8 ± 1.3[c]	<DL[b]	<DL[b]	0.02 ± 0.02[c]	0.59 ± 0.09[b]	9.8 ± 1.1[b]	0.45 ± 0.12[b]
Duwamish Estuary (3)	103 ± 29[a]	27 ± 1[b]	0.36 ± 0.03	0.18 ± 0.09[a]	0.09 ± .09[b]	3.5 ± 0.4[a]	22 ± 0.6[a]	0.61 ± 0.14[b]
Nisqually Esuary (3)	40 ± 4[b]	30 ± 4[b]	0.26 ± 0.03	0.09 ± 0.09[b]	0.04 ± 0.04[c]	3.4 ± 0.5[a]	26 ± 3.5[a]	0.34 ± 0.09[b]
Coquille River (1)	18[b,c]	9.2[c,d]	<DL[b]	<DL[b]	<DL[c]	1.3[b]	7.3[b]	0.58[b]
Tillamook Bay (1)	5.1[c]	0.5[d]	<DL[b]	<DL[b]	<DL[c]	<DL[b]	0.47[c]	<DL
Hatchery chinook								
Fall Creek (1)	49[b]	39[a]	0.51[a]	<DL[b]	0.03[c]	5.4[a]	32[a]	1.3[a]
Butte Falls (1)	49[b]	35[a]	0.56[a]	<DL[b]	<DL[c]	4.9[a]	28[a]	1.5[a]
Cole M. Rivers (1)	45[b]	31[a]	0.8[a]	<DL[b]	0.09[b]	6.1[a]	22[a]	2.0[a]
Elk River (2)	42[b]	30 ± 10[b]	0.04[b]	<DL[b]	0.21[a]	4.2[a]	23[a]	1.7[a]
Salmon River (1)	59[b]	45[a]	0.9[a]	<DL[b]	0.26[a]	8.3[a]	32[a]	3.0[a]
Trask (1)	39[b]	27[b]	0.67[a]	<DL[b]	<DL[c]	4.5[a]	20[a]	1.3[a]
Estuary Coho								
Alsea Bay (3)	5.9 ± 1[c]	1.4 ± 0.2[d]	<DL[b]	<DL[b]	<DL[c]	0.08 ± 0.04[b]	1.3 ± 0.2[c]	<DL[b]
Coos Bay (1)	14[c]	1.8[d]	<DL[b]	<DL[b]	<DL[c]	<DL[b]	1.8[c]	<DL[b]
Grays Harbor (1)	27[b,c]	3.4[d]	<DL[b]	<DL[b]	<DL[c]	0.26[b]	3.0[c]	0.13[b]
Willapa Bay (1)	6.4[c]	0.9[d]	<DL[b]	<DL[b]	<DL[c]	0.13[b]	0.63[c]	0.12[b]
Yaquina Bay (3)	11[c]	1.7 ± 0.4[d]	<DL[b]	<DL[b]	<DL[c]	0.13 ± 0.07[b]	1.6 ± 0.4[c]	0.4 ± 0.02[b]

from the Columbia River, Yaquina Bay, Grays Harbor, and Salmon River, 4% of total DDTs in juvenile coho from Grays Harbor, and 13% of total DDTs in coho from Willapa Bay. In hatchery chinook salmon, *p,p′*-DDT accounted for an average of 5% of total DDTs. Concentrations of estrogenic *o,p′*-DDT, *o,p′*-DDD, and *o,p′*-DDE (Fig. 6) were below detection limits in all coho and many chinook salmon sampled, but were present at concentrations above 0.1 ng/g ww or 10 n/g lw in chinook salmon from the Columbia, Nisqually, Duwamish and Yaquina Bay Estuaries. As with ΣDDTs, concentrations of the *o,p′* isomers were highest in chinook from the Columbia River. In hatchery chinook salmon, they averaged 8 ng/g lw.

We calculated the ΣDDTs/ΣPCBs ratios in whole body samples of chinook and coho salmon to identify groups of fish with distinct contaminant profiles (Fig. 7). In coho salmon, the mean ΣDDTs/ΣPCBs ratio was 0.2, and in estuarine chinook salmon, the mean ratio was 0.4. In both coho and chinook salmon from most of the sites we sampled (Nisqually, Skokomish, Coos Bay, Alsea Bay Estuary, Salmon River Estuary, Willapa Bay, Elk River Estuary, Duwamish Estuary, Tillamook Bay, Yaquina Bay), ΣDDT/ΣPCB ratios were 0.5 or lower. This was not true, however, of chinook salmon from the Columbia River, whose ΣDDTs/ΣPCBs ratios were 1.0–1.1. In hatchery chinook, the mean ΣDDTs/ΣPCBs ratio was ∼0.7.

In addition to PCBs and DDTs, chlordanes, hexachlorobenzene, and dieldrin were detected in whole bodies of estuarine chinook and coho salmon from one or more sampling sites, but at much lower concentrations than PCBs or DDTs (mean concentrations ranging from <1 ng/g ww to 4 ng/g ww; Table 4). Of the

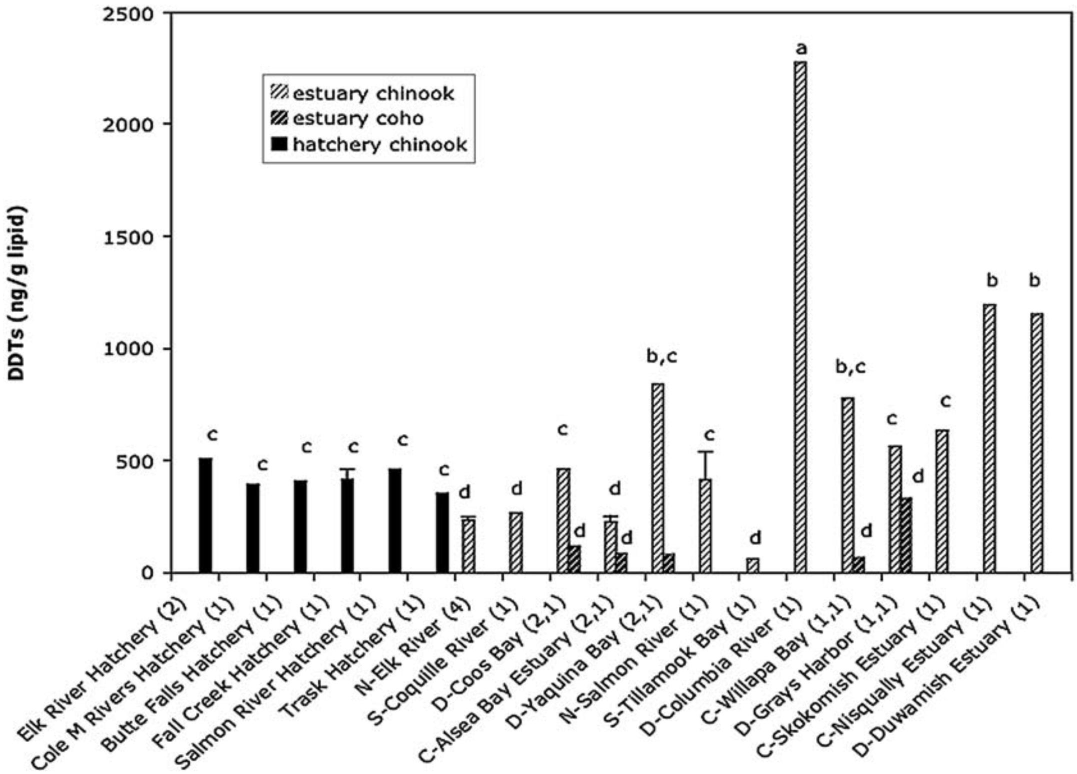

Fig. 4 Mean concentrations of ΣDDTs (ng/g lipid, ± SE) in whole bodies of juvenile chinook and coho salmon from Pacific Northwest estuaries and juvenile chinook salmon from associated hatcheries. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$)

pesticides detected, chlordanes were generally found at the highest concentrations. Other OC pesticides (i.e., lindane, mirex and aldrin) were below the limits of detection (generally <0.5 ng/g ww) in all samples. Dieldrin, chlordanes, and HCB were detected in whole bodies of juvenile chinook from all sampled hatcheries, typically at concentrations in the 1–5 ng/g ww range. Concentrations were comparable to the highest levels reported in estuarine chinook and coho (Table 4).

3.3 Bile metabolites

Levels of high molecular weight AH metabolites in bile (FACs-BaP) were low to moderate (100–400 ng/g bile) in juvenile fall chinook and coho salmon collected from most of the estuaries sampled along the Washington and Oregon Coast (Fig. 8). Concentrations in chinook salmon from the Duwamish Estuary (∼1930 ng BaP equiv/g bile) were significantly higher than in fish from any other sites. FAC-BaP levels were also somewhat elevated (350–500 ng/g bile) in chinook salmon from the Columbia River, Skokomish Estuary, Grays Harbor, and Willapa Bay, and in coho salmon from Grays Harbor. Lowest concentrations were observed in chinook and coho salmon from Elk River Estuary, Yaquina Bay Estuary, and Alsea Bay Estuary. At 100–200 ng BaP equiv/g bile, concentrations of FACs-BaP in fish at these sites were significantly lower than in chinook salmon from the Columbia, Skokomish, Willapa Bay, and Duwamish sites, and in chinook and coho salmon from Grays Harbor.

Concentrations of metabolites of low molecular weight PAHs (FAC-PHN; Fig. 8) were also significantly higher in chinook salmon from the Duwamish Estuary (359,000 ng PHN equiv/g bile) than in fish from any other sites. Concentrations in chinook salmon from Grays Harbor, Coos Bay, and the Columbia River (60,000–70,000 ng PHN equiv/g bile) were much lower than in the Duwamish chinook, but significantly above levels in either coho or

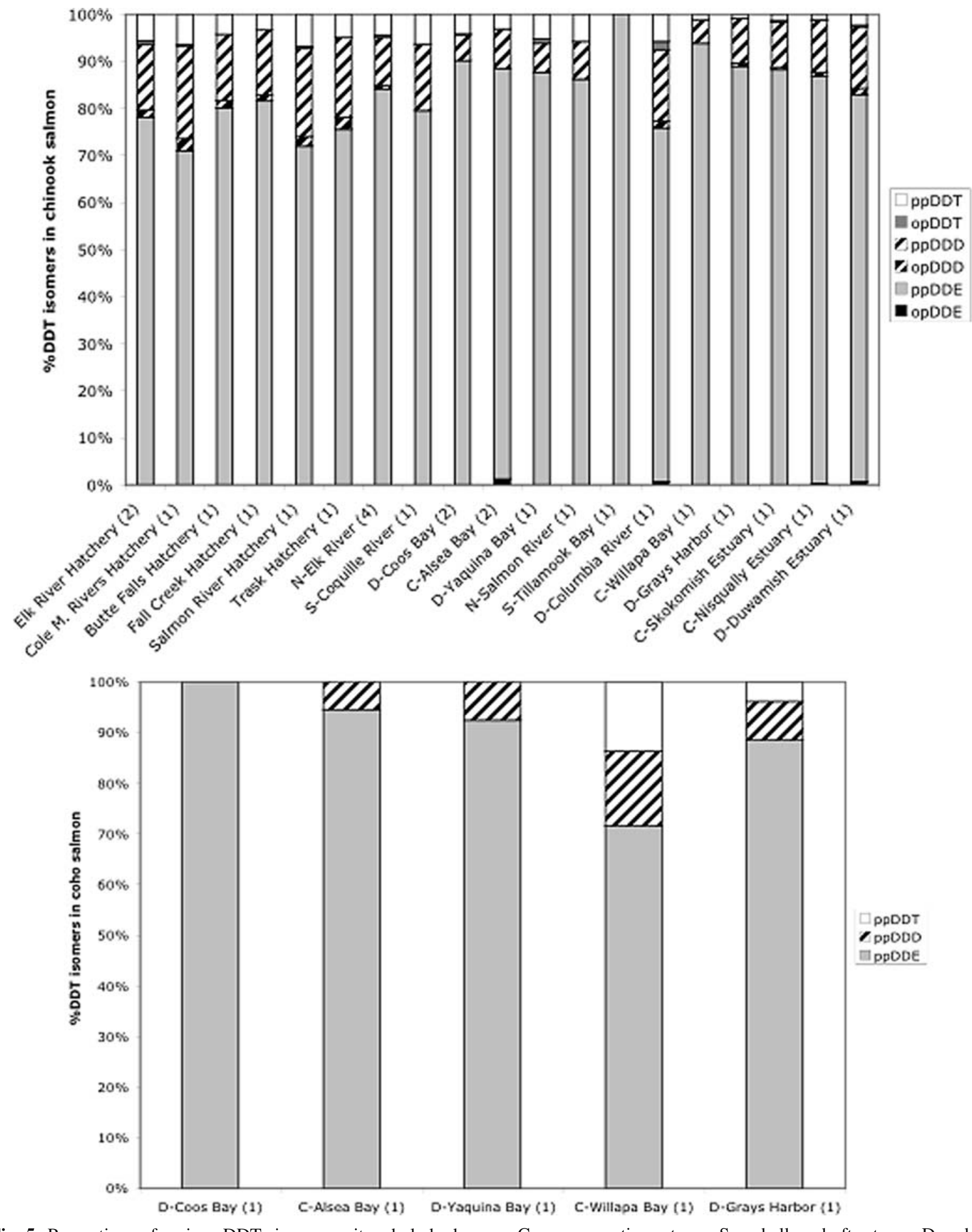

Fig. 5 Proportions of various DDTs in composite whole body samples of juvenile chinook and coho salmon collected from Pacific Northwest estuaries and hatcheries. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group

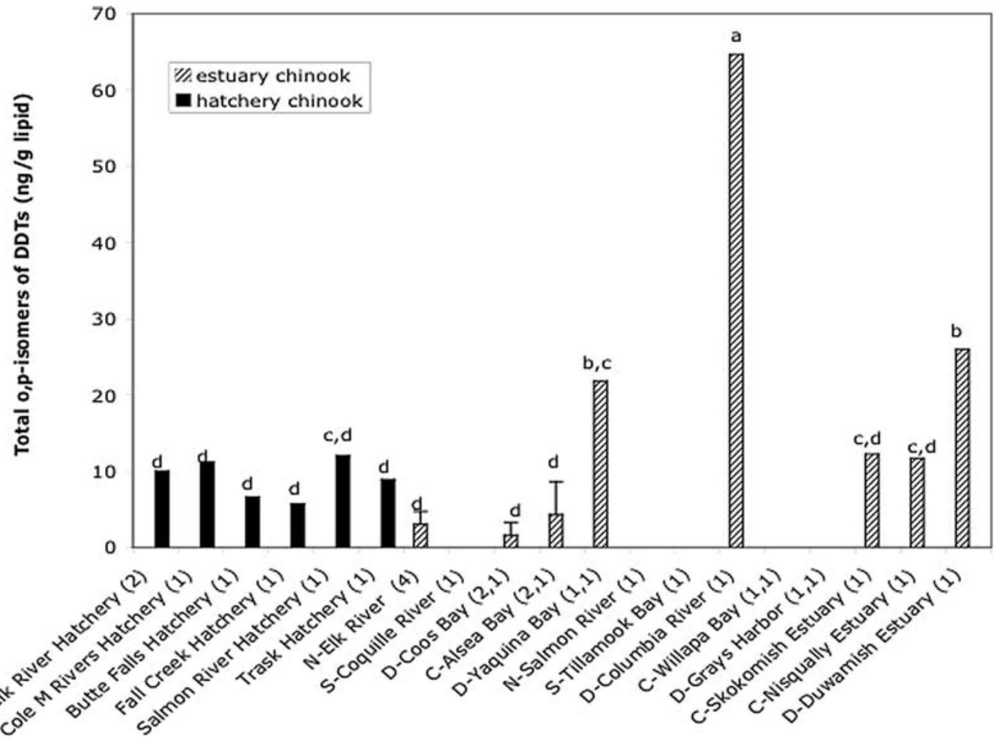

Fig. 6 Mean concentrations of $\Sigma o, p'$-isomers of DDTs (ng/g lipid, ± SE) in whole bodies of juvenile chinook and coho salmon from Pacific Northwest estuaries and juvenile chinook salmon from associated hatcheries. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$). Values were below detection limits for coho from all sites where they were sampled, and for chinook from Coquille River

chinook salmon from the other sampling sites, whose biliary FACs-PHN concentrations were 30,000 ng PHN equiv/g bile or less. Bile sample could not be collected from chinook salmon at the hatcheries.

3.4 Contaminants in stomach contents

Several classes of contaminants, including PCBs, DDTs, and low and high molecular weight PAHs, were present at detectable concentrations in stomach contents of outmigrant juvenile chinook and coho salmon. Concentrations of ΣLAHs in stomach contents of estuarine chinook salmon (Fig. 9; Table 2) ranged from 12 ng/g ww at the Elk River Estuary to 8000 ng/g ww at the Duwamish Estuary. Concentrations of ΣLAHs were also fairly high in fish from Willapa Bay, Yaquina Bay, and Grays Harbor in comparison to other sites, ranging from 350 to 1400 ng/g ww. Concentrations of ΣLAHs in stomach contents of chinook and coho salmon from all other sites were <100 ng/g ww (Fig. 9; Table 2). At sites where both species were collected, average ΣLAH concentrations in stomach contents of chinook salmon were higher than in coho salmon (920 ng/g ww vs. 5 ng/g ww). In chinook salmon from Elk River Hatchery, the concentration of ΣLAHs in stomach contents was 28 ng/g ww (Fig. 9; Table 2).

Concentrations of ΣHAHs in stomach contents of juvenile chinook salmon (Fig. 9, Table 2) were highest in fish from the Duwamish Estuary and Willapa Bay (6000–6300 ng/g ww). Concentrations of ΣHAHs at Grays Harbor and Yaquina Bay (330–340 ng/g ww) were also relatively high in comparison to other sites, where concentrations were ∼20 ng/g ww and below. The lowest levels ΣHAHs (1–2 ng/g ww) were observed in chinook from Salmon River and Elk River Estuary sites. In coho salmon (Fig. 9; Table 2) concentrations of ΣHAHs in stomach contents were ∼10 ng/g ww or below in fish from all sites; at sites where both species were collected, ΣHAH concentrations were higher in chinook salmon than in coho salmon (323 ng/g ww vs. 40 ng/g ww). In chinook and coho salmon from most sampling sites, HAHs accounted for

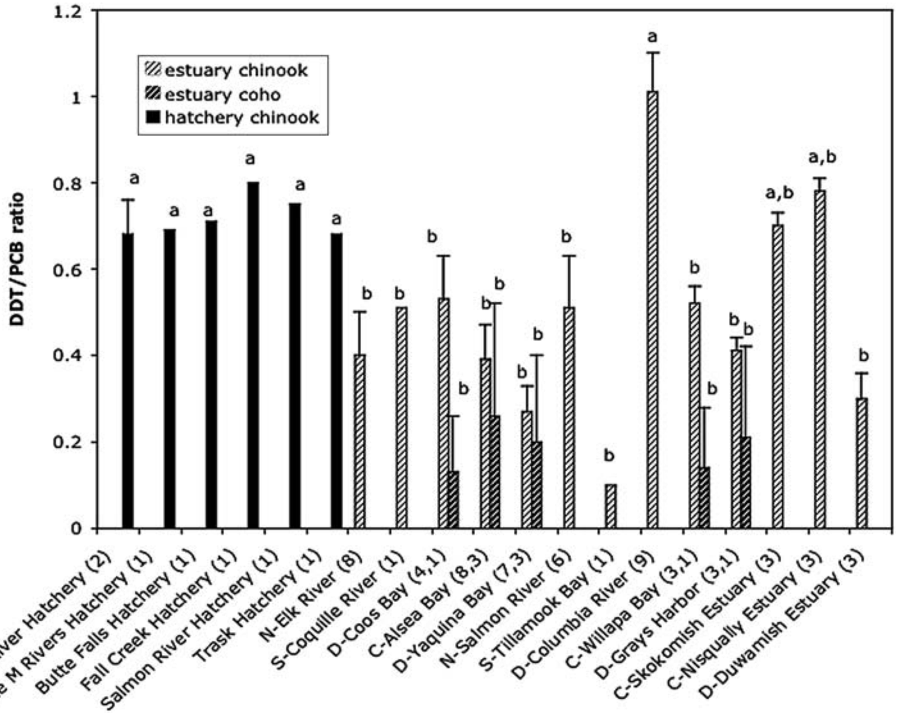

Fig. 7 Mean ΣDDT/ΣPCB ratios (± SE) in whole bodies of juvenile chinook and coho salmon from Pacific Northwest estuaries and juvenile chinook salmon from associated hatcheries. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$)

10–20% of total AHs. However, in chinook salmon from the Duwamish, Grays Harbor, Yaquina Bay, and Willapa Bay, HAHs were more predominant, accounting for 30–70% of total AHs. In chinook salmon from the Elk River Hatchery (Fig. 9), ΣHAH concentrations were relatively low (5 ng/g ww) and accounted for about 15% of total AHs.

Concentrations of ΣPCBs in stomach contents of estuarine chinook salmon (Fig. 10; Table 2) ranged from 5 ng/g ww in fish from the Salmon River Estuary to 200 ng/g ww in fish from the Duwamish Estuary. Concentrations of PCBs in salmon from the Columbia River and Grays Harbor were about 40 ng/g ww, and concentrations were about 20 ng/g ww or less at all other sampling sites. Lowest levels (5–10 ng/g ww) were observed at Yaquina Bay, Alsea Bay, Coos Bay, Elk River, and Salmon River Estuaries. In coho salmon (Fig. 10, Table 2), PCB concentrations in stomach contents ranged from 5 ng/g ww in fish from Alsea Bay Estuary to 22 ng/g ww in fish from Willapa Bay. At sites where both species were collected, PCB concentrations were similar in stomach contents of chinook salmon and coho salmon, 14 ng/g ww vs. 12 ng/g ww. At the Elk River Hatchery, PCB concentrations in stomach contents were 13 ng/g ww, comparable to levels in estuarine chinook salmon from non-urban sites (Fig. 10; Table 2).

Concentrations of ΣDDTs in stomach contents of estuarine chinook salmon (Fig. 11; Table 2) were highest in fish from Grays Harbor (45 ng/g ww) and the Columbia River (39 ng/g ww), significantly higher than in fish from all other sites. In stomach contents of chinook from all sampling sites except for the Columbia River and Grays Harbor, ΣDDT concentrations were <10 ng/g ww. Concentrations of ΣDDTs in stomach contents of coho salmon (Fig. 11, Table 2) were low (3 ng/g ww) in fish from all sites. At sites where both species were collected, ΣDDT concentrations were higher in chinook salmon than in coho salmon (9 ng/g ww vs. 1.5 ng/g ww). In chinook salmon from the Elk River Hatchery (Fig. 11, Table 2), concentrations of DDTs were also relatively low, 4.5 ng/g ww.

In stomach contents, as in tissues, p,p'-DDE was the predominant isomer detected, accounting for about

Table 4 Mean concentrations (± SE) in ng/g, wet wt of selected organochlorine pesticides in bodies of juvenile chinook and coho salmon collected from Pacific Northwest estuaries and hatcheries. Σchlordanes = summed concentrations of heptachlor, heptachlor epoxide, γ-chlordane, α-chlordane, *cis*-nonachlor, *trans*-nonachlor and nonachlor III. DL = detection limit. Pesticides were measured by GC/ECD in samples collected from 1996–1998 and by GC/MS in samples collected from 1999–2001. Values with different letter superscripts are significantly different (ANOVA, $p < 0.05$). Lindane was also measured, but was below DL (generally < 0.5 ng/g ww) in all samples

Site	dieldrin	aldrin	Σchlordanes	HCB	Mirex
Estuary Chinook					
Columbia River (6)	1.9 ± 0.88^{a}	$<DL^{b}$	3.1 ± 0.26^{b}	0.63 ± 0.05^{b}	$<DL^{a}$
Coquille River (1)	0.56^{b}	0.29^{a}	1.5^{c}	$0.65^{a,b}$	0.35^{c}
Alsea Bay (8)	0.69 ± 0.39^{b}	$<DL^{b}$	0.47 ± 0.30^{c}	0.21 ± 0.11^{b}	$<DL^{a}$
Coos Bay (4)	$0.83 \pm 0.83^{a,b}$	$<DL^{b}$	0.73 ± 0.12^{c}	0.33 ± 0.09^{b}	$<DL^{a}$
Duwamish Estuary (3)	$0.97 \pm 0.08^{a,b}$	$<DL^{b}$	4.3 ± 0.18^{a}	0.74 ± 0.09^{b}	$<DL^{a}$
Elk River (2)	0.14 ± 0.11^{b}	$<DL^{b}$	0.64 ± 0.33^{c}	0.21 ± 0.09^{b}	0.06 ± 0.06^{a}
Grays Harbor (3)	0.04 ± 0.04^{b}	$<DL^{b}$	1.53 ± 0.67^{c}	0.26 ± 0.06^{b}	$<DL^{a}$
Nisqually Estuary (3)	$0.71 \pm 0.14^{a,b}$	$<DL^{b}$	3.2 ± 0.46^{b}	0.59 ± 0.12^{b}	0.05 ± 0.05^{a}
Salmon River (11)	$0.78 \pm 0.38^{a,b}$	$<DL^{b}$	0.15 ± 0.09^{c}	0.08 ± 0.04^{c}	$<DL^{a}$
Skokomish Estuary (3)	0.28 ± 0.09^{b}	$<DL^{b}$	2.45 ± 0.51^{b}	0.46 ± 0.15^{b}	0.04 ± 0.04^{a}
Tillamook Bay (1)	$<DL^{b}$	$<DL^{b}$	$<DL^{c}$	$<DL^{c}$	$<DL^{a}$
Yaquina Bay (7)	0.06 ± 0.06^{b}	$<DL^{b}$	1.1 ± 0.6^{c}	0.18 ± 0.08^{b}	$<DL^{a}$
Willapa Bay (3)	$<DL^{b}$	$<DL^{b}$	0.32 ± 0.04^{c}	0.13 ± 0.07^{b}	$<DL^{a}$
Hatchery chinook					
Fall Creek (1)	2.1^{a}	0.22^{a}	4.5^{a}	1.2^{a}	$<DL^{a}$
Butte Falls (1)	1.9^{a}	0.25^{a}	4.7^{a}	1.1^{a}	$<DL^{a}$
Cole M. Rivers (1)	2.3^{a}	$<DL^{b}$	4.2^{a}	$0.88^{a,b}$	$<DL^{a}$
Elk River (2)	1.4 ± 0.9^{a}	$<DL^{b}$	3.7^{a}	$0.65^{a,b}$	0.13 ± 0.13^{b}
Trask (1)	1.7^{a}	$<DL^{b}$	3.6^{a}	$0.87^{a,b}$	$<DL^{a}$
Salmon River (1)	3.7^{a}	$<DL^{b}$	4.4^{a}	1.1^{a}	$<DL^{a}$
Estuary coho					
Alsea Bay (3)	2.5 ± 0.3^{a}	$<DL^{b}$	0.17 ± 0.04^{c}	0.2 ± 0.03b	$<DL^{a}$
Coos Bay (1)	3.3 ± 0.3^{a}	$<DL^{b}$	0.2^{c}	0.16^{b}	0.64^{d}
Grays Harbor (1)	$<DL^{b}$	$<DL^{b}$	0.35^{c}	0.13^{b}	$<DL^{a}$
Willapa Bay (1)	$<DL^{b}$	$<DL^{b}$	0.44 ± 0.26^{c}	0.13 ± 0.0^{b}	$<DL^{a}$
Yaquina Bay (3)	$<DL^{b}$	$<DL^{b}$	0.10^{c}	0.09^{b}	$<DL^{a}$

60–100% of ΣDDTs in stomach contents of both coho and chinook salmon from all sites (Fig. 12; Table 5). Additionally, *p,p*′-DDD and *p,p*′-DDT were found in both chinook and coho salmon stomach contents from several sites, with highest concentrations in juvenile chinook from the Columbia River (5.9 and 2.5 ng/g ww for *p,p*′-DDD and *p,p*′-DDT, respectively). These isomers accounted for 5–25% of total DDTs. In comparison with salmon whole bodies, *p,p*′-DDT was found at higher concentrations in stomach contents. The *o,p*'-DDTs were found only in stomach contents of chinook salmon from the Columbia River, which had measurable concentrations (0.6–1.1 ng/g ww) of both *o,p*′-DDT and *o,p*′-DDD. In stomach contents of juvenile chinook from the Elk River Hatchery, the only DDT isomer found was *p,p*′-DDE, which was present at a concentration of 4.5 ng/g ww.

In addition to PCBs, DDTs, and PAHs, chlordanes HCBs, HCHs, dieldrin, and mirex were detected in stomach contents of estuarine chinook or coho from one or more sampling sites (Table 6). In stomach contents of chinook from the Elk River Hatchery, chlordanes, HCB, and mirex were detected, all at relatively low levels (0.7–1.4 ng/g ww). Aldrin was below the limits of detection in all samples.

3.5 Relationship between contaminants in stomach contents and in salmon bodies

In chinook salmon, concentrations of PCBs and DDTs in stomach contents were significantly and positively

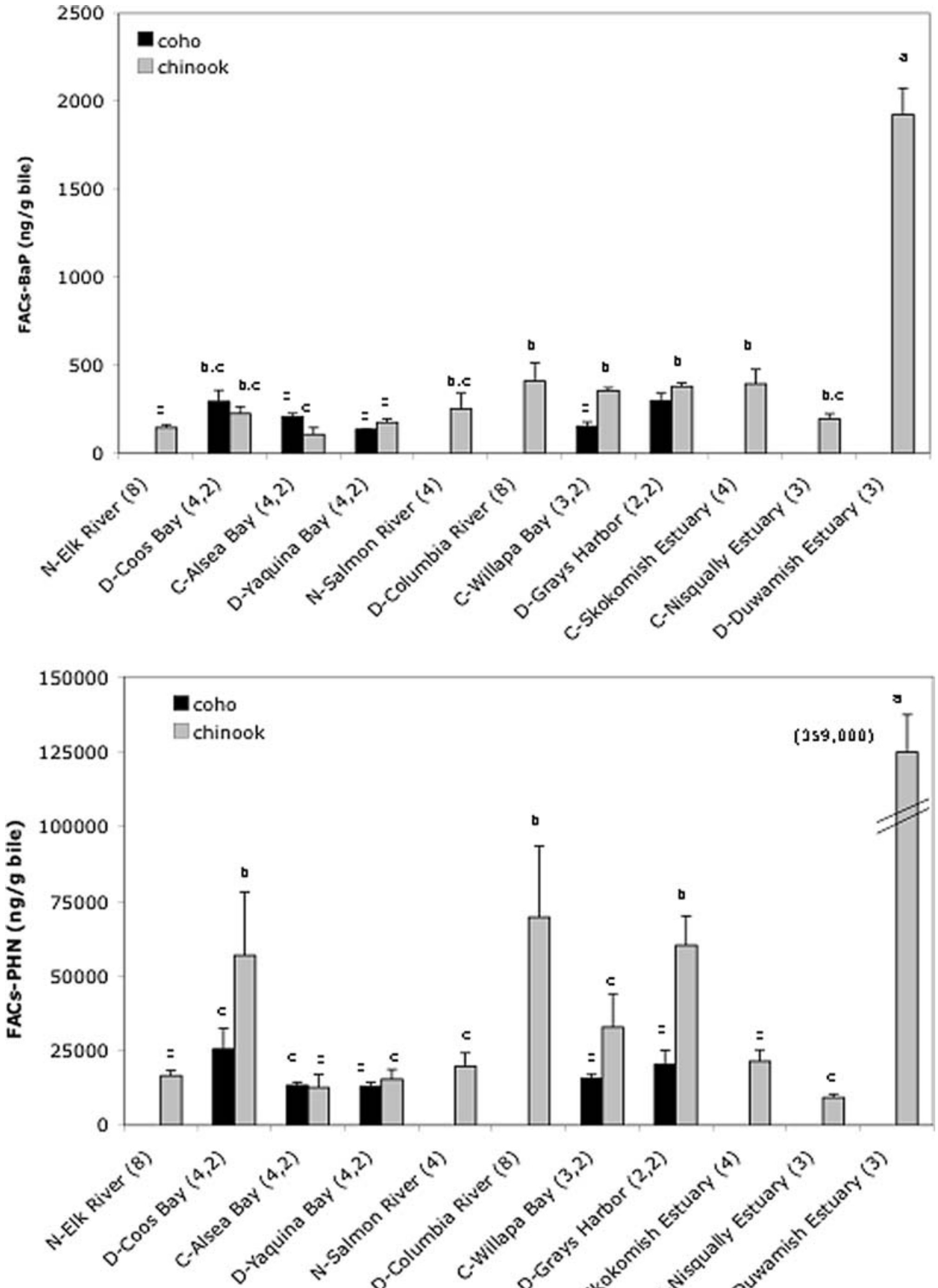

Fig. 8 Mean concentrations of fluorescent aromatic compounds (± SE) measured at phenanthrene wavelengths (FACs-PHN) and benzo[a]pyrene wavelengths (BaP-FACs) in bile of juvenile chinook and coho almon from Pacific Northwest estuaries. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Bile metabolites measured at PHN and BaP wavelengths are representative of metabolites of low and high molecular weight PAHs, respectively. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$)

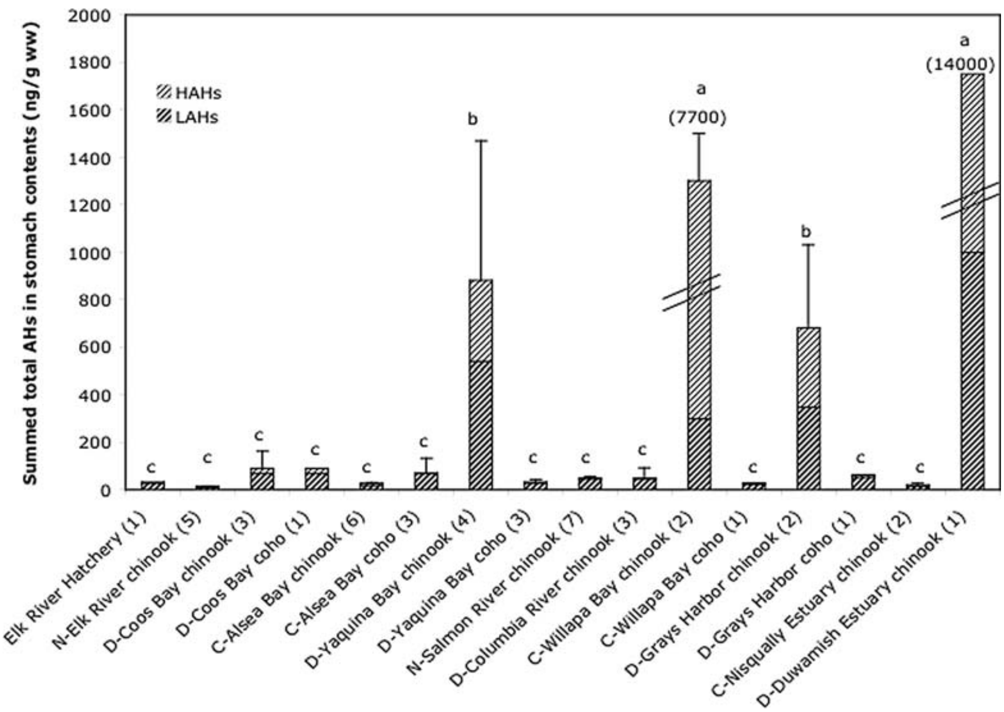

Fig. 9 Mean concentrations of total aromatic hydrocarbons (ΣAHs) (ng/g wet wt, ± SE) in stomach contents of juvenile chinook and coho salmon from Pacific Northwest estuaries and juvenile chinook salmon from Elk River hatchery. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Contributions of low molecular weight and high molecular weight AHs (LAHs and HAHs) to totals are indicated. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$)

correlated with body burdens of the same contaminants. For PCBs ($n = 46$), $r^2 = 0.32$, $p = 0.0001$; while for DDTs ($n = 40$), $r^2 = 0.38$, $p = 0.0001$. In coho salmon, concentrations of contaminant in bodies and stomach contents were also positively correlated, but relationships were marginally significant ($0.06 \leq p \leq 0.08$), in part because of smaller sample size. For body DDTs vs. stomach DDTs ($n = 9$), $r^2 = 0.34$, $p = 0.06$. For body PCBs vs. stomach PCBs ($n = 9$), $r^2 = 0.29$, $p = 0.08$.

In estuarine chinook salmon, concentrations of PCBs and DDTs (ng/g ww) in whole bodies were 3–4 times as high as in stomach contents on average, while in coho salmon, concentrations of PCBs and DDTs in whole bodies and stomach contents were about the same or only slightly higher (1–1.3 times). For chinook salmon from the Elk River Hatchery (the only hatchery where stomach contents data were available), concentrations of PCBs (ng/g ww) were 4.7 times as high in bodies as in stomach contents, while concentrations of DDTs (ng/g ww) were 25 times as high in bodies as in stomach contents.

In chinook salmon, concentrations of PAH metabolites in bile and PAHs in stomach contents were significantly, positively correlated. For ΣLAHs vs. FACs-PHN, $n = 35$, $p = 0.0001$, $r^2 = 0.56$, and for ΣHAHs vs. FACs-BaP, $n = 35$, $p = 0.0006$, $r^2 = 0.28$. In coho salmon, on the other hand, there was no significant correlation between concentrations of either ΣHAHs or ΣLAHs in stomach contents and concentrations of PAH metabolites in bile. For ΣHAHs, $n = 5$, $r^2 = 0.07$, $p = 0.33$. For ΣLAHs, $n = 5$, $r^2 = 0.18$, $p = 0.26$.

4 Discussion

Estuarine and nearshore ecosystems provide a vital role as juvenile rearing habitat for salmonid species (Levy and Northcote, 1982; Gray *et al.*, 2002; Rice *et al.*, 2005), and can be particularly important in the recovery of species at risk (Feist *et al.*, 2003; Fresh *et al.*, 2005). Unfortunately, estuarine and coastal ecosystems are also among the environments that are most heavily

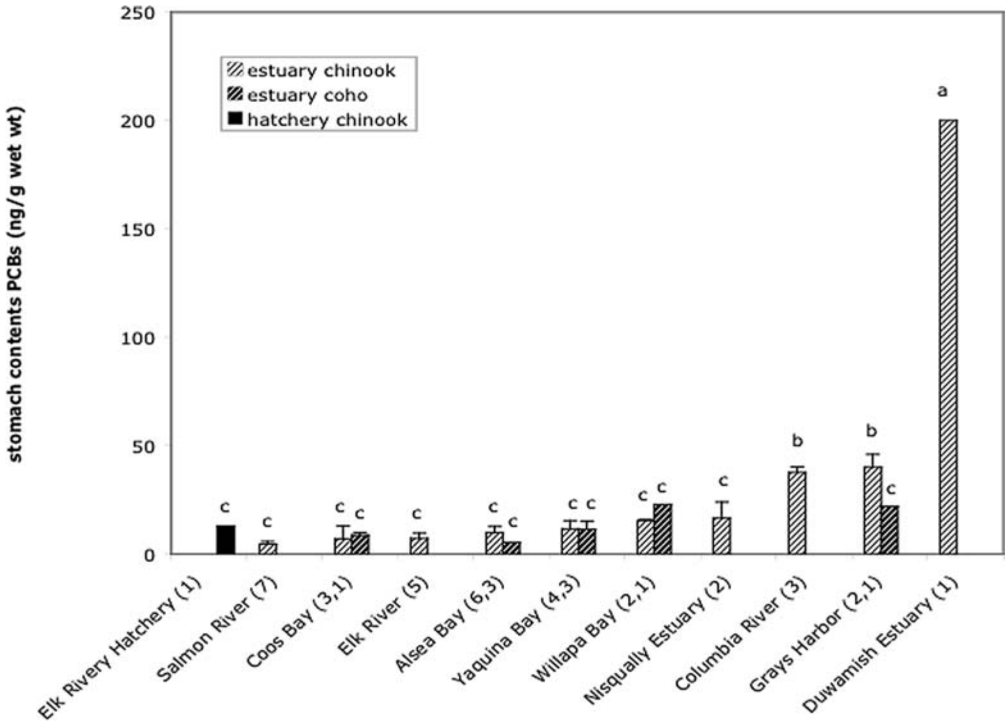

Fig. 10 Mean concentrations of ΣPCBs (ng/g wet wt. ± SE) in stomach contents of juvenile chinook and coho salmon from Pacific Northwest estuaries and juvenile chinook salmon from Elk River hatchery. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$)

impacted by anthropogenic activities (Shreffler *et al.*, 1990; Beck *et al.*, 2001; Rice *et al.*, 2005). Analyses of risks to salmon populations in estuarine environments have focused largely on alterations to or loss of physical habitat attributes (Bottom *et al.*, 2005; Gray *et al.*, 2002; Fresh *et al.*, 2005), but it is increasingly recognized that habitat degradation associated with chemical contaminants may also pose a significant risk to salmon populations (Spromberg and Meador, 2005; Fresh *et al.*, 2005; Loge *et al.*, 2005).

The importance of estuarine contamination in terms of the health of salmonid species depends in part on the life history strategy of the species in question. In general, ocean-type stocks, such as fall chinook, which spend an extended period during their first year of life in the estuary, are more vulnerable to the impacts of contaminants in this environment than stream-type stocks, such as coho salmon, which pass through the estuary relatively quickly (Fresh *et al.*, 2005). The same may be true of chum salmon, which have a long estuarine residence time (Dorcey *et al.*, 1978; Healey, 1982). Juvenile chum have shown relatively high contaminant body burdens at urban sites in previous surveys in Puget Sound, WA (Stehr *et al.*, 2000).

The results of the current study confirm that chemical contaminants are present in the prey and tissues of outmigrant juvenile salmon from a number of estuaries in the Pacific Northwest. The most widespread contaminants were PCBs, DDTs, and PAHs, which were observed in both tissues and stomach contents of chinook and coho salmon from all estuarine sampling sites, as well as in chinook salmon from local hatcheries. Although additional organochlorine pesticides (chlordanes, lindane, hexachlorobenzene, dieldrin, aldrin and mirex) were also detected in salmon tissues or stomach contents, the measured concentrations were relatively low. Like earlier studies in Puget Sound, the present study highlights the importance of the estuary as a source of exposure to chemical contaminants, especially for juvenile chinook salmon. The observation of elevated contaminant concentrations in stomach contents of salmon from sites in several estuaries indicates that fish are being exposed to these contaminants during estuarine residence through their

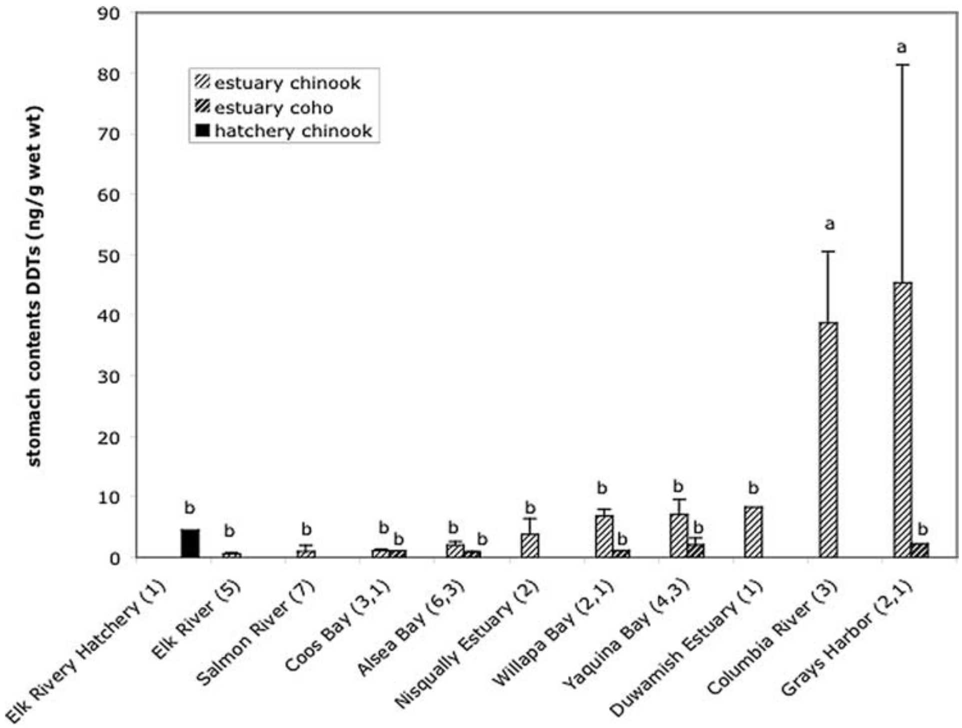

Fig. 11 Mean concentrations of ΣDDTs (ng/g ww, ± SE) in stomach contents of juvenile chinook and coho salmon from Pacific Northwest estuaries and juvenile chinook salmon from Elk River hatchery. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group. Measurements with different letters are significantly different (ANOVA, $p < 0.05$)

prey. The hypothesis that this could be an important source of uptake is further supported by the significant correlations between concentrations of PCBs and DDTs in stomach contents and whole bodies of juvenile chinook salmon, and between PAHs in stomach contents and PAH metabolites in bile. Contaminants in the water column, and in suspended particulate material, are also potential sources of exposure, although they were not measured in this study. Depending on their origin, chinook and coho salmon from some populations could also be taking up certain contaminants through the water column or the diet in freshwater before entering the estuary. This is especially true if they are passing through urbanized watersheds. However, the potential contribution of contaminants in freshwater habitats to juvenile salmon body burdens cannot be evaluated based on the samples collected in the present study.

4.1 Species differences in contaminant uptake

Of the two species we examined, chinook salmon exhibited the highest degree of uptake and accumulation of contaminants. On both a lipid weight and a wet weight basis, contaminant concentrations in whole bodies of chinook salmon were significantly higher than in coho salmon sampled from the same sites, with levels typically 2–5 times as great in chinook than in coho salmon collected at the same sites. Concentrations of contaminants in chinook salmon stomach contents tended to be higher as well, although the difference was less marked. Additionally, correlations between contaminant body burdens and contaminant concentrations in stomach contents were stronger in chinook than in coho salmon.

These findings are consistent with results of other studies on chinook and coho salmon in the Great Lakes (Manchester-Neesvig *et al*., 2001; Jackson *et al*., 2001; Rohrer *et al*., 1982), and are likely related to differences in life history and habitat use, as well as diet and metabolism. Assuming that the estuary is an important source of contaminants for outmigrant salmonids, these differences are consistent with the more prolonged period of estuarine residence in chinook salmon. Of the five species of Pacific salmon, chinook salmon

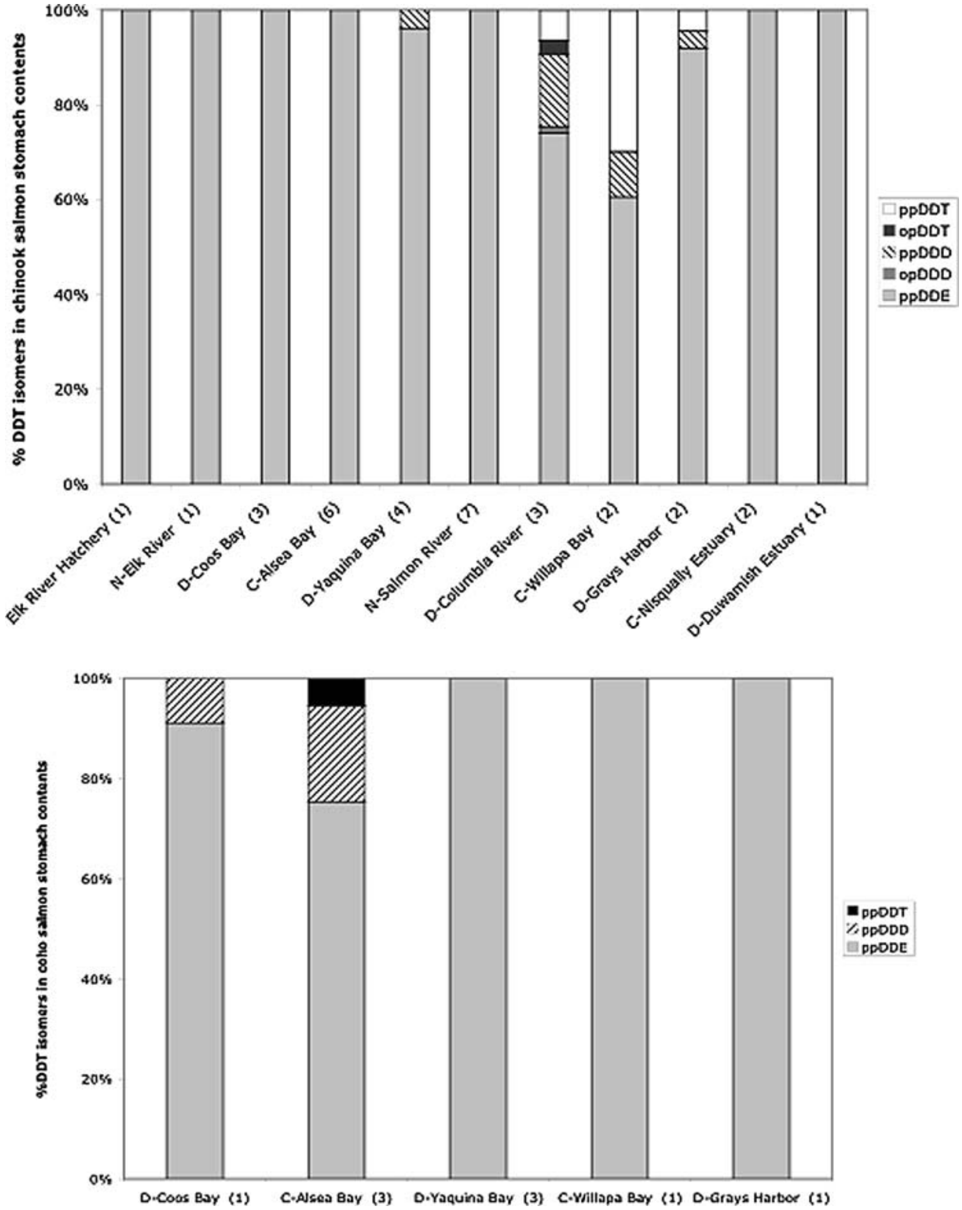

Fig. 12 Proportions of different DDTs in composite stomach contents samples of juvenile chinook and coho salmon collected from Pacific Northwest Estuaries. N = natural estuary; C = conservation estuary; S = shallow draft estuary; D = deep draft estuary. Numbers in parentheses indicate number of composite samples (10–15 fish each) analyzed per site or group

are most dependent upon estuaries during the early stages of their life cycle (Healey, 1982; 1991; Healey and Prince, 1995), typically residing in estuaries for one to two months (Simenstead *et al*., 1982), but in some cases for up to 6 months (Healey, 1982; Reimers, 1973; Levy and Northcote, 1982; Simenstad *et al*., 1982). Outmigrant juvenile coho, on the other hand, are much less estuarine-dependent, typically passing through the estuary within a few days (Moser *et al*., 1991; McMahon and Holtby, 1992; Magnusson, 2003; Duffy *et al*., 2005). Increased bioaccumulation in chinook salmon may also indicate that they are feeding at a higher trophic level than coho salmon, which would be supported by the generally higher concentrations of PCBs and DDTs in stomach contents of chinook salmon in comparison with levels in stomach contents of coho salmon collected from the same sites. This is consistent with dietary studies showing that,

Table 5 Mean concentrations (± SE) in ng/g wet wt of DDT isomers in stomach contents composites of juvenile chinook and coho salmon from Pacific Northwest estuaries, and juvenile chinook salmon from Elk River Hatchery. DDTs were measured by GC/ECD in samples collected from 1996–1998 and by GC/MS in samples collected from 1999–2001. Composites contain stomach contents from 10–15 fish. Values with different letter superscripts are significantly different (ANOVA, $p \leq 0.05$)

Site	o,p'-DDD	o,p'-DDT	p,p'-DDE	p,p'-DDD	p,p'-DDT
Hatchery chinook					
Elk River (1)	<DL^b	<DL^b	4.5^b	<DL^b	<DL^b
Estuary chinook					
Alsea Bay (6)	<DL^b	<DL^b	2.0 ± 0.6^b	<DL^b	<DL^b
Columbia River (3)	0.6 ± 0.6^a	1.1 ± 0.6^a	28.7 ± 9.1^a	5.9 ± 0.7^a	2.5 ± 1.4^a
Coos Bay (3)	<DL^b	<DL^b	1.1 ± 0.3^b	<DL^b	<DL^b
Duwamish Estuary (1)	<DL^b	<DL^b	5.8^b	<DL^b	2.5^a
Elk River (5)	<DL^b	<DL^b	0.6 ± 0.2^b	<DL^b	<DL^b
Grays Harbor (2)	<DL^b	<DL^b	41.7 ± 32.3^a	1.6 ± 1.6^b	2.1 ± 2.1^a
Nisqually Estuary (2)	<DL^b	<DL^b	3.5 ± 2.3^b	0.3 ± 0.3^b	<DL^b
Salmon River (7)	<DL^b	<DL^b	1.0 ± 1.0^b	<DL^b	<DL^b
Willapa Bay (2)	<DL^b	<DL^b	4.2 ± 0.4^b	0.7 ± 0.7^b	2.1 ± 2.1^a
Yaquina Bay (3)	<DL^b	<DL^b	6.9 ± 2.2^b	0.3 ± 0.3^b	<DL^b
Estuary coho					
Alsea Bay (3)	<DL^b	<DL^b	0.8 ± 0.1^b	0.11 ± 0.1^b	<DL^b
Coos Bay (1)	<DL^b	<DL^b	1.1^b	<DL^b	<DL^b
Grays Harbor (1)	<DL^b	<DL^b	2.3^b	<DL^b	<DL^b
Willapa Bay (1)	<DL^b	<DL^b	1.2^b	<DL^b	2.5^a
Yaquina Bay (3)	<DL^b	<DL^b	1.9 ± 0.9^b	0.2 ± 0.1^b	0.1 ± 0.1^b

Table 6 Mean concentrations (± SE) in ng/g, wet wt of selected organochlorine pesticides measured in stomach contents of juvenile chinook and coho salmon collected from the Pacific Northwest estuaries and hatcheries. Σchlordanes = summed concentrations of heptachlor, heptachlor epoxide, γ-chlordane, α-chlordane, *cis*-nonachlor, *trans*-nonachlor and nonachlor III. DL = detection limit. Pesticides were measured by GC/ECD in samples collected from 1996–1998 and by GC/MS in samples collected from 1999–2001. Values with different letter superscripts are significantly different (ANOVA, $p \leq 0.05$)

Site	lindane	dieldrin	Σchlordanes	HCB	mirex
Hatchery chinook					
Elk River (1)	<DL^b	<DL^b	1.4^c	0.7^b	0.7^b
Estuary chinook					
Alsea Bay (6)	<DL^b	<DL^b	<DL^c	0.6 ± 0.3^{b,c}	0.2 ± 0.2^b
Columbia River (3)	<DL^b	6.0 ± 6.0^a	0.8 ± 0.5^c	1.5 ± 0.8^{a,b}	0.3 ± 0.3^b
Coos Bay (3)	<DL^b	<DL^b	<DL^c	0.3 ± 0.2^c	0.6 ± 0.6^b
Duwamish Estuary (1)	<DL^b	<DL^b	12^a	<DL^c	2.5^b
Elk River (5)	<DL^b	<DL^b	1.4^c	0.3 ± 0.2^c	0.24 ± 0.25^b
Grays Harbor (2)	1.8 + 1.8^a	1.5 ± 1.5^{a,b}	6.1 ± 0.6^b	1.9 ± 1.9^a	2.7 ± 2.7^b
Nisqually Estuary (2)	<DL^b	0.9^b	0.5 ± 0.5^c	0.17 ± 0.17^c	<DL^b
Salmon River (7)	<DL^b	<DL^b	<DL^c	<DL^c	<DL^b
Willapa Bay (2)	<DL^b	6.5 ± 6.5^a	<DL^c	<DL^c	6 ± 6^a
Yaquina Bay (3)	0.6 + 0.6^a	<DL^b	1.8 ± 1.8^c	0.24 ± 0.24^c	0.4 ± 0.4^b
Estuary coho					
Alsea Bay (3)	<DL^b	<DL^b	0.17 ± 0.06^c	0.72 ± 0.22^b	<DL^b
Coos Bay (1)	<DL^b	4.0 ± 4.0^b	0.31^c	0.25^c	<DL^b
Grays Harbor (1)	<DL^b	<DL^b	<DL^c	<DL^c	<DL^b
Willapa Bay (1)	<DL^b	<DL^b	0.65^c	0.65^b	<DL^b
Yaquina Bay (3)	<DL^b	<DL^b	0.69 ± 0.36^c	0.12 ± 0.07^c	<DL^b

while there is considerable overlap in the diet of juvenile coho and chinook salmon, coho tend to consume a lower proportion of juvenile and larval fish and a higher proportion of invertebrates than chinook (Schabetsberger *et al.*, 2003; Brodeur and Pearcy, 1990).

4.2 Site-related differences in contaminant body burdens

Although contaminant concentrations in coho salmon showed no strong spatial trends, in chinook salmon there were marked intersite differences in contaminant concentrations in tissues and stomach contents, with highest exposure levels in the industrial and urbanized estuaries. Concentrations of PCBs were highest in samples from the Duwamish Estuary, and were similar to or somewhat lower than concentrations reported in earlier Puget Sound studies at this location (Stein *et al.*, 1995; Varanasi *et al.*, 1993; Meador *et al.*, 2002). Total PCB concentrations 2 to 3 times higher than those reported in this study have been measured in juvenile chinook collected from heavily contaminated Duwamish Estuary sites (Varanasi *et al.*, 1993; Meador *et al.*, 2002). The somewhat lower concentrations of PCBs observed in juvenile salmon sampled in the present study may be due to differences in sampling location, or because sampling occurred early in the season, when juvenile salmon may have only recently entered the estuary (Bottom *et al.*, 2005). The lower concentrations may also be reflective of a low proportion of hatchery fish in this sample. Such differences in contaminant concentrations between wild and hatchery-released fish have been noted in other studies (Meador *et al.*, 2002). In addition to Duwamish chinook, concentrations of PCBs were also relatively high in chinook salmon from the Columbia River and Yaquina Bay.

Interestingly, PCB concentrations in the juvenile chinook salmon we sampled were quite similar to concentrations reported in returning adult chinook salmon from Washington State (Missildine *et al.*, 2005). Mean concentrations of PCBs in adult chinook ranged from 48–50 ng/g ww in salmon returning to Puget Sound hatcheries (Deschutes and Issaquah), and from 15–29 ng/g ww in salmon returning to coastal hatcheries (Makah and Quinault). Although it is unlikely that exposures occurring in the juvenile stage make a major contribution to adult contaminant body burdens (O'Neill *et al.*, 1998), these data do suggest consistent exposure at multiple life stages for salmon from urban estuaries.

Concentrations of DDTs were especially high in juvenile chinook salmon from the Lower Columbia River and in the Nisqually Estuary in Puget Sound. The high DDT concentrations in Columbia River chinook are consistent with elevated DDT concentrations observed in other resident marine and freshwater fish from the Columbia River in earlier studies by EPA, NOAA, and USGS, and the States of Washington and Oregon (USEPA, 2000; Tetra-Tech Inc., 1993, 1994, 1996; LCREP, 1999; Brown *et al.*, 1998; Foster *et al.*, 2001a,b). As in most environmental samples, DDT breakdown products, especially p,p'-DDE, predominated in coho and chinook salmon body and stomach contents samples. However, p,p'-DDT and o,p'-DDT were also detected in samples from some sites, particularly chinook salmon from the Columbia River and Yaquina Bay, and coho salmon from Willapa Bay. The presence of these parent compounds suggests that there may be fresher sources of DDT in these areas, although the half-lives of p,p'- and o,p'-DDT in soils can be quite variable (ATSDR, 2002).

Concentrations of PAHs were especially high in stomach contents of fish from the Duwamish Estuary, Willapa Bay, Grays Harbor and Yaquina Bay, although very high concentrations of PAH metabolites in bile (i.e., >1000 ng/g bile for FACs-BaP and >200,000 ng/g bile for FACs-PHN) were observed only in fish from the Duwamish Estuary. In fish from more pristine estuaries such as Alsea Bay, Salmon River, Elk River, and Tillamook, PAH concentrations were lower than any of those previously reported in Puget Sound (Stein *et al.*, 1995; Varanasi *et al.*, 1993; McCain *et al.*, 1990). High molecular weight AHs, which originate primarily from combustion products (Varanasi *et al.*, 1992; MacDonald and Crecelius, 1994), accounted for a higher proportion of total AHs in stomach contents of fish from the Duwamish Estuary, Willapa Bay, Grays Harbor and Yaquina Bay, than in fish from other estuaries. This suggests that atmospheric emissions from incineration and automobile emissions may be major contamination sources in these areas, as well as releases from industries that generate high molecular weight PAHs (e.g., aluminum smelters, oil refineries, creosote plants; Varanasi *et al.*, 1992; MacDonald and Crecelius, 1994). The predominance of LAHs, which are primarily associated with petroleum products (Varanasi *et al.*, 1992; MacDonald and Crecelius, 1994), in stomach contents of salmon from Alsea Bay, Coos Bay, Nisqually, Salmon River, the Columbia River, and Elk River, suggests that PAHs in these areas come mainly from releases of fuel oil, crude oil, and related materials into the environment.

Ratios of ΣDDT/ΣPCB varied from site to site, indicating differences in contaminant profiles among different groups of fish. For example, the ΣDDT/ΣPCB ratio in bodies of salmon from the Columbia Estuary site (∼1.1) was higher than in juvenile chinook salmon the other estuarine sites, suggesting particularly high uptake of DDTs from the environment at this site. Fish from the Duwamish Estuary, the other hand, had one of the lowest DDT/PCB ratios, reflecting the very high concentrations of PCBs in fish from this site.

4.3 Contaminants in hatchery salmon

Measurable concentrations of PCBs and DDTs were also present in bodies of juvenile chinook salmon sampled directly from Pacific Northwest hatcheries. On a wet weight basis, concentrations of both PCBs and DDTs in hatchery chinook were relatively high, comparable to those in juvenile chinook from the more contaminated estuarine sites. However, as the lipid content of hatchery fish was also quite high (8% as compared to 1–3% in estuarine fish), when PCB and DDT body burdens were calculated on a lipid weight basis, concentrations in hatchery chinook were relatively low in comparison to levels in chinook from urban and industrialized estuaries. In stomach contents of juvenile hatchery chinook, levels of PAHs, PCBs, DDTs, were also relatively low, similar to concentrations in rural estuaries such as Elk River and Alsea Bay. This suggests that elevated contaminant concentrations in the hatchery fish we sampled are due not so much to high concentrations of contaminants in feed, but to the high body fat levels in hatchery reared juveniles that facilitate the uptake of lipid soluble contaminants. It is uncertain, though, whether the Elk River Hatchery sample is representative of feed from other sampled hatcheries, or of feeds in current use.

Chemical contaminants, especially PCBs, have been detected in hatchery fish and feed and in farmed fish in several other studies (Easton *et al.*, 2002; Parkins, 2003; Karl *et al.*, 2003; Hites *et al.*, 2004). Available data suggest that the problem is widespread, and also that contaminant concentrations in different lots of feed and in fish from different hatcheries are highly variable. Concentrations of PCBs in juvenile salmon from the Pacific Northwest hatcheries sampled in this study were similar to mean levels (∼50 ng/g ww) reported by Easton *et al.* (2002) and Hites *et al.* (2004) in farmed salmon. However, PCB concentrations in commercial feed analyzed by Easton *et al.* (2002) and Hites *et al.* (2004) were generally higher than PCB concentrations in stomach contents of Elk River Hatchery salmon, with a number of samples in the 30–90 ng/g ww range.

In the hatchery chinook we analyzed, the DDT isomers *p,p′*-DDT and *o,p′*-DDT made up a substantial proportion of DDTs present. This appears to be common in farmed and hatchery fish, and may indicate use of oils or fish meals from sources where there was relatively recent usage of DDTs (Jacobs *et al.*, 2002).

The observation of chemical contaminants in prerelease hatchery fish is likely to be a concern for the management of these animals. If contaminant body burdens are already moderate to high when fish leave the hatchery, they have an increased risk of reaching exposure concentrations during estuarine residence that could significantly reduce their likelihood of survival. Moreover, contaminated salmon may be a significant source of toxicants in the environment and in the food chain (Kreummel *et al.*, 2003). This represents a hazard for birds and other piscivorous wildlife. More comprehensive sampling of fish and feed from hatcheries is needed to determine the extent of this problem in the Pacific Northwest.

4.4 Potential health effects of contaminants on salmon

For some contaminants, exposure levels in juvenile salmon from selected sites are approaching concentrations that could affect their health and survival. Indeed, adverse health effects have been observed in juvenile salmon from the Duwamish Estuary, which is contaminated with PAHs and PCBs. Fish from this area showed immunosuppression, reduced disease resistance and decreased growth rates (Arkoosh *et al.*, 1991, 1994, 1998, 2001; Varanasi *et al.*, 1993; Casillas *et al.*, 1995, 1998), as well as biochemical alterations such as DNA damage (i.e., PAH-DNA adducts in liver) and induction of cytochrome P4501A (CYP1A), an enzyme that metabolizes selected contaminants including PAHs, dioxins and furans, and dioxin-like PCB congeners (Stein *et al.*, 1995; McCain *et al.*, 1990; Varanasi *et al.*, 1993; Collier *et al.*, 1998; Stehr *et al.*, 2000). These biochemical alterations are not necessarily indicative of adverse health effects in themselves, but are associated with disease conditions including reproductive and developmental abnormalities and liver disease (Williams *et al*., 1998; Whyte *et al*., 2000; Myers *et al*., 2003). Fish from several sites sampled in the present study (Grays Harbor, Yaquina Bay, the Columbia River) had concentrations of PCBs, PAHs or both in tissues or stomach contents that were comparable to those found in Duwamish Estuary fish, suggesting that they may also be at risk for the types of adverse health effects documented in fish from that Puget Sound site. The possibility of increased disease-induced mortality is increased by recent finding of widespread occurrence of potentially lethal parasites and pathogens in juvenile chinook and coho salmon from the estuaries sampled in this study (Arkoosh *et al*., 2004).

The potential for health risks in Pacific Northwest salmon can also be evaluated by comparing measured tissue contaminant concentrations against established effects thresholds. For PCBs, Meador *et al*. (2002) estimated a critical body residue of 2400 ng/g lipid for protection against 95% of effects ranging from enzyme induction to mortality, based on a range of sublethal effects observed in salmonids in peer-reviewed studies conducted by NMFS and other researchers. Mean PCB body burdens in juvenile salmon analyzed in this study were near or above 2400 ng/g lw in fish from three sampling sites, the Columbia River, the Duwamish Estuary, and Willapa Bay. These findings suggest that a significant portion of outmigrant juvenile chinook salmon from these sites may be at risk of some type of health impairment due to PCB exposure.

A threshold concentration for the impact of DDTs on listed salmon has not been systematically determined, unlike the PCBs (Meador *et al*., 2002). Most reported effects in salmonids are associated with whole body tissue total DDT concentrations at or above 500 ng/g ww (Allison *et al*., 1963; Burdick *et al*., 1964; Buhler *et al*., 1969; Johnson and Pecor, 1969; Peterson, 1976; Poels *et al*., 1980), or about 5000 ng/g lipid, assuming that the test fish had a lipid content of around 10%, which is typical of laboratory-reared salmonids (Meador *et al*., 2002). A number of recent studies suggest that certain DDT isomers, such as o,p'-DDT and o,p'-DDE, have estrogenic activity, and may have endocrine-disrupting or immunotoxic effects (Donohoe and Curtis, 1996; Arukwe *et al*., 1998; Celius and Walther, 1998; Khan and Thomas, 1998; Christiansen *et al*., 2000; Zaroogian *et al*., 2001; Milston *et al*., 2003; Papoulias *et al*., 2003). However, measured or estimated body burdens associated with these effects are typically in the 10–20 ng/g ww or 100–200 ng/g lipid range or above. Lipid-adjusted concentrations of total DDTs and o,p'-isomers of DDTs approached these concentrations in some fish from the Columbia River, but DDT body burdens typically found in estuarine chinook and coho salmon were substantially lower. This suggests that, by themselves, body burdens of DDTs would be unlikely to cause adverse health effects in most Pacific Northwest juvenile salmon. However, DDTs do not occur in isolation in Pacific Northwest estuaries, but are present with a variety of other contaminants. Estrogenic DDT metabolites, for example, even at low concentrations, could act in concert with other estrogenic contaminants (e.g., plasticizers, pharmaceuticals, and surfactants) to alter reproductive processes or other physiological functions. In fact, some field studies have reported effect thresholds for DDTs lower than those observed in laboratory exposure studies [e.g., maternal muscle concentrations of 25–30 ng/g ww for increased yolk sac fry mortality in Baltic salmon; Vuorinen *et al*. (1997)], possibly because of the presence of other contaminants, as well as lower lipid concentrations in wild fish. More work is needed to understand the potential cumulative effects of DDTs and other contaminants present in salmon habitats.

Exposure to PAHs may also contribute to health risks in juvenile chinook salmon from some of the sampling sites. In juvenile chinook salmon from Puget Sound sites where immunosuppression and other health effects have been observed (Arkoosh *et al*., 1991, 1994, 1998, 2001; Varanasi *et al*., 1993; Stein *et al*., 1995; Casillas *et al*., 1995, 1998; Stehr *et al*., 2000), concentrations of total PAHs in stomach contents of these fish were in the 1,200 to 8,000 ng/g ww range for ΣLAHs and in the 2,000 to 6,000 ng/g ww range for ΣHAHs, or 4,000 to 15,000 ng/g ww for total PAHs (Stein *et al*., 1995; Varanasi *et al*., 1993; Stehr *et al*., 2000). In the present study, PAH concentrations in this range were detected once again in chinook salmon from the Duwamish Estuary, suggesting a potential for health risks to fish from this site. Concentrations of ΣHAHs were also surprisingly high in stomach contents of chinook salmon from Willapa Bay, but this was not reflected in bile metabolite levels of fish from this site. Additional sampling may be needed to determine if there is consistent exposure to PAHs in Willapa Bay salmon.

In laboratory feeding studies where fish were exposed to PAHs alone, reported effect concentrations are somewhat higher than levels of PAHs measured in stomach contents of salmon from sites in where biological effects have been reported in the field, or PAH levels measured in the present study. Meador *et al.* (2005) found physiological changes in juvenile chinook exposed to 120 ppm total PAHs dry wt, or about 25,000 ng/g ww, while Bravo *et al.* (2005) observed immunosuppression, CYP1A induction and DNA damage in rainbow trout exposed to concentrations of 40,000 ng/g ww PAH in diet. Reported no effect doses for immunosuppressive and other physiological effects are in the 8,000–16,000 ng/g ww range (Palm *et al.*, 2004; Meador *et al.*, 2005). Total PAH concentrations in stomach contents of juvenile chinook collected from the Duwamish Estuary and Willapa Bay as part of this study are similar, and thus might be considered as being close to a threshold effect level. Moreover, PAHs may contribute to immunosuppressive or growth-altering impacts of other contaminants in environmental mixtures, even if they are below toxicity thresholds when considered alone (e.g., see Loge *et al.* (2005).

4.5 Trophic transfer and health effects on wildlife

Even if levels of bioaccumulative compounds such as DDTs and PCBs are not sufficient to cause direct effects on juvenile salmonids, they may represent a hazard to fish-eating predators through bioaccumulation and bioconcentration. The U.S. Fish and Wildlife Service (2004) estimated a no-observable adverse effects level (NOAEL) for impacts of fish prey on bald eagles of 60 ng/g ww for PCBs and 40 ng/g ww for DDTs, while Nendza *et al.* (1997) estimated a ΣDDTs NOAEL of 22–50 ng/g ww in fish tissue for impacts of related to bioaccumulation and bioconcentration of DDTs in estuarine systems. Juvenile chinook salmon sampled in this study from the Columbia River, the Duwamish Estuary, and the Nisqually Estuary had whole body DDT concentrations in the 20–50 ng/g ww range, and chinook salmon from the Duwamish Estuary had PCB concentrations above 60 ng/g ww, suggesting these fish may pose a hazard to fish-eating wildlife. Indeed, there is considerable evidence of bioconcentration of DDTs in birds and other wildlife that use the Columbia River, resulting in body burdens high enough to cause reproductive problems (Anthony *et al.*, 1993; USFWS, 1999, 2004; Thomas and Anthony, 2003; Henny *et al.*, 2003; Buck *et al.*, 2005).

4.6 Summary

Overall, the results of this study indicate significant exposure to PCBs, DDTs, and PAHs in outmigrant juvenile chinook salmon from several Pacific Northwest estuaries. Contaminant concentrations were generally highest in stomach contents and tissues of salmon from the deep draft estuaries, with the highest levels of urban and industrial development (i.e., the Duwamish Estuary, the Columbia River, Yaquina Bay, Coos Bay and Grays Harbor), and lowest in the natural estuaries (Elk River and Salmon River), which are largely undeveloped. However, relatively high concentrations of contaminants were detected in juvenile chinook from some of the conservation estuaries (Nisqually Estuary, Skokomish Estuary, Willapa Bay, and Alsea Bay), where land use is primarily agricultural. For example, concentrations of DDTs in salmon from the Nisqually Estuary were among the highest observed in this survey. For juvenile chinook salmon from the Duwamish Estuary, the Columbia River, and Yaquina Bay, whole body PCBs were within the range where they could potentially affect fish health and survival. In juvenile coho salmon, on the other hand, contaminant concentrations were relatively low, below estimated biological effects thresholds, and showed minimal variation from site to site. Juvenile chinook salmon are likely absorbing some contamination during estuarine residence through their prey, as PCBs, PAHs, and DDTs were consistently present in stomach contents, and PCBs and DDTs were significantly correlated with contaminant body burdens in fish from the same sites. Hatchery chinook also showed evidence of contaminant uptake. Although contaminant concentrations were not especially high in stomach contents of fish from the hatchery we tested, body burdens were elevated, in part because of the high lipid content of the fish. More research is needed to document exposure and associated effects of chemical contaminants on endangered Pacific Northwest salmon, but the available data show clearly that tissue burdens of some classes of contaminants are within the range where they could potentially affect survival and productivity of listed stocks or have adverse effects on the ecosystem of which salmon are a part.

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References

Allison, D., Kallman, B.J., Cope, O.B., & Van Valin C. (1963). Insecticides: Effects on cutthroat trout of repeated exposure to DDT. *Science*, *142*, 958–961.

Anthony, R.G., Garrett, M.G., & Schuler, C. (1993). Environmental contaminants in bald eagles in the Columbia River Estuary. *Journal of Wildlife Management, 57*, 10–19.

Arkoosh, M.R., Casillas, E., Clemons, E., McCain, B.B., & Varanasi, U. (1991). Suppression of immunological memory in juvenile chinook salmon (*Oncorhynchus tshawytscha*) from an urban estuary. *Fish & Shellfish Immunology*, *1*, 261–277.

Arkoosh, M.R., Clemons, E., Myers, M., & Casillas, E. (1994). Suppression of B-cell mediated immunity in juvenile chinook *salmon* (*Oncorhynchus tshawytscha*) after exposure to either a polycyclic aromatic hydrocarbon or to polychlorinated biphenyls'. *Immunopharmacology and Immunotoxicology*, *16*, 293–314.

Arkoosh, M.R, Casillas, E., Huffman, P., Clemons, E., Evered, J. Stein, J.E., & Varanasi., U. (1998). Increased susceptibility of juvenile chinook salmon from a contaminated estuary to the pathogen *Vibrio anguillarum*. *Transactions of the American Fisheries Society, 127*, 360–374.

Arkoosh, M.R., Casillas, E., Clemons, E., Huffman, P., Kagley, A.N., Collier, T.K., & Stein, J.E. (2001). Increased susceptibility of juvenile chinook salmon (*Oncorhynchus tshawytscha*) to vibriosis after exposure to chlorinated and aromatic compounds found in contaminated urban estuaries. *Journal of Aquatic Animal Health*, *13*, 257–268.

Arkoosh, M.R, Clemons, E., Kagley, A.N., Stafford, C., Glass, A.C., Jacobson, K., Reno, P., Myers, M.S., Casillas, E., Johnson, L.L., & Collier.T.K. (2004). Survey of pathogens in juvenile (*Onchorhynchus* spp.) migrating through Pacific Northwest estuaries. *Journal of Aquatic Animal Health, 16*, 186–196.

Arukwe, A.T., Celius, B., Walther, T., & Goksoyr, A. (1998). Plasma levels of vitellogenin and eggshell Zona radiata proteins in 4-nonyphenol and *o,p′*-DDT treated juvenile Atlantic salmon (*Salmo salar*). *Marine Environmental Research, 46*, 133–136.

ATSDR (Agency for Toxic Substances and Disease Registry): (2002). *Toxicological profile for DDT, DDE, DDD*, U.S. Department of Health and Human Services, Public Health Service. Atlanta, Georgia.

Beck, M.W., Heck, K.L., Jr., Able, K.W., Childers, D.L., Eggleston, D.B., Gillanders, B.M., Halpern, B., Hays, C.G., Hoshino, K., Minello, T.J., Orth, R.J., Sheridan, P.F., & Weinstein, M.P. (2001). The identification, conservation, and management of estuarine and marine nurseries for fish and invertebrates. *Bioscience*, *51*, 633–641.

Bottom, D.L., Simenstad, C.A., Burke, J., Baptista, A.M., Jay, D.A., Jones, K.K., Casillas, E., & Schiewe, M.H. (2005). Salmon at River's End: The Role of the Estuary in the Decline and Recovery of Columbia River Salmon. NOAA Technical Memorandum, NMFS-NWFSC-68, Northwest Fisheries Science Center, National Marine Fisheries Service, U.S. Department of Commerce, Seattle, Washington.

Bravo, C., Curtis, L., Bayne, C., Gerwick, L., Arkoosh, M., Lambertini, E., Loge, F., & Collier, T. (2005). Increased disease susceptibility in *Oncorhynchus mykiss* associated with exposure to environmentally relevant concentrations of PAH. In: Proceedings of SETAC 26th Annual Meeting in North America, 'Environmental Science in a Global Society: SETAC's Role in the Next 25 Years', November 13–17, 2005, Baltimore, Maryland, USA. Paper BRA-1117-846804.

Brodeur, R.D. & Pearcy, W.G. (1990). Trophic relations of juvenile Pacific salmon off the Oregon and Washington coast. *Fisheries Bulletin, 88*, 617–636.

Brown, D.W., McCain, B.B., Horness, B.H., Sloan, C.A., Tilbury, K.L., S.M.Pierce, S.M., Burrows, D., Chan, S-L., Landahl, J.T., & Krahn, M.M. (1998). Status, correlations, and temporal trends of chemical contaminants in fish and sediment from selected sites on the Pacific Coast of the USA. *Marine Pollution Bulletin, 37*, 67–85.

Buck, J.A., Anthony, R.G., Schuler, C.A., Isaacs, F.B., & Tillitt, D.E. (2005). Changes in productivity and contaminants in bald eagles nesting along the Lower Columbia River, USA. *Environmental Toxicology and Chemistry, 24*, 1779–1792.

Buhler, D.R., Rasmusson, M.E., & Shanks, W.E. (1969). Chronic oral DDT toxicity in juvenile coho and chinook salmon. *Toxicology and Applied Pharmacology, 14*, 535–555.

Burdick, G.E., Harris, E.J., Dean, H.J., Walker, T.M., Skea, J., & Colby, D. (1964). The accumulation of DDT in lake trout and the effect on reproduction. *Transactions of the American Fisheries Society, 93*, 127–136.

Casillas E., Arkoosh, M.R., Clemons, E., Hom, T., Misitano, D., Collier, T.K., Stein, J.E., & Varanasi, U. (1995). Chemical contaminant exposure and physiological effects in outmigrant juvenile chinook salmon from selected urban estuaries of Puget Sound, Washington. In: M. Keefe (ed), *Salmon Ecosystem Restoration: Myth and Reality: Proceedings of the 1994 Northeast Pacific chinook and Coho Salmon Workshop*, Oregon Chapter, Corvallis, OR: American Fisheries Society, pp. 85–102.

Casillas, E., Eberhart, B-T.L. Sommers, F.C., Collier, T.K., Krahn, M.M., & Stein, J.E. (1998). Effects of Chemical contaminants from the Hylebos Waterway on growth of juvenile chinook salmon. *Interpretive Report*, prepared for NOAA Damage Assessment Center by the Northwest Fisheries Science Center, Naional Marine Fisheries Service, Seattle, Washington.

Celius, T., & Walther, B.T. (1998). Differential sensitivity of zonagenesis and vitellogenesis in Atlantic salmon (*Salmo salar* L) to DDT pesticides. *Journal of Experimental Zoology, 281*, 346–353.

Christiansen, L.B., Pedersen, K.L., Pedersen, S.N., Korsgaard, B., & Bjerregaard, P. (2000). In vivo comparison of xenoestrogens using rainbow trout vitellogenin induction as a screening system. *Environmental Toxicology and Chemistry, 19*, 1867–1874.

Collier, T.K., Johnson, L.L., Stehr, C.M., Myers, M.S., Krahn, M.M., & Stein, J.E. (1998). Fish Injury in the Hylebos Waterway of Commencement Bay, Washington. NOAA Technical Memorandum, NMFS-NWFSC-36, Northwest Fisheries Science Center, National Marine Fisheries Service, Seattle, Washington.

Cortright, R., Weber, J., & Bailey, R. (1987). The Oregon Estuary Plan Book. Oregon Department of Land Conservation and Development, State of Oregon, Salem, Oregon.

Dorcey, A.H.J, Northcote, R.G., & Ward, D.V. (1978). Are the Fraser marshes essential to salmon? Technical Report, Univ. British Columbia Westwater Res. Cent. Tech. Rep. 1, University of British Columbia, Vancouver, B.C., Canada.

Donohoe, R.M., & Curtis, L.R. (1996). Estrogenic activity of chlordecone, *o,p′*-DDT and *o,p′*-DDE in juvenile rainbow trout: Induction of vitellogenesis and interaction with hepatic estrogen binding sites. *Aquatic Toxicology, 36*, 31–52.

Duffy, E.J., Beauchamp, D.A., & Buckley, R.M. (2005). Early marine life history of juvenile Pacific salmon in two regions of Puget Sound. *Estuarine*, *Coastal and Shelf Science, 64*, 94–107.

Easton, M.D.K., Luszniak, D., & Von der Geest, E. (2002). Preliminary examination of contaminant loadings in farmed salmon, wild salmon and commercial salmon feed. *Chemosphere*, *46*, 1053–1074.

Feist, B.D., Steel, E.A., Pess, G.R., & Bilby, R.E. (2003). The influence of scale on salmon habitat restoration priorities. *Animal Conservation, 6*, 271–282.

Foster, E.P, Fitzpatrick, M.S., Feist, G.W., Schreck, C.B., Yates, J., Spitsbergen, J.M., & J.R. Heidel, J.R. (2001a). Plasma androgen correlation, EROD Induction, reduced condition factor, and the occurrence of organochlorine pollutants in reproductively immature white sturgeon (*Acipenser transmontanus*) from the Columbia River, USA. *Archives of Environmental Contamination and Toxicology, 41*, 182–191.

Foster, E.P., Fitzpatrick, M.S., Feist, G.W., Schreck, C.B., & Yates, J. (2001b). Gonad organochlorine concentrations and plasma steroid levels in white sturgeon (*Acipenser transmontanus*) from the Columbia River, USA. *Bulletin of Environmental of Contamination and Toxicology*, *67*, 239–245.

Fresh, K.L., Casillas, E., Johnson, L.L., & Bottom, D.L. (2005). Role of the Estuary in the Recovery of Columbia River Basin Salmon and Steelhead: An Evaluation of the Effects of Selected Factors on Salmonid Population Viability. NOAA Technical Memorandum, NMFS-NWFSC-69, Northwest Fisheries Science Center, NOAA Fisheries, Seattle, Washington.

Gray, A., Simenstad, C.A., D.L. Bottom, D.L., & Cornwell, T.J. (2002). Contrasting functional performance of juvenile salmon habitat in recovering wetlands of the Salmon River Estuary, Oregon, U.S.A. *Restoration Ecology*, *10*, 514–526.

Healey, M.C. (1982). Juvenile Pacific salmon in estuaries: the life support system. In: V.S. Kennedy (ed), *Estuarine Comparisons*. New York: Academic Press pp. 315–341.

Healey, M.C. (1991). Life-history of chinook salmon (*Oncorhynchus tshawytscha*). In: C. Groot and L. Margolis (eds), *Pacific Salmon Life Histories*. Vancouver, British Columbia: UBC Press, pp. 311–393.

Healey, M.C., & Prince, A. (1995). Scales of variation in life history tactics of Pacific salmon and the conservation of phenotype and genotype. *American Fisheries Society Symposium*, *17*, 176–184.

Henny, C.J., Kaiser, J.L., Grove, R.A., Bentley, V.R., & Elliott, J.E. (2003). Biomagnification factors (fish to Osprey eggs from Willamette River, Oregon, U.S.A.) for PCDDs, PCDFs, PCBs and OC pesticides. *Environmental Monitoring and Assessment, 84*, 275–315.

Hites, R.A., Foran, J.A., Carpenter, D.O., Hamilton, M.C., Knuth, B.A., & Schwager, S.J. (2004). Global assessment of organic contaminants in farmed salmon. *Science*, *303*, 226–229.

Jackson, L.J., Carpenter, S.R., Manchester-Neesvig, J., & Stow, C.A. (2001). PCB congeners in Lake Michigan coho (*Oncorhynchus kisutch*) and chinook (*Oncorhynchus tshawytscha*) salmon. *Environmental Science and Technology, 35*, 856–62.

Jacobs, M.N, Covaci, A., & Schepens, P. (2002). Investigation of selected persistent organic pollutants in farmed Atlantic salmon (*Salmo salar*), salmon aquaculture feed, and fish oil components of feed. *Environmental Science and Technology, 36*, 2797–2805.

Johnson, H.E., & Pecor, C. (1969). Coho salmon mortality and DDT in Lake Michigan. *Transactions of the North American Wildlife and Natural Resources Conference*, *34*, 159.

Karl, H., Khulmann, H., & Ruhoff, U. (2003). Transfer of PCDDs and PCDFs into the edible parts of farmed rainbow trout, *Oncorhynchus mykiss* (Walbaum), via feed. *Aquaculture Research*, *34*, 1009–1014.

Khan, A. & Thomas, P. (1998). Estradiol-17 beta and *o,p′*-DDT stimulate gonadotropin release in Atlantic croaker. *Marine Environmental Research, 46*, 149–152.

Krahn, M.M., Moore, L.K., & MacLeod, J.W.D. (1986). Standard Analytical Procedures of the NOAA National Analytical Facility, 1986. Metabolites of Aromatic Compounds in Fish Bile. NOAA Technical Memorandum, NMFS-F/NWC-102, Northwest Fisheries Science Center, NOAA Fisheries, Seattle, Washington.

Kreummel, E., MacDonald, R.W., Kimpe, L.E., Gregory-Eaves, I., Demers, M.J., Smol, J.P., Finney, B., & Blais, J.M. (2003). Aquatic ecology – Delivery of pollutants by spawning salmon. *Nature*, *425*, 255–256.

Lauenstein, G.G., Cantillo A.Y., & Dolvin, S.S. (1993). NOAA National Status and Trends Program Development and Methods. In: Lauenstein, G.G., Cantillo, A.Y., (eds), *Sampling and Analytical Methods of the National Status and Trends Programs National Benthic Surveillance and Mussel Watch Projects 1984–1992,* Vol 1—Overview and Summary Methods. NOAA Technical Memorandum NOS ORCA 71. National Oceanic and Atmospheric Administration, Silver Spring, MD, USA.

LCREP (Lower Columbia River Estuary Partnership): (1999). Lower Columbia River Estuary Program Comprehensive Conservation and Management Plan. Technical Report. LCREP, Portland, Oregon, USA.

Levy, D.A. & Northcote, T.G. (1982). Juvenile salmon residency in a marsh area of the Fraser River Estuary. *Canadian Journal of Fisheries and Aquatic Sciences, 39*, 270–276.

Loge, F.J., Arkoosh, M.R., Ginn, T.R., Johnson, L.L., & Collier, T.K. (2005). Impact of environmental stressors on dynamics of disease transmission. *Environmental Science and Technology, 39*, 7329–7336. .

MacDonald, R.W., & Crecelius, E.A. (1994). Marine sediments in the Strait of Georgia, Juan de Fuca Strait, and Puget Sound: What can they tell us about contamination? *Canadian Technical Report of Fisheries and Aquatic Sciences*, *1948*, 101–134.

Magnusson, A. (2003). Estuarine influence on survival rates of coho (*Oncorhynchus kisutch*) and chinook salmon (*Oncorhynchus tshawytscha*) released from hatcheries on the U. S. Pacific Coast. Estuaries, *26*, 1094–1103.

Malins, D.C., McCain, B.B., Brown, D.W., Sparks, A.K., Hodgins, H.O., & Chan, S.-L. (1982). Chemical contaminants and abnormalities in fish and invertebrates from Puget Sound. NOAA Technical Memorandum OMPA 19. National Oceanic and Atmospheric Administration, Silver Spring, MD, USA.

Manchester-Neesvig, J.B., Valters, K., & Sonzogni, W.C. (2001). Comparison of polybrominated diphenyl ethers (PBDEs) and polychlorinated biphenyls (PCBs) in Lake Michigan salmonids. *Environmental Science and Technology, 35*, 1072–1077.

McCain, B.B., Malins, D.C., Krahn, M.M., Brown, D.W., Gronlund, W.D., Moore, L.K., & Chan. S.-L. (1990). Uptake or aromatic and chlorinated hydrocarbons by juvenile chinook salmon (*Oncorynchus tshawytscha*) in an urban estuary. *Arch Environ Contam Toxicol*, *19*, 10–16.

McMahon, T.E. & Holtby, L.B. (1992). Behavior, habitat use, and movements of coho salmon (*Oncorhynchus kisutch*) smolts during seaward migration. *Canadian Journal of Fisheries and Aquatic Sciences, 49*, 1478–1485.

Meador, J.P., Collier, T.K., & J.E. Stein, J.E. (2002). Use of tissue and sediment-based threshold concentrations of polychlorinated biphenyls (PCBs) to protect juvenile salmonids listed under the US Endangered Species Act. *Aquatic Conservation Marine and Freshwater Ecosystems*, *12*, 493–516.

Meador, J.P., Sommers, F.C., Ylitalo, G.M., & Brown, D.W. (2005). Biological responses in juvenile chinook salmon from dietary exposure to polycyclic aromatic hydrocarbons (PAHs)', in: Proceedings of SETAC 26th Annual Meeting in North America, 'Environmental Science in a Global Society: SETAC's Role in the Next 25 Years', November 13–17, 2005, Baltimore, Maryland, USA. Paper MEA-1117-84663.

Milston, R.H., Fitzpatrick, M.S., Vella, A.T., Clements, S., Gunderson, D., Feist, G., Crippe, T.L., Leong, J., & Schreck, C.B. (2003). Short-term exposure of chinook salmon (*Onchorhynchus tschawytstcha*) to *o,p′*-DDE or DMSO during early life-history stages causes long-term humoral immunosuppression. *Environmental Health Perspectives, 111*, 1601–1607.

Missildine, B.R., Peters, R.J., Chin-Leo, G., & Houck, D. (2005). Polychlorinated biphenyl concentrations in adult chinook salmon (*Oncorhynchus tshawytscha*) returning to coastal and Puget Sound hatcheries of Washington State. *Environmental Science and Technology, 39*, 6944–6951.

Moser, M.L., Olson, A.F., & Quinn, T.P. (1991). Riverine and estuarine migratory behavior of coho salmon (*Oncorhynchus kisutch*) smolts. *Canadian Journal of Fisheries and Aquatic Sciences, 48*, 1670–1678.

Myers, M.M., L.L., & Collier, T.K. (2003). Establishing the causal relationship between polycyclic aromatic hydrocarbon (PAH) exposure and hepatic neoplasms and neoplasia-related liver lesions in English sole (*Pleuronectes vetulus*). *Human and Ecological Risk Assessment, 9*, 67–94.

Nendza, M., Herbst, T., Kussatz, C., & Gies, A. (1997). Potential for secondary poisoning and biomagnification in marine organisms. *Chemosphere*, *35*, 1875–1885.

O'Neill, S.M., West, J.E., & Hoeman, J.C. (1998). Spatial trends in the concentrations of polychlorinated biphenyls (PCBs) in chinook (*Oncorhynchus tshawytscha*) and coho (*Oncorhynchus kisutch*) in Puget Sound and factors affecting PCB accumulation: results from the Puget Sound Ambient Monitoring Program. Puget Sound Research Proceedings, Olympia, WA.

Palm, R.C. Jr., Powell, D.B., Skillman, A., & Godtfredsen, K. (2004). Immunocompetence of juvenile chinook salmon against *Listonella anguillarum* following dietary exposure to polycyclic aromatic hydrocarbons. *Environmental Toxicology and Chemistry, 22*, 2986–2994.

Papoulias, D.M., Villalobos, S.A., Meadows, J., Noltie, D.B., Giesy, J.P., & Tillitt, D.E. (2003). In ovo exposure to o,p′-DDE affects sexual development but not sexual differentiation in Japanese medaka (*Oryzias latipes*). *Environmental Health Perspectives, 111*, 29–32

Parkins, C. (2003). The potential of Polychlorinated Biphenyls contamination of aquaculture products through feed. *Journal of Shellfish Research, 22*, 298–299.

Peterson, R.H. (1976). Temperature selection of Atlantic salmon (*Salmo salar*) as influenced by various toxic substances. *Journal of the Fisheries Research Board of Canada*, *33*, 1722–1730.

Poels, C.L.M., van Der Gaag, M.A., & van de Kerkhoff, J.F.J. (1980). An investigation into the long-term effect of Rhine water on rainbow trout. *Water Research, 14*, 1029–1033.

Reimers, P.E. (1973). The length of residence of juvenile fall chinook salmon in Sixes River. Oregon.Res. Rep. Fish Comm. Oreg, *4*, 3–43.

Rice, C.A. Johnson, L.L., P. Roni, P., Feist, B.E., Hood, W.G., Tear, L.A., Simenstad, C.A., & Williams G.D. (2005). Monitoring rehabilitation in temperate North American estuaries. In: Roni, P., (ed), *Monitoring Stream and Watershed Restoration*. Alpharetta, GA: American Fisheries Society, pp. 165–204.

Roher, T.K., Forney, J.C., & Hartig, J.H. (1982). Organochlorine and heavy metal residues in standard fillets of coho and chinook salmon of the Great Lakes – 1980. *Journal of Great Lakes Research, 8*, 623–634.

Schabetsberger, R., Morgan, C.A., Brodeur, R.D., Potts, C.L., Peterson, W.T., & Emmett, R.L. (2003). Prey selectivity and diel feeding chronology of juvenile chinook (*Oncorhynchus* *tshawytscha*) and coho (*O. kisutch*) salmon in the Columbia River plume. *Fisheries Oceanography, 12*, 523–540.

Shreffler, D.K., Simenstead, C.A., & Thom, R.M. (1990). Temporary residence by juvenile salmon in a restored estuarine wetland. *Canadian Journal of Fisheries and Aquatic Sciences, 47*, 2079–2084.

Simenstad, C.A., Fresh, K.L., & Salo E.O. (1982). The role of Puget Sound and Washington coastal estuaries in the life history of Pacific salmon: an unappreciated function. In: V.S. Kennedy (ed), *Estuarine Comparisons*. New York: *Academic Press*, pp. 343–364.

Sloan, C.A., N.G. Adams, N.G., Pearce, R.W., Brown, D.W., & Chan, S-L. (1993). Northwest Fisheries Science Center Organic Analytical Procedures. In: Lauenstein, G.G. and Cantillo, A.Y., (eds.) *Sampling and Analytical Methods of the National Status and Trends Program, National Benthic Surveillance and Mussel Watch Projects 1984–1992*. Volume IV. Comprehensive Descriptions of Trace Organic Analytical Methods. U.S. Dept. Commerce, NOAA Technical. Memorandum. NOS ORCA 71, National Oceanic and Atmospheric Administration, Maryland, USA: Silver Spring, pp. 53–97

Sloan, C.A., Brown, D.W., Pearce, R.W., Boyer, R.H., Bolton, J.L., Burrows, D.G., Herman, D.P., & Krahn, M.M. (2005). Determining aromatic hydrocarbons and chlorinated hydrocarbons in sediments and tissues using accelerated solvent extraction and gas chromatography/mass spectrometry. In: Ostrander, G.K., (ed), *Techniques in Aquatic Toxicology – Volume 2*, Boca Raton, FL: CRC Press.

Spromberg, J.A., & Meador, J.P. (2005). Population-level effects on chinook salmon from chronic toxicity test measurement endpoints. *Integrated Environmental Monitoring and Assessment*, *1*, 9–21.

Stehr, C.M., Brown, D.W., Hom, T., Anulacion, B.F., Reichert, W.L., & Collier, T.K. (2000). Exposure of juvenile chinook and chum salmon to chemical contaminants in the Hylebos Waterway of Commencement Bay, Tacoma, Washington. *Journal of Aquatic Ecosystem Stress and Recovery*, *7*, 215–227.

Stein, J.E., Hom, T., Collier, T.K., Brown, D.W., & Varanasi, U. (1995). Contaminant exposure and biochemical effects in outmigrant juvenile chinook salmon from urban and nonurban estuaries of Puget Sound, WA. *Environmental Toxicology and Chemistry, 14*, 1019–1029.

Telliard, W.A. (1999). EPA analytical methods for the determination of pollutants in the environment. *Critical Reviews in Analytical Chemistry, 29*, 249–257.

TetraTech Inc. (1993). Reconnaissance survey of the Lower Columbia River. *Final Reconnaissance Report* TC-8526-06. Prepared for Lower Columbia River Bi- State Water Quality Program by Tetra Tech, Inc., Redmond, Washington, USA.

TetraTech Inc. (1994). Lower Columbia River backwater reconnaissance survey. *Reconnaissance Report* TC 9405-01 Prepared for Lower Columbia River Bi-State Water Quality Program by Tetra Tech, Inc., Redmond, Washington, USA.

TetraTech Inc. (1996). Lower Columbia River Bi-State Program-The Health of the River, 1990–1996. *Integrated Technical Report* 0253-01, prepared for Oregon Department of Environmental Quality and Washington Department of Ecology by Tetra Tech, Inc., Redmond, Washington, USA.

Thomas, C.M. & Anthony, R.G. (2003). Environmental contaminants in great blue herons (*Ardea herodias*) from the Lower Columbia and Willamette Rivers, Oregon and Washington, USA. *Environmental Toxicology and Chemistry, 18*, 2804–2816.

USEPA (U.S. Environmental Protection Agency). (1997). The Incidence and Severity of Sediment Contamination in Surface Waters of the United States. Volume 1: National Sediment Quality Survey. *EPA Report* No. EPA 823-R-97-006. Washington, D.C.: Office of Science and Technology.

USEPA. (2000). Columbia River Basin Fish Contaminant Survey1996–1998. *EPA Report* No. EPA 910-R-02-006. U.S. Environmental Protection Agency. Region 10. Seattle, Washington 98101.

USFWS (U.S. Fish and Wildlife Service): (1999). Organochlorine contaminants in double-crested cormorants from Lewis and Clark National Wildlife Refuge in the Columbia River Estuary. *Technical Report*, U.S. Fish and Wildlife Service. Portland, OR: Oregon Fish and Wildlife Office.

UWFWS. (2004). Environmental contaminants in aquatic resources from the Columbia River. U.S. Fish and Wildlife Service, *Technical Report*, Portland, Oregon, USA: Oregon Fish and Wildlife Office.

Varanasi, U., Stein, J.E., Reichert, W.L., Tilbury, K.L., Krahn, M.M., & Chan, S.-L. (1992). Chlorinated and aromatic hydrocarbons in bottom sediments, fish and marine mammals in US coastal waters: Laboratory and field studies of metabolism and accumulation. In: Walker, C., and D.R. Livingstone (eds), *Persistent Pollutants in the Marine Environment*. New York, New York, USA: Permagon Press.

Varanasi, U., Casillas, E., Arkoosh, M.R., Hom, T., Misitano, D.A., Brown, D.W., Chan, S.-L,, Collier, T.K., McCain, B.B., & Stein, J.E. (1993). Contaminant exposure and associated biological effects in juvenile chinook salmon (*Oncorhynchus tshawytscha*) from urban and nonurban estuaries of Puget Sound, *NOAA Technical Memorandum*. NMFS-NWFSC-8, Northwest Fisheries Science Center, Seattle, Washington.

Vuorinen, P.J., Paasivirta, J., Keinaenen, M., Koistinen, J., Rantio, T., Hyoetylaeinen, T., & Welling, L. (1997). The M74 syndrome of Baltic salmon (*Salmo salar*) and organochlorine concentrations in the muscle of female salmon. *Chemosphere*, *34*, 1151–1166.

Whyte J.J., Jung R.E., Schmitt C.J., & Tillitt D.E. (2000). Ethoxyresorufin-O-deethylase (EROD) activity in fish as a biomarker of chemical exposure. *Critical Reviews in Toxicology, 30*, 347–570

Williams, D.E., Lech, J.J., & Buhler, D.R. (1998). Xenobiotics and xenoestrogens in fish: modulation of cytochrome P450 and carcinogenesis. *Mutation Research, 399*, 179–92.

Zaroogian, G. Gardner, D., Borsay Horowitz, B., Gutjahr-Gobell, R., Haebler, R., & Mills, L. (2001). Effect of 17beta-estradiol, o,p-DDT, octylphenol and p,p-DDE on gonadal development and liver and kidney pathology in juvenile male summer flounder (*Paralichthys dentatus*). *Aquatic Toxicology, 54*, 101–112.

Circular A-4

September 17, 2003

TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS

Subject: Regulatory Analysis

This Circular provides the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order12866, "Regulatory Planning and Review," the Regulatory Right-to-Know Act, and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This Circular refines OMB's "best practices" document of 1996 (http://www.whitehouse.gov/omb/inforeg/riaguide.html), which was issued as a guidance in 2000 (http://www.whitehouse.gov/omb/memoranda/m00-08.pdf), and reaffirmed in 2001 (http://www.whitehouse.gov/omb/memoranda/m01-23.html). It replaces both the 1996 "best practices" and the 2000 guidance.

In developing this Circular, OMB first developed a draft that was subject to public comment, interagency review, and peer review. Peer reviewers included Cass Sunstein, University of Chicago; Lester Lave, Carnegie Mellon University; Milton C. Weinstein and James K. Hammitt of the Harvard School of Public Health; Kerry Smith, North Carolina State University; Jonathan Weiner, Duke University Law School; Douglas K. Owens, Stanford University; and W. Kip Viscusi, Harvard Law School. Although these individuals submitted comments, OMB is solely responsible for the final content of this Circular.

A. Introduction

This Circular is designed to assist analysts in the regulatory agencies by defining good regulatory analysis – called either "regulatory analysis" or "analysis" for brevity – and standardizing the way benefits and costs of Federal regulatory actions are measured and reported. Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1). This requirement applies to rulemakings that rescind or modify existing rules as well as to rulemakings that establish new requirements.

The Need for Analysis of Proposed Regulatory Actions[1]

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects –

[1] We use the term "proposed" to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

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good and bad – of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis sometimes will show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

Benefit-cost analysis is a primary tool used for regulatory analysis.[2] Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. If the non-quantified benefits and costs are likely to be important, you should carry out a "threshold" analysis to evaluate their significance. Threshold or "break-even" analysis answers the question, "How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?" In addition to threshold analysis you should indicate, where possible, which non-quantified effects are most important and why.

Key Elements of a Regulatory Analysis

A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.

To evaluate properly the benefits and costs of regulations and their alternatives, you will need to do the following:

- Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.
- Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This normally will be a "no action" baseline: what the world will be like if the proposed rule is not adopted. Comparisons to a "next best" alternative are also especially useful.

[2] See Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.

As you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

A good analysis is transparent. It should be possible for a qualified third party reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the time horizon for the analysis and the discount rates applied to future benefits and costs. It is usually necessary to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to plausible changes in the main assumptions and numeric inputs.

A good analysis provides specific references to all sources of data, appendices with documentation of models (where necessary), and the results of formal sensitivity and other uncertainty analyses. Your analysis should also have an executive summary, including a standardized accounting statement.

B. The Need for Federal Regulatory Action

Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary. If the regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use. Executive Order 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people ... ."

Executive Order 12866 also states that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." Thus, you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy. If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively. You should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values.

Market Failure or Other Social Purpose

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality, common property resource and public good

An externality occurs when one party's actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. If bargaining were costless and all property rights were well defined, people would eliminate externalities through bargaining without the need for government regulation.[3] From this perspective, externalities arise from high transactions costs and/or poorly defined property rights that prevent people from reaching efficient outcomes through market transactions.

Resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent common property resources. "Public goods," such as defense or basic scientific research, are goods where provision of the good to some individuals cannot occur without providing the same level of benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices. They may exercise market power collectively or unilaterally. Government action can be a source of market power, such as when regulatory actions exclude low-cost imports. Generally, regulations that increase market power

[3] See Coase RH (1960), *Journal of Law and Economics*, 3, 1-44.

for selected entities should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer – local gas and electricity distribution services, for example – a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and/or production decisions. Nevertheless, you should keep in mind that technological advances often affect economies of scale. This can, in turn, transform what was once considered a natural monopoly into a market where competition can flourish.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. Because information, like other goods, is costly to produce and disseminate, your evaluation will need to do more than demonstrate the possible existence of incomplete or asymmetric information. Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, such as a seller offering a warranty or a third party providing information.

Even when adequate information is available, people can make mistakes by processing it poorly. Poor information-processing often occurs in cases of low probability, high-consequence events, but it is not limited to such situations. For instance, people sometimes rely on mental rules-of-thumb that produce errors. If they have a clear mental image of an incident which makes it cognitively "available," they might overstate the probability that it will occur. Individuals sometimes process information in a biased manner, by being too optimistic or pessimistic, without taking sufficient account of the fact that the outcome is exceedingly unlikely to occur. When mistakes in information processing occur, markets may overreact. When it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met. However, the mere possibility of poor information processing is not enough to justify regulation. If you think there is a problem of information processing that needs to be addressed, it should be carefully documented.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In addition, Congress establishes some regulatory programs to redistribute resources to select groups. Such regulations should be examined to ensure that they are both effective and cost-effective. Congress also authorizes some regulations to prohibit discrimination that conflicts with generally accepted norms within our society. Rulemaking may also be appropriate to protect privacy, permit more personal freedom or promote other democratic aspirations.

Showing That Regulation at the Federal Level Is the Best Way to Solve the Problem

Even where a market failure clearly exists, you should consider other means of dealing with the failure before turning to Federal regulation. Alternatives to Federal regulation include antitrust enforcement, consumer-initiated litigation in the product liability system, or administrative compensation systems.

In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally.

The advantages of leaving regulatory issues to State and local authorities can be substantial. If public values and preferences differ by region, those differences can be reflected in varying State and local regulatory policies. Moreover, States and localities can serve as a testing ground for experimentation with alternative regulatory policies. One State can learn from another's experience while local jurisdictions may compete with each other to establish the best regulatory policies. You should examine the proper extent of State and local discretion in your rulemaking context.

A diversity of rules may generate gains for the public as governmental units compete with each other to serve the public, but duplicative regulations can also be costly. Where Federal regulation is clearly appropriate to address interstate commerce issues, you should try to examine whether it would be more efficient to retain or reduce State and local regulation. The local benefits of State regulation may not justify the national costs of a fragmented regulatory system. For example, the increased compliance costs for firms to meet different State and local regulations may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking.

The role of Federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.

The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- price controls in competitive markets;

- production or sales quotas in competitive markets;
- mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

C. Alternative Regulatory Approaches

Once you have determined that Federal regulatory action is appropriate, you will need to consider alternative regulatory approaches. Ordinarily, you will be able to eliminate some alternatives through a preliminary analysis, leaving a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order. The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. The following is a list of alternative regulatory actions that you should consider.

Different Choices Defined by Statute

When a statute establishes a specific regulatory requirement and the agency is considering a more stringent standard, you should examine the benefits and costs of reasonable alternatives that reflect the range of the agency's statutory discretion, including the specific statutory requirement.

Different Compliance Dates

The timing of a regulation may also have an important effect on its net benefits. Benefits may vary significantly with different compliance dates where a delay in implementation may result in a substantial loss in future benefits (e.g., a delay in implementation could result in a significant reduction in spawning stock and jeopardize a fishery). Similarly, the cost of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs. In this instance, a regulation that provides sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

Different Enforcement Methods

Compliance alternatives for Federal, State, or local enforcement include on-site inspections, periodic reporting, and noncompliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their benefits and costs, you should identify the most appropriate enforcement framework. For example, in some circumstances random monitoring or parametric monitoring will be less expensive and nearly as effective as continuous monitoring.

Different Degrees of Stringency

In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups.

Different Requirements for Different Sized Firms

You should consider setting different requirements for large and small firms, basing the requirements on estimated differences in the expected costs of compliance or in the expected benefits. The balance of benefits and costs can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost. This has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create. You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act. (5 U.S.C. 603(c), 604).

Different Requirements for Different Geographic Regions

Rarely do all regions of the country benefit uniformly from government regulation. It is also unlikely that costs will be uniformly distributed across the country. Where there are significant regional variations in benefits and/or costs, you should consider the possibility of setting different requirements for the different regions.

Performance Standards Rather than Design Standards

Performance standards express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.

Market-Oriented Approaches Rather than Direct Controls

Market-oriented approaches that use economic incentives should be explored. These alternatives include fees, penalties, subsidies, marketable permits or offsets, changes in liability or property rights (including policies that alter the incentives of insurers and insured parties), and required bonds, insurance or warranties. One example of a market-oriented approach is a program that allows for averaging, banking, and/or trading (ABT) of credits for achieving additional emission reductions beyond the required air emission standards. ABT programs can be extremely valuable in reducing costs or achieving earlier or greater benefits, particularly when the costs of achieving compliance vary across production lines, facilities, or firms. ABT can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable local air quality outcomes (such as "hot spots" from local pollution concentration).

Informational Measures Rather than Regulation

If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.

Specific informational measures should be evaluated in terms of their benefits and costs. Some effects of informational measures are easily overlooked. The costs of a mandatory disclosure requirement for a consumer product will include not only the cost of gathering and communicating the required information, but also the loss of net benefits of any information displaced by the mandated information. The other costs also may include the effect of providing information that is ignored or misinterpreted, and inefficiencies arising from the incentive that mandatory disclosure may give to overinvest in a particular characteristic of a product or service.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. To correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use, because competing firms that score well according to the system should thereby have an incentive to publicize the fact.

D. Analytical Approaches

Both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, you should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety to the extent that a valid effectiveness measure can be developed to represent expected health and safety outcomes. You should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes. In undertaking these analyses, it is important to keep in mind the larger objective of analytical consistency in estimating benefits and costs across regulations and agencies, subject to statutory limitations. Failure to maintain such consistency may prevent achievement of the most risk reduction for a given level of resource expenditure. For all other major rulemakings, you should carry out a BCA. If some of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA. In unusual cases where no quantified information on benefits, costs and effectiveness can be produced, the regulatory analysis should present a qualitative discussion of the issues and evidence.

Benefit-Cost Analysis

A distinctive feature of BCA is that both benefits and costs are expressed in monetary units, which allows you to evaluate different regulatory options with a variety of attributes using a common measure.[4] By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that maximizes net benefits.

The size of net benefits, the absolute difference between the projected benefits and costs, indicates whether one policy is more efficient than another. The ratio of benefits to costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results.

Even when a benefit or cost cannot be expressed in monetary units, you should still try to measure it in terms of its physical units. If it is not possible to measure the physical units, you should still describe the benefit or cost qualitatively. For more information on describing qualitative information, see the section "*Developing Benefit and Cost Estimates.*"

When important benefits and costs cannot be expressed in monetary units, BCA is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.

You should exercise professional judgment in identifying the importance of non-quantified factors and assess as best you can how they might change the ranking of alternatives based on estimated net benefits. If the non-quantified benefits and costs are likely to be important, you should recommend which of the non-quantified factors are of sufficient importance to justify consideration in the regulatory decision. This discussion should also include a clear explanation that support designating these non-quantified factors as important. In this case, you should also consider conducting a threshold analysis to help decision makers and other users of the analysis to understand the potential significance of these factors to the overall analysis.

Cost-Effectiveness Analysis[5]

[4] Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.
[5] For a full discussion of CEA, see Gold, ML, Siegel, JE, Russell, LB, and Weinstein, MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York.

Cost-effectiveness analysis can provide a rigorous way to identify options that achieve the most effective use of the resources available without requiring monetization of all of relevant benefits or costs. Generally, cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome (e.g., an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (e.g., units of health improvement).

Cost-effectiveness results based on averages need to be treated with great care. They suffer from the same drawbacks as benefit-cost ratios. The alternative that exhibits the smallest cost-effectiveness ratio may not be the best option, just as the alternative with the highest benefit-cost ratio is not always the one that maximizes net benefits. Incremental cost-effectiveness analysis (discussed below) can help to avoid mistakes that can occur when policy choices are based on average cost-effectiveness.

CEA can also be misleading when the "effectiveness" measure does not appropriately weight the consequences of the alternatives. For example, when effectiveness is measured in tons of reduced pollutant emissions, cost-effectiveness estimates will be misleading unless the reduced emissions of diverse pollutants result in the same health and environmental benefits.

When you have identified a range of alternatives (e.g., different levels of stringency), you should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements. Ideally, your CEA would present an array of cost-effectiveness estimates that would allow comparison across different alternatives. However, analyzing all possible combinations is not practical when there are many options (including possible interaction effects). In these cases, you should use your judgment to choose reasonable alternatives for careful consideration.

When constructing and comparing incremental cost-effectiveness ratios, you should be careful to determine whether the various alternatives are mutually exclusive or whether they can be combined. If they can be combined, you should consider which might be favored under different regulatory budget constraints (implicit or explicit). You should also make sure that inferior alternatives identified by the principles of strong and weak dominance are eliminated from consideration.[6]

The value of CEA is enhanced when there is consistency in the analysis across a diverse set of possible regulatory actions. To achieve consistency, you need to carefully construct the two key components of any CEA: the cost and the "effectiveness" or performance measures for the alternative policy options.

With regard to measuring costs, you should be sure to include all the relevant costs to society – whether public or private. Rulemakings may also yield cost savings (e.g., energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred to comply with the requirements (sometimes

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[6] Gold ML, Siegel JE, Russell LB, and Weinstein MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 284-285.

called “total” costs) minus any cost savings. You should be careful to avoid double-counting effects in both the numerator and the denominator of the cost-effectiveness ratios. For example, it would be incorrect to reduce gross costs by an estimated monetary value on life extension if life-years are already used as the effectiveness measure in the denominator.

In constructing measures of “effectiveness”, final outcomes, such as lives saved or life-years saved, are preferred to measures of intermediate outputs, such as tons of pollution reduced, crashes avoided, or cases of disease avoided. Where the quality of the measured unit varies (e.g., acres of wetlands vary substantially in terms of their ecological benefits), it is important that the measure capture the variability in the value of the selected “outcome” measure. You should provide an explanation of your choice of effectiveness measure.

Where regulation may yield several different beneficial outcomes, a cost-effectiveness comparison becomes more difficult to interpret because there is more than one measure of effectiveness to incorporate in the analysis. To arrive at a single measure you will need to weight the value of disparate benefit categories, but this computation raises some of the same difficulties you will encounter in BCA. If you can assign a reasonable monetary value to all of the regulation's different benefits, then you should do so. But in this case, you will be doing BCA, not CEA.

When you can estimate the monetary value of *some* but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost. (This net cost estimate for the rule may turn out to be negative – that is, the monetized benefits exceed the cost of the rule.) If you are unable to estimate the value of some of the ancillary benefits, the cost-effectiveness ratio will be overstated, and this should be acknowledged in your analysis. CEA does not yield an unambiguous choice when there are benefits or costs that have not been incorporated in the net-cost estimates. You also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved.

The Effectiveness Metric for Public Health and Safety Rulemakings

When CEA is applied to public health and safety rulemakings, one or more measures of effectiveness must be selected that permits comparison of regulatory alternatives. Agencies currently use a variety of effectiveness measures.

There are relatively simple measures such as the number of lives saved, cases of cancer reduced, and cases of paraplegia prevented. Sometimes these measures account only for mortality information, such as the number of lives saved and the number of years of life saved. There are also more comprehensive, integrated measures of effectiveness such as the number of "equivalent lives" (ELs) saved and the number of "quality-adjusted life years" (QALYs) saved.

The main advantage of the integrated measures of effectiveness is that they account for a rule's impact on morbidity (nonfatal illness, injury, impairment and quality of life) as well as premature death. The inclusion of morbidity effects is important because (a) some illnesses (e.g., asthma) cause more instances of pain and suffering than they do premature death, (b) some population groups are known to experience elevated rates of morbidity (e.g, the elderly and the poor) and thus have a strong interest in morbidity measurement[7], and (c) some regulatory alternatives may be more effective at preventing morbidity than premature death (e.g., some advanced airbag designs may diminish the nonfatal injuries caused by airbag inflation without changing the frequency of fatal injury prevented by airbags).

However, the main drawback of these integrated measures is that they must meet some restrictive assumptions to represent a valid measure of individual preferences.[8] For example, a QALY measure implicitly assumes that the fraction of remaining lifespan an individual would give up for an improvement in health-related quality of life does not depend on the remaining lifespan. Thus, if an individual is willing to give up 10 years of life among 50 remaining years for a given health improvement, he or she would also be willing to give up 1 year of life among 5 remaining years. To the extent that individual preferences deviate from these assumptions, analytic results from CEA using QALYs could differ from analytic results based on willingness-to-pay-measures.[9] Though willingness to pay is generally the preferred economic method for evaluating preferences, the CEA method, as applied in medicine and health, does not evaluate health changes using individual willingness to pay. When performing CEA, you should consider using at least one integrated measure of effectiveness when a rule creates a significant impact on both mortality and morbidity.

When CEA is performed in specific rulemaking contexts, you should be prepared to make appropriate adjustments to ensure fair treatment of all segments of the population. Fairness is important in the choice and execution of effectiveness measures. For example, if QALYs are used to evaluate a lifesaving rule aimed at a population that happens to experience a high rate of disability (i.e., where the rule is not designed to affect the disability), the number of life years saved should not necessarily be diminished simply because the rule saves the lives of people with life-shortening disabilities. Both analytic simplicity and fairness suggest that the estimated number of life years saved for the disabled population should be based on average life expectancy information for the relevant age cohorts. More generally, when numeric adjustments are made for life expectancy or quality of life, analysts should prefer use of population averages rather than information derived from subgroups dominated by a particular demographic or income group.

OMB does not require agencies to use any specific measure of effectiveness. In fact, OMB encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives. The regulatory analysis should explain which measures were selected and why, and how they were implemented.

The analytic discretion provided in choice of effectiveness measure will create some inconsistency in how agencies evaluate the same injuries and diseases, and it will be difficult for

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[7] Russell LB and Sisk JE (2000), "Modeling Age Differences in Cost Effectiveness Analysis", *International Journal of Technology Assessment in Health Care*, 16(4), 1158-1167.
[8] Pliskin JS, Shepard DS, and Weinstein MC (1980), "Utility Functions for Life Years and Health Status," *Operations Research*, 28(1), 206-224.
[9] Hammitt JK (2002), "QALYs Versus WTP," *Risk Analysis*, 22(5), pp. 985-1002.

OMB and the public to draw meaningful comparisons between rulemakings that employ different effectiveness measures. As a result, agencies should use their web site to provide OMB and the public with the underlying data, including mortality and morbidity data, the age distribution of the affected populations, and the severity and duration of disease conditions and trauma, so that OMB and the public can construct apples-to-apples comparisons between rulemakings that employ different measures.

There are sensitive technical and ethical issues associated with choosing one or more of these integrated measures for use throughout the Federal government. The Institute of Medicine (IOM) may assemble a panel of specialists in cost-effectiveness analysis and bioethics to evaluate the advantages and disadvantages of these different measures and other measures that have been suggested in the academic literature. OMB believes that the IOM guidance will provide Federal agencies and OMB useful insight into how to improve the measurement of effectiveness of public health and safety regulations.

Distributional Effects

Those who bear the costs of a regulation and those who enjoy its benefits often are not the same people. The term "distributional effect" refers to the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography). Benefits and costs of a regulation may also be distributed unevenly over time, perhaps spanning several generations. Distributional effects may arise through "transfer payments" that stem from a regulatory action as well. For example, the revenue collected through a fee, surcharge in excess of the cost of services provided, or tax is a transfer payment.

Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency. Executive Order 12866 authorizes this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups. You should be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups. Effects on the distribution of income that are transmitted through changes in market prices can be important, albeit sometimes difficult to assess. Your analysis should also present information on the streams of benefits and costs over time in order to provide a basis for assessing intertemporal distributional consequences, particularly where intergenerational effects are concerned.

E. Identifying and Measuring Benefits and Costs

This Section provides guidelines for your preparation of the benefit and cost estimates required by Executive Order 12866 and the "Regulatory Right-to-Know Act." The discussions in previous sections will help you identify a workable number of alternatives for consideration in your analysis and an appropriate analytical approach to use.

General Issues

1. Scope of Analysis

Your analysis should focus on benefits and costs that accrue to citizens and residents of the United States. Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately. The time frame for your analysis should cover a period long enough to encompass all the important benefits and costs likely to result from the rule.

2. Developing a Baseline

You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action. The choice of an appropriate baseline may require consideration of a wide range of potential factors, including:

- evolution of the market,
- changes in external factors affecting expected benefits and costs,
- changes in regulations promulgated by the agency or other government entities, and
- the degree of compliance by regulated entities with other regulations.

It may be reasonable to forecast that the world absent the regulation will resemble the present. If this is the case, however, your baseline should reflect the future effect of current government programs and policies. For review of an existing regulation, a baseline assuming "no change" in the regulatory program generally provides an appropriate basis for evaluating regulatory alternatives. When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies' regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline. You should also discuss the reasonableness of the baselines used in the sensitivity analyses. For each baseline you use, you should identify the key uncertainties in your forecast.

EPA's 1998 final PCB disposal rule provides a good example of using different baselines. EPA used several alternative baselines, each reflecting a different interpretation of existing regulatory requirements. In particular, one baseline reflected a literal interpretation of EPA's 1979 rule and another the actual implementation of that rule in the year immediately preceding the 1998 revision. The use of multiple baselines illustrated the substantial effect changes in EPA's implementation policy could have on the cost of a regulatory program. In the years after EPA adopted the 1979 PCB disposal rule, changes in EPA policy -- especially allowing the disposal of automobile "shredder fluff" in municipal landfills -- reduced the cost of the program by more than $500 million per year.

In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.

3. Evaluation of Alternatives

You should describe the alternatives available to you and the reasons for choosing one alternative over another. As noted previously, alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For instance, user fees and information dissemination may be good alternatives to direct command-and-control regulation. Within a command-and-control regulatory program, performance-based standards generally offer advantages over standards specifying design, behavior, or manner of compliance.

You should carefully consider all appropriate alternatives for the key attributes or provisions of the rule. The previous discussion outlines examples of appropriate alternatives. Where there is a "continuum" of alternatives for a standard (such as the level of stringency), you generally should analyze at least three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

You should choose reasonable alternatives deserving careful consideration. In some cases, a regulatory program will focus on an option that is near or at the limit of technical feasibility. In this case, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs.

It is not adequate simply to report a comparison of the agency's preferred option to the chosen baseline. Whenever you report the benefits and costs of alternative options, you should present both total and incremental benefits and costs. You should present incremental benefits and costs as differences from the corresponding estimates associated with the next less-stringent alternative.[10] It is important to emphasize that incremental effects are simply differences between successively more stringent alternatives. Results involving a comparison to a "next best" alternative may be especially useful.

In some cases, you may decide to analyze a wide array of options. In 1998, DOE analyzed a large number of options in setting new energy efficiency standards for refrigerators and freezers and produced a rich amount of information on their relative effects. This analysis -- examining more than 20 alternative performance standards for one class of refrigerators with top-mounted freezers -- enabled DOE to select an option that produced $200 more in estimated net benefits per refrigerator than the least attractive option.

[10] For the least stringent alternative, you should estimate the incremental benefits and costs relative to the baseline. Thus, for this alternative, the incremental effects would be the same as the corresponding totals. For each alternative that is more stringent than the least stringent alternative, you should estimate the incremental benefits and costs relative to the closest less-stringent alternative.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

Analyzing all possible combinations of provisions is impractical if the number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis. You are expected to document all of the alternatives that were considered in a list or table and which were selected for emphasis in the main analysis.

You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost. Such information may be useful to Congress under the Regulatory Right-to-Know Act.

4. Transparency and Reproducibility of Results

Because of its influential nature and its special role in the rulemaking process, it is appropriate to set minimum quality standards for regulatory analysis. You should provide documentation that the analysis is based on the best reasonably obtainable scientific, technical, and economic information available. To achieve this, you should rely on peer-reviewed literature, where available, and provide the source for all original information.

A good analysis should be transparent and your results must be reproducible. You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. A qualified third party reading the analysis should be able to understand the basic elements of your analysis and the way in which you developed your estimates.

To provide greater access to your analysis, you should generally post it, with all the supporting documents, on the internet so the public can review the findings. You should also disclose the use of outside consultants, their qualifications, and history of contracts and employment with the agency (e.g., in a preface to the RIA). Where other compelling interests (such as privacy, intellectual property, trade secrets, etc.) prevent the public release of data or key elements of the analysis, you should apply especially rigorous robustness checks to analytic results and document the analytical checks used.

Finally, you should assure compliance with the Information Quality Guidelines for your agency and OMB's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" ("data quality guidelines") http://www.whitehouse.gov/omb/fedreg/reproducible.html.

Developing Benefit and Cost Estimates

1. Some General Considerations

The analysis document should discuss the expected benefits and costs of the selected regulatory option and any reasonable alternatives. How is the proposed action expected to provide the anticipated benefits and costs? What are the monetized values of the potential real incremental benefits and costs to society? To present your results, you should:

- include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs, and express the estimates in this table in constant, undiscounted dollars (for more on discounting see "*Discount Rates*" below);
- list the benefits and costs you can quantify, but cannot monetize, including their timing;
- describe benefits and costs you cannot quantify; and
- identify or cross-reference the data or studies on which you base the benefit and cost estimates.

When benefit and cost estimates are uncertain (for more on this see "*Treatment of Uncertainty*" below), you should report benefit and cost estimates (including benefits of risk reductions) that reflect the full probability distribution of potential consequences. Where possible, present probability distributions of benefits and costs and include the upper and lower bound estimates as complements to central tendency and other estimates.

If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits or costs under plausible scenarios and characterize the evidence and assumptions underlying each alternative scenario.

2. The Key Concepts Needed to Estimate Benefits and Costs

"Opportunity cost" is the appropriate concept for valuing both benefits and costs. The principle of "willingness-to-pay" (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit. In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual's "willingness-to-accept" (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost.

WTP and WTA are comparable measures under special circumstances. WTP and WTA measures may be comparable in the following situations: if a regulation affects a price change rather than a quantity change; the change being evaluated is small; there are reasonably close substitutes available; and the income effect is small.[11] However, empirical evidence from experimental economics and psychology shows that even when income/wealth effects are "small", the measured differences between WTP and WTA can be large.[12] WTP is generally

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[11] See Hanemann WM (1991), *American Economic Review*, 81(3), 635-647.
[12] See Kahneman D, Knetsch JL, and Thaler RH (1991), "Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias," *Journal of Economic Perspectives* 3(1), 192-206.

considered to be more readily measurable. Adoption of WTP as the measure of value implies that individual preferences of the affected population should be a guiding factor in the regulatory analysis.

Market prices provide rich data for estimating benefits and costs based on willingness-to-pay if the goods and services affected by the regulation are traded in well-functioning competitive markets. The opportunity cost of an alternative includes the value of the benefits forgone as a result of choosing that alternative. The opportunity cost of banning a product -- a drug, food additive, or hazardous chemical -- is the forgone net benefit (i.e., lost consumer and producer surplus[13]) of that product, taking into account the mitigating effects of potential substitutes.

The use of any resource has an opportunity cost regardless of whether the resource is already owned or has to be purchased. That opportunity cost is equal to the net benefit the resource would have provided in the absence of the requirement. For example, if regulation of an industrial plant affects the use of additional land or buildings within the existing plant boundary, the cost analysis should include the opportunity cost of using the additional land or facilities.

To the extent possible, you should monetize any such forgone benefits and add them to the other costs of that alternative. You should also try to monetize any cost savings as a result of an alternative and either add it to the benefits or subtract it from the costs of that alternative. However, you should not assume that the "avoided" costs of not doing another regulatory alternative represent the benefits of a regulatory action where there is no direct, necessary relationship between the two. You should also be careful when the costs avoided are attributable to an existing regulation. Even when there is a direct relationship between the two regulatory actions, the use of avoided costs is problematic because the existing regulation may not maximize net benefits and thus may itself be questionable policy. (See the section, "Direct Use of Market Data," for more detail.)

Estimating benefits and costs when market prices are hard to measure or markets do not exist is more difficult. In these cases, you need to develop appropriate proxies that simulate market exchange. Estimates of willingness-to-pay based on revealed preference methods can be quite useful. As one example, analysts sometimes use "hedonic price equations" based on multiple regression analysis of market behavior to simulate market prices for the commodity of interest. The hedonic technique allows analysts to develop an estimate of the price for specific attributes associated with a product. For instance, a house is a product characterized by a variety of attributes including the number of rooms, total floor area, and type of heating and cooling. If there are enough data on transactions in the housing market, it is possible to develop an estimate of the implicit price for specific attributes, such as the implicit price of an additional bathroom or for central air conditioning. This technique can be extended, as well, to develop an estimate for

[13] Consumer surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the area between the price and the demand curve for that unit. Producer surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the area between the price and the supply curve for that unit.

the implicit price of public goods that are not directly traded in markets. An analyst can develop implicit price estimates for public goods like air quality and access to public parks by assessing the effects of these goods on the housing market. Going through the analytical process of deriving benefit estimates by simulating markets may also suggest alternative regulatory strategies that create such markets.

You need to guard against double-counting, since some attributes are embedded in other broader measures. To illustrate, when a regulation improves the quality of the environment in a community, the value of real estate in the community generally rises to reflect the greater attractiveness of living in a better environment. Simply adding the increase in property values to the estimated value of improved public health would be double counting if the increase in property values reflects the improvement in public health. To avoid this problem you should separate the embedded effects on the value of property arising from improved public health. At the same time, an analysis that fails to incorporate the consequence of land use changes when accounting for costs will not capture the full effects of regulation.

3. Revealed Preference Methods

Revealed preference methods develop estimates of the value of goods and services -- or attributes of those goods and services -- based on actual market decisions by consumers, workers and other market participants. If the market participant is well informed and confronted with a real choice, it may be feasible to determine accurately and precisely the monetary value needed for a rulemaking. There is a large and well-developed literature on revealed preference in the peer-reviewed, applied economics literature.

Although these methods are well grounded in economic theory, they are sometimes difficult to implement given the complexity of market transactions and the paucity of relevant data. When designing or evaluating a revealed preference study, the following principles should be considered:

- the market should be competitive. If the market isn't competitive (e.g., monopoly, oligopoly), then you should consider making adjustments such that the price reflects the true value to society (often called the "shadow price");
- the market should not exhibit a significant information gap or asymmetric information problem. If the market suffers from information problems, then you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the market should not exhibit an externality. In this case, you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the specific market participants being studied should be representative of the target populations to be affected by the rulemaking under consideration;
- a valid research design and framework for analysis should be adopted. Examples include using data and/or model specifications that include the markets for substitute and complementary goods and services and using reasonably unrestricted functional forms. When specifying substitute and complementary goods, the analysis should preferably be

based on data about the range of alternatives perceived by market participants. If such data are not available, you should adopt plausible assumptions and describe the limitations of the analysis.

- the statistical and econometric models employed should be appropriate for the application and the resulting estimates should be robust in response to plausible changes in model specification and estimation technique; and
- the results should be consistent with economic theory.

You should also determine whether there are multiple revealed-preference studies of the same good or service and whether anything can be learned by comparing the methods, data and findings from different studies. Professional judgment is required to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used in regulatory analysis despite their technical weaknesses (e.g., due to the absence of other evidence), the regulatory analysis should discuss any biases or uncertainties that are likely to arise due to those weaknesses. If a study has major weaknesses, the study should not be used in regulatory analysis.

a. Direct Uses of Market Data

Economists ordinarily consider market prices as the most accurate measure of the marginal value of goods and services to society. In some instances, however, market prices may not reflect the true value of goods and services due to market imperfections or government intervention. If a regulation involves changes to goods or services where the market price is not a good measure of the value to society, you should use an estimate that reflects the shadow price. Suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant is the value of the crop yield increase as a result of the controls. That value is typically measured by the price of the crop. However, if the price is held above the market price by a government program that affects supply, a value estimate based on this price may not reflect the true benefits of controlling the pollutant. In this case, you should calculate the value to society of the increase in crop yields by estimating the shadow price, which reflects the value to society of the marginal use of the crop. If the marginal use is for exports, you should use the world price. If the marginal use is to add to very large surplus stockpiles, you should use the value of the last units released from storage minus storage cost. If stockpiles are large and growing, the shadow price may be low or even negative.

Other goods whose market prices may not reflect their true value include those whose production or consumption results in substantial (1) positive or negative external effects or (2) transfer payments. For example, the observed market price of gasoline may not reflect marginal social value due to the inclusion of taxes, other government interventions, and negative externalities (e.g., pollution). This shadow price may also be needed for goods whose market price is substantially affected by existing regulations that do not maximize net benefits.

b. Indirect Uses of Market Data

Many goods or attributes of goods that are affected by regulation--such as preserving environmental or cultural amenities--are not traded directly in markets. The value for these goods or attributes arise both from use and non-use. Estimation of these values is difficult because of the absence of an organized market. However, overlooking or ignoring these values in your regulatory analysis may significantly understate the benefits and/or costs of regulatory action.

"Use values" arise where an individual derives satisfaction from using the resource, either now or in the future. Use values are associated with activities such as swimming, hunting, and hiking where the individual makes use of the natural environment.

"Non-use values" arise where an individual places value on a resource, good or service even though the individual will not use the resource, now or in the future. Non-use value includes bequest and existence values.

General altruism for the health and welfare of others is a closely related concept but may not be strictly considered a "non-use" value.[14] A general concern for the welfare of others should supplement benefits and costs equally; hence, it is not necessary to measure the size of general altruism in regulatory analysis. If there is evidence of selective altruism, it needs to be considered specifically in both benefits and costs.

Some goods and services are indirectly traded in markets, which means that their value is reflected in the prices of related goods and services that are directly traded in markets. Their use values are typically estimated through revealed preference methods. Examples include estimates of the values of environmental amenities derived from travel-cost studies, and hedonic price models that measure differences or changes in the value of real estate. It is important that you utilize revealed preference models that adhere to economic criteria that are consistent with utility maximizing behavior. Also, you should take particular care in designing protocols for reliably estimating the values of these attributes.

4. Stated Preference Methods

Stated Preference Methods (SPM) have been developed and used in the peer-reviewed literature to estimate both "use" and "non-use" values of goods and services. They have also been widely used in regulatory analyses by Federal agencies, in part, because these methods can be creatively employed to address a wide variety of goods and services that are not easy to study through revealed preference methods.

The distinguishing feature of these methods is that hypothetical questions about use or non-use values are posed to survey respondents in order to obtain willingness-to-pay estimates relevant to benefit or cost estimation. Some examples of SPM include contingent valuation, conjoint analysis and risk-tradeoff analysis. The surveys used to obtain the health-utility values used in CEA are similar to stated-preference surveys but do not entail monetary measurement of value. Nevertheless, the principles governing quality stated-preference research, with some obvious exceptions involving monetization, are also relevant in designing quality health-utility research.

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[14] See McConnell KE (1997), *Journal of Environmental Economics and Management*, *32*, 22-37.

When you are designing or evaluating a stated-preference study, the following principles should be considered:

- the good or service being evaluated should be explained to the respondent in a clear, complete and objective fashion, and the survey instrument should be pre-tested;
- willingness-to-pay questions should be designed to focus the respondent on the reality of budgetary limitations and alerted to the availability of substitute goods and alternative expenditure options;
- the survey instrument should be designed to probe beyond general attitudes (e.g., a "warm glow" effect for a particular use or non-use value) and focus on the magnitude of the respondent's economic valuation;
- the analytic results should be consistent with economic theory using both "internal" (within respondent) and "external" (between respondent) scope tests such as the willingness to pay is larger (smaller) when more (less) of a good is provided;
- the subjects being interviewed should be selected/sampled in a statistically appropriate manner. The sample frame should adequately cover the target population. The sample should be drawn using probability methods in order to generalize the results to the target population;
- response rates should be as high as reasonably possible. Best survey practices should be followed to achieve high response rates. Low response rates increase the potential for bias and raise concerns about the generalizability of the results. If response rates are not adequate, you should conduct an analysis of non-response bias or further study. Caution should be used in assessing the representativeness of the sample based solely on demographic profiles. Statistical adjustments to reduce non-response bias should be undertaken whenever feasible and appropriate;
- the mode of administration of surveys (in-person, phone, mail, computer, internet or multiple modes) should be appropriate in light of the nature of the questions being posed to respondents and the length and complexity of the instrument;
- documentation should be provided about the target population, the sampling frame used and its coverage of the target population, the design of the sample including any stratification or clustering, the cumulative response rate (including response rate at each stage of selection if applicable); the item non-response rate for critical questions; the exact wording and sequence of questions and other information provided to respondents; and the training of interviewers and techniques they employed (as appropriate);
- the statistical and econometric methods used to analyze the collected data should be transparent, well suited for the analysis, and applied with rigor and care.

Professional judgment is necessary to apply these criteria to one or more studies, and thus there is no mechanical formula that can be used to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used despite having weaknesses on one or more of these criteria, those weaknesses should be acknowledged in the regulatory analysis, including any resulting biases or uncertainties that are likely to result. If a study has too many weaknesses with unknown consequences for the quality of the data, the study should not be used.

The challenge in designing quality stated-preference studies is arguably greater for non-use values and unfamiliar use values than for familiar goods or services that are traded (directly or indirectly) in market transactions. The good being valued may have little meaning to respondents, and respondents may be forming their valuations for the first time in response to the questions posed. Since these values are effectively constructed by the respondent during the elicitation, the instrument and mode of administration should be rigorously pre-tested to make sure that responses are not simply an artifact of specific features of instrument design and/or mode of administration.

Since SPM generate data from respondents in a hypothetical setting, often on complex and unfamiliar goods, special care is demanded in the design and execution of surveys, analysis of the results, and characterization of the uncertainties. A stated-preference study may be the only way to obtain quantitative information about non-use values, though a number based on a poor quality study is not necessarily superior to no number at all. Non-use values that are not quantified should be presented as an "intangible" benefit or cost.

If both revealed-preference and stated-preference studies that are directly applicable to regulatory analysis are available, you should consider both kinds of evidence and compare the findings. If the results diverge significantly, you should compare the overall size and quality of the two bodies of evidence. Other things equal, you should prefer revealed preference data over stated preference data because revealed preference data are based on actual decisions, where market participants enjoy or suffer the consequences of their decisions. This is not generally the case for respondents in stated preference surveys, where respondents may not have sufficient incentives to offer thoughtful responses that are more consistent with their preferences or may be inclined to bias their responses for one reason or another.

5. Benefit-Transfer Methods

It is often preferable to collect original data on revealed preference or stated preference to support regulatory analysis. Yet conducting an original study may not be feasible due to the time and expense involved. One alternative to conducting an original study is the use of "benefit transfer" methods. (The transfer may involve cost determination as well). The practice of "benefit transfer" began with transferring existing estimates obtained from indirect market and stated preference studies to new contexts (i.e., the context posed by the rulemaking). The principles that guide transferring estimates from indirect market and stated preference studies should apply to direct market studies as well.

Although benefit-transfer can provide a quick, low-cost approach for obtaining desired monetary values, the methods are often associated with uncertainties and potential biases of unknown magnitude. It should therefore be treated as a last-resort option and not used without explicit justification.

In conducting benefit transfer, the first step is to specify the value to be estimated for the rulemaking. You should identify the relevant measure of the policy change at this initial stage. For instance, you can derive the relevant willingness-to-pay measure by specifying an indirect utility function. This identification allows you to "zero in" on key aspects of the benefit transfer.

The next step is to identify appropriate studies to conduct benefit transfer. In selecting transfer studies for either point transfers or function transfers, you should base your choices on the following criteria:

- The selected studies should be based on adequate data, sound and defensible empirical methods and techniques.
- The selected studies should document parameter estimates of the valuation function.
- The study context and policy context should have similar populations (e.g., demographic characteristics). The market size (e.g., target population) between the study site and the policy site should be similar. For example, a study valuing water quality improvement in Rhode Island should not be used to value policy that will affect water quality throughout the United States.
- The good, and the magnitude of change in that good, should be similar in the study and policy contexts.
- The relevant characteristics of the study and the policy contexts should be similar. For example, the effects examined in the original study should be "reversible" or "irreversible" to a degree that is similar to the regulatory actions under consideration.
- The distribution of property rights should be similar so that the analysis uses the same welfare measure. If the property rights in the study context support the use of WTA measures while the rights in the rulemaking context support the use of WTP measures, benefit transfer is not appropriate.
- The availability of substitutes across study and policy contexts should be similar.

If you can choose between transferring a function or a point estimate, you should transfer the entire demand function (referred to as benefit function transfer) rather than adopting a single point estimate (referred to as benefit point transfer).[15]

Finally, you should not use benefit transfer in estimating benefits if:

- resources are unique or have unique attributes. For example, if a policy change affects snowmobile use in Yellowstone National Park, then a study valuing snowmobile use in the state of Michigan should not be used to value changes in snowmobile use in the Yellowstone National Park.
- If the study examines a resource that is unique or has unique attributes, you should not transfer benefit estimates or benefit functions to value a different resource and vice versa. For example, if a study values visibility improvements at the Grand Canyon, these results should not be used to value visibility improvements in urban areas.
- There are significant problems with applying an *"ex ante"* valuation estimate to an *"ex post"* policy context. If a policy yields a significant change in the attributes of the good, you should not use the study estimates to value the change using a benefit transfer approach.
- You also should not use a value developed from a study involving, small marginal

[15] See Loomis JB (1992), *Water Resources Research*, *28*(3), 701-705 and Kirchoff, S, Colby, BG, and LaFrance, JT (1997), *Journal of Environmental Economics and Management*, *33*, 75-93.

changes in a policy context involving large changes in the quantity of the good.

Clearly, all of these criteria are difficult to meet. However, you should attempt to satisfy as many as possible when choosing studies from the existing economic literature. Professional judgment is required in determining whether a particular transfer is too speculative to use in regulatory analysis.

6. Ancillary Benefits and Countervailing Risks

Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks. An ancillary benefit is a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking (e.g., reduced refinery emissions due to more stringent fuel economy standards for light trucks) while a countervailing risk is an adverse economic, health, safety, or environmental consequence that occurs due to a rule and is not already accounted for in the direct cost of the rule (e.g., adverse safety impacts from more stringent fuel-economy standards for light trucks).

You should begin by considering and perhaps listing the possible ancillary benefits and countervailing risks. However, highly speculative or minor consequences may not be worth further formal analysis. Analytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis. In some cases the mere consideration of these secondary effects may help in the generation of a superior regulatory alternative with strong ancillary benefits and fewer countervailing risks. For instance, a recent study suggested that weight-based, fuel-economy standards could achieve energy savings with fewer safety risks and employment losses than would occur under the current regulatory structure.

Like other benefits and costs, an effort should be made to quantify and monetize ancillary benefits and countervailing risks. If monetization is not feasible, quantification should be attempted through use of informative physical units. If both monetization and quantification are not feasible, then these issues should be presented as non-quantified benefits and costs. The same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks.

One way to combine ancillary benefits and countervailing risks is to evaluate these effects separately and then put both of these effects on the benefits side, not on the cost side. Although it is theoretically appropriate to include disbenefits on the cost side, legal and programmatic considerations generally support subtracting the disbenefits from direct benefits.

7. Methods for Treating Non-Monetized Benefits and Costs

Sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision makers understand the magnitudes of the effects of alternative actions. However, some important benefits and costs (e.g., privacy protection) may be inherently too difficult to quantify or monetize given current data and methods. You should carry out a careful evaluation of non-quantified benefits and costs. Some authorities[16] refer to these non-monetized and non-quantified effects as "intangible".

a. Benefits and Costs that are Difficult to Monetize

You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize benefits and costs, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information. For example, if you can quantify but cannot monetize increases in water quality and fish populations resulting from water quality regulation, you can describe benefits in terms of stream miles of improved water quality for boaters and increases in game fish populations for anglers. You should describe the timing and likelihood of such effects and avoid double-counting of benefits when estimates of monetized and physical effects are mixed in the same analysis.

b. Benefits and Costs that are Difficult to Quantify

If you are not able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantified effects, such as ecological gains, improvements in quality of life, and aesthetic beauty. You should provide a discussion of the strengths and limitations of the qualitative information. This should include information on the key reason(s) why they cannot be quantified. In one instance, you may know with certainty the magnitude of a risk to which a substantial, but unknown, number of individuals are exposed. In another instance, the existence of a risk may be based on highly speculative assumptions, and the magnitude of the risk may be unknown.

For cases in which the unquantified benefits or costs affect a policy choice, you should provide a clear explanation of the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the unquantified benefits and costs. Also, please include a summary table that lists all the unquantified benefits and costs, and use your professional judgment to highlight (e.g., with categories or rank ordering) those that you believe are most important (e.g., by considering factors such as the degree of certainty, expected magnitude, and reversibility of effects).

While the focus is often placed on difficult to quantify benefits of regulatory action, some costs are difficult to quantify as well. Certain permitting requirements (e.g., EPA's New Source Review program) restrict the decisions of production facilities to shift to new products and adopt innovative methods of production. While these programs may impose substantial costs on the economy, it is very difficult to quantify and monetize these effects. Similarly, regulations that establish emission standards for recreational vehicles, like motor bikes, may adversely affect the performance of the vehicles in terms of driveability and 0 to 60 miles per hour acceleration. Again, the cost associated with the loss of these attributes may be difficult to quantify and monetize. They need to be analyzed qualitatively.

[16] Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

8. Monetizing Health and Safety Benefits and Costs

We expect you to provide a benefit-cost analysis of major health and safety rulemakings in addition to a CEA. The BCA provides additional insight because (a) it provides some indication of what the public is willing to pay for improvements in health and safety and (b) it offers additional information on preferences for health using a different research design than is used in CEA. Since the health-preference methods used to support CEA and BCA have some different strengths and drawbacks, it is important that you provide decision makers with both perspectives.

In monetizing health benefits, a WTP measure is the conceptually appropriate measure as compared to other alternatives (e.g., cost of illness or lifetime earnings), in part because it attempts to capture pain and suffering and other quality-of-life effects. Using the WTP measure for health and safety allows you to directly compare your results to the other benefits and costs in your analysis, which will typically be based on WTP.

If well-conducted revealed-preference studies of relevant health and safety risks are available, you should consider using them in developing your monetary estimates. If appropriate revealed-preference data are not available, you should use valid and relevant data from stated-preference studies. You will need to use your professional judgment when you are faced with limited information on revealed preference studies and substantial information based on stated preference studies.

A key advantage of stated-preference and health-utility methods compared to revealed preference methods is that they can be tailored to address the ranges of probabilities, types of health risks and specific populations affected by your rule. In many rulemakings there will be no relevant information from revealed-preference studies. In this situation you should consider commissioning a stated-preference study or using values from published stated-preference studies. For the reasons discussed previously, you should be cautious about using values from stated-preference studies and describe in the analysis the drawbacks of this approach.

a. Nonfatal Health and Safety Risks

With regard to nonfatal health and safety risks, there is enormous diversity in the nature and severity of impaired health states. A traumatic injury that can be treated effectively in the emergency room without hospitalization or long-term care is different from a traumatic injury resulting in paraplegia. Severity differences are also important in evaluation of chronic diseases. A severe bout of bronchitis, though perhaps less frequent, is far more painful and debilitating than the more frequent bouts of mild bronchitis. The duration of an impaired health state, which can range from a day or two to several years or even a lifetime (e.g., birth defects inducing mental retardation), need to be considered carefully. Information on both the severity and duration of an impaired health state is necessary before the task of monetization can be performed.

When monetizing nonfatal health effects, it is important to consider two components: (1) the private demand for prevention of the nonfatal health effect, to be represented by the preferences of the target population at risk, and (2) the net financial externalities associated with poor health such as net changes in public medical costs and any net changes in economic production that are not experienced by the target population. Revealed-preference or stated-preference studies are necessary to estimate the private demand; health economics data from published sources can typically be used to estimate the financial externalities caused by changes in health status. If you use literature values to monetize nonfatal health and safety risks, it is important to make sure that the values you have selected are appropriate for the severity and duration of health effects to be addressed by your rule.

If data are not available to support monetization, you might consider an alternative approach that makes use of health-utility studies. Although the economics literature on the monetary valuation of impaired health states is growing, there is a much larger clinical literature on how patients, providers and community residents value diverse health states. This literature typically measures health utilities based on the standard gamble, the time tradeoff or the rating scale methods. This health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of different severity and duration. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates.

b. Fatality Risks

Since agencies often design health and safety regulation to reduce risks to life, evaluation of these benefits can be the key part of the analysis. A good analysis must present these benefits clearly and show their importance. Agencies may choose to monetize these benefits. The willingness-to-pay approach is the best methodology to use if reductions in fatality risk are monetized.

Some describe the monetized value of small changes in fatality risk as the "value of statistical life" (VSL) or, less precisely, the "value of a life." The latter phrase can be misleading because it suggests erroneously that the monetization exercise tries to place a “value” on individual lives. You should make clear that these terms refer to the measurement of willingness to pay for reductions in only small risks of premature death. They have no application to an identifiable individual or to very large reductions in individual risks. They do not suggest that any individual’s life can be expressed in monetary terms. Their sole purpose is to help describe better the likely benefits of a regulatory action.

Confusion about the term "statistical life" is also widespread. This term refers to the sum of risk reductions expected in a population. For example, if the annual risk of death is reduced by one in a million for each of two million people, that is said to represent two "statistical lives" extended per year (2 million people x 1/1,000,000 = 2). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives extended.

The adoption of a value for the projected reduction in the risk of premature mortality is the subject of continuing discussion within the economic and public policy analysis community. A considerable body of academic literature is available on this subject. This literature involves either explicit or implicit valuation of fatality risks, and generally involves the use of estimates of

VSL from studies on wage compensation for occupational hazards (which generally are in the range of 10^{-4} annually), on consumer product purchase and use decisions, or from an emerging literature using stated preference approaches. A substantial majority of the resulting estimates of VSL vary from roughly $1 million to $10 million per statistical life.[17]

There is a continuing debate within the economic and public policy analysis community on the merits of using a single VSL for all situations versus adjusting the VSL estimates to reflect the specific rule context. A variety of factors have been identified, including whether the mortality risk involves sudden death, the fear of cancer, and the extent to which the risk is voluntarily incurred.[18] The consensus of EPA's recent Science Advisory Board (SAB) review of this issue was that the available literature does not support adjustments of VSL for most of these factors. The panel did conclude that it was appropriate to adjust VSL to reflect changes in income and any time lag in the occurrence of adverse health effects.

The age of the affected population has also been identified as an important factor in the theoretical literature. However, the empirical evidence on age and VSL is mixed. In light of the continuing questions over the effect of age on VSL estimates, you should not use an age-adjustment factor in an analysis using VSL estimates.[19]

Another way that has been used to express reductions in fatality risks is to use the life expectancy method, the "value of statistical life-years (VSLY) extended." If a regulation protects individuals whose average remaining life expectancy is 40 years, a risk reduction of one fatality is expressed as "40 life-years extended." Those who favor this alternative approach emphasize that the value of a statistical life is not a single number relevant for all situations. In particular, when there are significant differences between the effect on life expectancy for the population affected by a particular health risk and the populations studied in the labor market studies, they prefer to adopt a VSLY approach to reflect those differences. You should consider providing estimates of both VSL and VSLY, while recognizing the developing state of knowledge in this area.

Longevity may be only one of a number of relevant considerations pertaining to the rule. You should keep in mind that regulations with greater numbers of life-years extended are not necessarily better than regulations with fewer numbers of life-years extended. In any event, when you present estimates based on the VSLY method, you should adopt a larger VSLY estimate for senior citizens because senior citizens face larger overall health risks from all causes and they may have accumulated savings to spend on their health and safety.[20]

The valuation of fatality risk reduction is an evolving area in both results and methodology. Hence, you should utilize valuation methods that you consider appropriate for the

[17] See Viscusi WK and Aldy JE, *Journal of Risk and Uncertainty* (forthcoming) and Mrozek JR and Taylor LO (2002), *Journal of Policy Analysis and Management*, *21*(2), 253-270.
[18] Distinctions between "voluntary" and "involuntary" should be treated with care. Risks are best considered to fall within a continuum from "voluntary" to "involuntary" with very few risks at either end of this range. These terms are also related to differences in the cost of avoiding risks.
[19] Graham JD (2003), Memorandum to the President's Management Council, Benefit-Cost Methods and Lifesaving Rules. This memorandum can be found at http://www.whitehouse.gov/omb/inforeg/pmc_benefit_cost_memo.pdf
[20] Office of Information and Regulatory Affairs, OMB, Memorandum to the President's Management Council, ibid.

regulatory circumstances. Since the literature-based VSL estimates may not be entirely appropriate for the risk being evaluated (e.g., the use of occupational risk premia to value reductions in risks from environmental hazards), you should explain your selection of estimates and any adjustments of the estimates to reflect the nature of the risk being evaluated. You should present estimates based on alternative approaches, and if you monetize mortality risk reduction, you should do so on a consistent basis to the extent feasible. You should clearly indicate the methodology used and document your choice of a particular methodology. You should explain any significant deviations from the prevailing state of knowledge. If you use different methodologies in different rules, you should clearly disclose the fact and explain your choices.

c. Valuation of Reductions in Health and Safety Risks to Children

The valuation of health outcomes for children and infants poses special challenges. It is rarely feasible to measure a child's willingness to pay for health improvement and an adult's concern for his or her own health is not necessarily relevant to valuation of child health. For example, the wage premiums demanded by workers to accept hazardous jobs are not readily transferred to rules that accomplish health gains for children.

There are a few studies that examine parental willingness to pay to invest in health and safety for their children. Some of these studies suggest that parents may value children's health more strongly than their own health. Although this parental perspective is a promising research strategy, it may need to be expanded to include a societal interest in child health and safety.

Where the primary objective of a rule is to reduce the risk of injury, disease or mortality among children, you should conduct a cost-effectiveness analysis of the rule. You may also develop a benefit-cost analysis to the extent that valid monetary values can be assigned to the primary expected health outcomes. For rules where health gains are expected among both children and adults and you decide to perform a benefit-cost analysis, the monetary values for children should be at least as large as the values for adults (for the same probabilities and outcomes) unless there is specific and compelling evidence to suggest otherwise.[21]

Discount Rates

Benefits and costs do not always take place in the same time period. When they do not, it is incorrect simply to add all of the expected net benefits or costs without taking account of when the actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.

As a first step, you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur. The beginning point for your stream of estimates should be the year in which the final rule will begin to have effects, even if that is expected to be some time in the future. The ending point should be far enough in the future to encompass all the significant benefits and costs likely to result from the rule.

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[21] For more information, see Dockins C., Jenkins RR, Owens N, Simon NB, and Wiggins LB (2002), *Risk Analysis*, 22(2), 335-346.

In presenting the stream of benefits and costs, it is important to measure them in constant dollars to avoid the misleading effects of inflation in your estimates. If the benefits and costs are initially measured in prices reflecting expected future inflation, you can convert them to constant dollars by dividing through by an appropriate inflation index, one that corresponds to the inflation rate underlying the initial estimates of benefits or costs.

1. The Rationale for Discounting

Once these preliminaries are out of the way, you can begin to adjust your estimates for differences in timing. (This is a separate calculation from the adjustment needed to remove the effects of future inflation.) Benefits or costs that occur sooner are generally more valuable. The main rationales for the discounting of future impacts are:

(a) Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, since you are giving up that expected return on investment when you consume today.
(b) Postponed benefits also have a cost because people generally prefer present to future consumption. They are said to have positive time preference.
(c) Also, if consumption continues to increase over time, as it has for most of U.S. history, an increment of consumption will be less valuable in the future than it would be today, because the principle of diminishing marginal utility implies that as total consumption increases, the value of a marginal unit of consumption tends to decline.

There is wide agreement with point (a). Capital investment is productive, but that point is not sufficient by itself to explain positive interest rates and observed saving behavior. To understand these phenomena, points (b) and (c) are also necessary. If people are really indifferent between consumption now and later, then they should be willing to forgo current consumption in order to consume an equal or slightly greater amount in the future. That would cause saving rates and investment to rise until interest rates were driven to zero and capital was no longer productive. As long as we observe positive interest rates and saving rates below 100 percent, people must be placing a higher value on current consumption than on future consumption.

To reflect this preference, a discount factor should be used to adjust the estimated benefits and costs for differences in timing. The further in the future the benefits and costs are expected to occur, the more they should be discounted. The discount factor can be calculated given a discount rate. The formula is $1/(1+\text{the discount rate})^t$ where "t" measures the number of years in the future that the benefits or costs are expected to occur. Benefits or costs that have been adjusted in this way are called "discounted present values" or simply "present values". When, and only when, the estimated benefits and costs have been discounted, they can be added to determine the overall value of net benefits.

2. Real Discount Rates of 3 Percent and 7 Percent

OMB's basic guidance on the discount rate is provided in OMB Circular A-94 (http://www.whitehouse.gov/omb/circulars/index.html). This Circular points out that the analytically preferred method of handling temporal differences between benefits and costs is to adjust all the benefits and costs to reflect their value in equivalent units of consumption and to discount them at the rate consumers and savers would normally use in discounting future consumption benefits. This is sometimes called the "shadow price" approach to discounting because doing such calculations requires you to value benefits and costs using shadow prices, especially for capital goods, to correct for market distortions. These shadow prices are not well established for the United States. Furthermore, the distribution of impacts from regulations on capital and consumption are not always well known. Consequently, any agency that wishes to tackle this challenging analytical task should check with OMB before proceeding.

As a default position, OMB Circular A-94 states that a real discount rate of 7 percent should be used as a base-case for regulatory analysis. The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. OMB revised Circular A-94 in 1992 after extensive internal review and public comment. In a recent analysis, OMB found that the average rate of return to capital remains near the 7 percent rate estimated in 1992. Circular A-94 also recommends using other discount rates to show the sensitivity of the estimates to the discount rate assumption.

Economic distortions, including taxes on capital, create a divergence between the rate of return that savers earn and the private rate of return to capital. This divergence persists despite the tendency for capital to flow to where it can earn the highest rate of return. Although market forces will push after-tax rates of return in different sectors of the economy toward equality, that process will not equate pre-tax rates of return when there are differences in the tax treatment of investment. Corporate capital, in particular, pays an additional layer of taxation, the corporate income tax, which requires it to earn a higher pre-tax rate of return in order to provide investors with similar after-tax rates of return compared with non-corporate investments. The pre-tax rates of return better measure society's gains from investment. Since the rates of return on capital are higher in some sectors of the economy than others, the government needs to be sensitive to possible impacts of regulatory policy on capital allocation.

The effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the "social rate of time preference." This simply means the rate at which "society" discounts future consumption flows to their present value. If we take the rate that the average saver uses to discount future consumption as our measure of the social rate of time preference, then the real rate of return on long-term government debt may provide a fair approximation. Over the last thirty years, this rate has averaged around 3 percent in real terms on a pre-tax basis. For example, the yield on 10-year Treasury notes has averaged 8.1 percent since

1973 while the average annual rate of change in the CPI over this period has been 5.0 percent, implying a real 10-year rate of 3.1 percent.

For regulatory analysis, you should provide estimates of net benefits using both 3 percent and 7 percent. An example of this approach is EPA's analysis of its 1998 rule setting both effluent limits for wastewater discharges and air toxic emission limits for pulp and paper mills. In this analysis, EPA developed its present-value estimates using real discount rates of 3 and 7 percent applied to benefit and cost streams that extended forward for 30 years. You should present a similar analysis in your own work.

In some instances, if there is reason to expect that the regulation will cause resources to be reallocated away from private investment in the corporate sector, then the opportunity cost may lie outside the range of 3 to 7 percent. For example, the average real rate of return on corporate capital in the United States was approximately 10 percent in the 1990s, returning to the same level observed in the 1950s and 1960s. If you are uncertain about the nature of the opportunity cost, then you should present benefit and cost estimates using a higher discount rate as a further sensitivity analysis as well as using the 3 and 7 percent rates.

3. Time Preference for Health-Related Benefits and Costs

When future benefits or costs are health-related, some have questioned whether discounting is appropriate, since the rationale for discounting money may not appear to apply to health. It is true that lives saved today cannot be invested in a bank to save more lives in the future. But the resources that would have been used to save those lives can be invested to earn a higher payoff in future lives saved. People have been observed to prefer health gains that occur immediately to identical health gains that occur in the future. Also, if future health gains are not discounted while future costs are, then the following perverse result occurs: an attractive investment today in future health improvement can always be made more attractive by delaying the investment. For such reasons, there is a professional consensus that future health effects, including both benefits and costs, should be discounted at the same rate. This consensus applies to both BCA and CEA.

A common challenge in health-related analysis is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status will be observed in the target population. In such situations, you must carefully consider the timing of health benefits before performing present-value calculations. It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect. For rules addressing traumatic injury, this lag period may be short. For chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population.

When a delay period between exposure to a toxin and increased probability of disease is likely (a so-called latency period), a lag between exposure reduction and reduced probability of disease is also likely. This latter period has sometimes been referred to as a "cessation lag," and it may or may not be of the same duration as the latency period. As a general matter, cessation lags will only apply to populations with at least some high-level exposure (e.g., before the rule takes effect). For populations with no such prior exposure, such as those born after the rule takes effect, only the latency period will be relevant.

Ideally, your exposure-risk model would allow calculation of reduced risk for each year following exposure cessation, accounting for total cumulative exposure and age at the time of exposure reduction. The present-value benefits estimate could then reflect an appropriate discount factor for each year's risk reduction. Recent analyses of the cancer benefits stemming from reduction in public exposure to radon in drinking water have adopted this approach. They were supported by formal risk-assessment models that allowed estimates of the timing of lung cancer incidence and mortality to vary in response to different radon exposure levels.[22]

In many cases, you will not have the benefit of such detailed risk assessment modeling. You will need to use your professional judgment as to the average cessation lag for the chronic diseases affected by your rule. In situations where information exists on latency but not on cessation lags, it may be reasonable to use latency as a proxy for the cessation lag, unless there is reason to believe that the two are different. When the average lag time between exposures and disease is unknown, a range of plausible alternative values for the time lag should be used in your analysis.

4. Intergenerational Discounting

Special ethical considerations arise when comparing benefits and costs across generations. Although most people demonstrate time preference in their own consumption behavior, it may not be appropriate for society to demonstrate a similar preference when deciding between the well-being of current and future generations. Future citizens who are affected by such choices cannot take part in making them, and today's society must act with some consideration of their interest.

One way to do this would be to follow the same discounting techniques described above and supplement the analysis with an explicit discussion of the intergenerational concerns (how future generations will be affected by the regulatory decision). Policymakers would be provided with this additional information without changing the general approach to discounting.

Using the same discount rate across generations has the advantage of preventing time-inconsistency problems. For example, if one uses a lower discount rate for future generations, then the evaluation of a rule that has short-term costs and long-term benefits would become more favorable merely by waiting a year to do the analysis. Further, using the same discount rate across generations is attractive from an ethical standpoint. If one expects future generations to be better off, then giving them the advantage of a lower discount rate would in effect transfer resources from poorer people today to richer people tomorrow.

Some believe, however, that it is ethically impermissible to discount the utility of future generations. That is, government should treat all generations equally. Even under this approach,

[22] Committee on Risk Assessment of Exposure to Radon in Drinking Water, Board on Radiation Effects Research, Commission on Life Sciences (1996), *Risk Assessment of Radon in Drinking Water*, National Research Council, National Academy Press, Washington, DC.

it would still be correct to discount future costs and consumption benefits generally (perhaps at a lower rate than for intragenerational analysis), due to the expectation that future generations will be wealthier and thus will value a marginal dollar of benefits or costs by less than those alive today. Therefore, it is appropriate to discount future benefits and costs relative to current benefits and costs, even if the welfare of future generations is not being discounted. Estimates of the appropriate discount rate appropriate in this case, from the 1990s, ranged from 1 to 3 percent per annum.[23]

A second reason for discounting the benefits and costs accruing to future generations at a lower rate is increased uncertainty about the appropriate value of the discount rate, the longer the horizon for the analysis. Private market rates provide a reliable reference for determining how society values time within a generation, but for extremely long time periods no comparable private rates exist. As explained by Martin Weitzman[24], in the limit for the deep future, the properly averaged certainty-equivalent discount factor (i.e., $1/[1+r]^t$) corresponds to the minimum discount rate having any substantial positive probability. From today's perspective, the only relevant limiting scenario is the one with the lowest discount rate – all of the other states at the far-distant time are relatively much less important because their expected present value is so severely reduced by the power of compounding at a higher rate.

If your rule will have important intergenerational benefits or costs you might consider a further sensitivity analysis using a lower but positive discount rate in addition to calculating net benefits using discount rates of 3 and 7 percent.

5. Time Preference for Non-Monetized Benefits and Costs

Differences in timing should be considered even for benefits and costs that are not expressed in monetary units, including health benefits. The timing differences can be handled through discounting. EPA estimated cost-effectiveness in its 1998 rule, "Control of Emissions from Nonroad Diesel Engines," by discounting both the monetary costs and the non-monetized emission reduction benefits over the expected useful life of the engines at the 7 percent real rate recommended in OMB Circular A-94.

Alternatively, it may be possible in some cases to avoid discounting non-monetized benefits. If the expected flow of benefits begins as soon as the cost is incurred and is expected to be constant over time, then annualizing the cost stream is sufficient, and further discounting of benefits is unnecessary. Such an analysis might produce an estimate of the annualized cost per ton of reduced emissions of a pollutant.

6. The Internal Rate of Return

The internal rate of return is the discount rate that sets the net present value of the discounted benefits and costs equal to zero. The internal rate of return does not generally

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[23] Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.
[24] Weitzman ML In Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.

provide an acceptable decision criterion, and regulations with the highest internal rate of return are not necessarily the most beneficial. Nevertheless, it does provide useful information and for many it will offer a meaningful indication of regulation's impact. You should consider including the internal rate of return implied by your regulatory analysis along with other information about discounted net present values.

Other Key Considerations

1. Other Benefit and Cost Considerations

You should include these effects in your analysis and provide estimates of their monetary values when they are significant:

- Private-sector compliance costs and savings;
- Government administrative costs and savings;
- Gains or losses in consumers' or producers' surpluses;
- Discomfort or inconvenience costs and benefits; and
- Gains or losses of time in work, leisure and/or commuting/travel settings.

Estimates of benefits and costs should be based on credible changes in technology over time. For example, retrospective studies may provide evidence that "learning" will likely reduce the cost of regulation in future years. The weight you give to a study of past rates of cost savings resulting from innovation (including "learning curve" effects) should depend on both its timeliness and direct relevance to the processes affected by the regulatory alternative under consideration. In addition, you should take into account cost-saving innovations that result from a shift to regulatory performance standards and incentive-based policies. On the other hand, significant costs may result from a slowing in the rate of innovation or of adoption of new technology due to delays in the regulatory approval process or the setting of more stringent standards for new facilities than existing ones. In some cases agencies are limited under statute to consider only technologies that have been demonstrated to be feasible. In these situations, it may be useful to estimate costs and cost savings assuming a wider range of technical possibilities.

When characterizing technology changes over time, you should assess the likely technology changes that would have occurred in the absence of the regulatory action (technology baseline). Technologies change over time in both reasonably functioning markets and imperfect markets. If you assume that technology will remain unchanged in the absence of regulation when technology changes are likely, then your analysis will over-state both the benefits and costs attributable to the regulation.

Occasionally, cost savings or other forms of benefits accrue to parties affected by a rule who also bear its costs. For example, a requirement that engine manufacturers reduce emissions from engines may lead to technologies that improve fuel economy. These fuel savings will normally accrue to the engine purchasers, who also bear the costs of the technologies. There is no apparent market failure with regard to the market value of fuel saved because one would expect that consumers would be willing to pay for increased fuel economy that exceeded the cost of providing it. When these cost savings are substantial, and particularly when you estimate them to be greater than the cost associated with achieving them, you should examine and discuss why market forces would not accomplish these gains in the absence of regulation. As a general matter, any direct costs that are averted as a result of a regulatory action should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

2. The Difference between Costs (or Benefits) and Transfer Payments

Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. Benefit and cost estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. A regulation that restricts the supply of a good, causing its price to rise, produces a transfer from buyers to sellers. The net reduction in the total surplus (consumer plus producer) is a real cost to society, but the transfer from buyers to sellers resulting from a higher price is not a real cost since the net reduction automatically accounts for the transfer from buyers to sellers. However, transfers from the United States to other nations <u>should</u> be included as costs, and transfers from other nations to the United States as benefits, as long as the analysis is conducted from the United States perspective.

You should not include transfers in the estimates of the benefits and costs of a regulation. Instead, address them in a separate discussion of the regulation's distributional effects. Examples of transfer payments include the following:

- Scarcity rents and monopoly profits
- Insurance payments
- Indirect taxes and subsidies

Treatment of Uncertainty

The precise consequences (benefits and costs) of regulatory options are not always known for certain, but the probability of their occurrence can often be developed. The important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis. You should begin your analysis of uncertainty at the earliest possible stage in developing your analysis. You should consider both the statistical variability of key elements underlying the estimates of benefits and costs (for example, the expected change in the distribution of automobile accidents that might result from a change in automobile safety standards) and the incomplete knowledge about the relevant relationships (for example, the uncertain knowledge of how some economic activities might affect future climate change).[25] By assessing the sources of uncertainty and the way in which benefit and cost estimates may be affected under plausible assumptions, you can shape your analysis to inform decision makers and the public about the effects and the uncertainties of alternative regulatory actions.

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[25] In some contexts, the word “variability” is used as a synonym for statistical variation that can be described by a theoretically valid distribution function, whereas “uncertainty” refers to a more fundamental lack of knowledge. Throughout this discussion, we use the term “uncertainty” to refer to both concepts.

The treatment of uncertainty must be guided by the same principles of full disclosure and transparency that apply to other elements of your regulatory analysis. Your analysis should be credible, objective, realistic, and scientifically balanced.[26] Any data and models that you use to analyze uncertainty should be fully identified. You should also discuss the quality of the available data used. Inferences and assumptions used in your analysis should be identified, and your analytical choices should be explicitly evaluated and adequately justified. In your presentation, you should delineate the strengths of your analysis along with any uncertainties about its conclusions. Your presentation should also explain how your analytical choices have affected your results.

In some cases, the level of scientific uncertainty may be so large that you can only present discrete alternative scenarios without assessing the relative likelihood of each scenario quantitatively. For instance, in assessing the potential outcomes of an environmental effect, there may be a limited number of scientific studies with strongly divergent results. In such cases, you might present results from a range of plausible scenarios, together with any available information that might help in qualitatively determining which scenario is most likely to occur.

When uncertainty has significant effects on the final conclusion about net benefits, your agency should consider additional research prior to rulemaking. The costs of being wrong may outweigh the benefits of a faster decision. This is true especially for cases with irreversible or large upfront investments. If your agency decides to proceed with rulemaking, you should explain why the costs of developing additional information—including any harm from delay in public protection—exceed the value of that information.

For example, when the uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data.[27] Delaying a decision will also have costs, as will further efforts at data gathering and analysis. You will need to weigh the benefits of delay against these costs in making your decision. Formal tools for assessing the value of additional information are now well developed in the applied decision sciences and can be used to help resolve this type of complex regulatory question.

"Real options" methods have also formalized the valuation of the added flexibility inherent in delaying a decision. As long as taking time will lower uncertainty, either passively or actively through an investment in information gathering, and some costs are irreversible, such as the potential costs of a sunk investment, a benefit can be assigned to the option to delay a decision. That benefit should be considered a cost of taking immediate action versus the alternative of delaying that action pending more information. However, the burdens of delay—including any harm to public health, safety, and the environment—need to be analyzed carefully.

1. Quantitative Analysis of Uncertainty

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[26] When disseminating information, agencies should follow their own information quality guidelines, issued in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002).
[27] Clemen RT (1996), *Making Hard Decisions: An Introduction to Decision Analysis*, second edition, Duxbury Press, Pacific Grove.

Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, such as the cost savings associated with increased energy efficiency. Thus, your analysis should include two fundamental components: a quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes. It is essential that both parts be conceptually consistent. In particular, the quantitative analysis should be conducted in a way that permits it to be applied within a more general analytical framework, such as benefit-cost analysis. Similarly, the general framework needs to be flexible enough to incorporate the quantitative analysis without oversimplifying the results. For example, you should address explicitly the implications for benefits and costs of any probability distributions developed in your analysis.

As with other elements of regulatory analysis, you will need to balance thoroughness with the practical limits on your analytical capabilities. Your analysis does not have to be exhaustive, nor is it necessary to evaluate each alternative at every step. Attention should be devoted to first resolving or studying the uncertainties that have the largest potential effect on decision making. Many times these will be the largest sources of uncertainties. In the absence of adequate data, you will need to make assumptions. These should be clearly identified and consistent with the relevant science. Your analysis should provide sufficient information for decision makers to grasp the degree of scientific uncertainty and the robustness of estimated probabilities, benefits, and costs to changes in key assumptions.

For major rules involving annual economic effects of $1 billion or more, you should present a formal quantitative analysis of the relevant uncertainties about benefits and costs. In other words, you should try to provide some estimate of the probability distribution of regulatory benefits and costs. In summarizing the probability distributions, you should provide some estimates of the central tendency (e.g., mean and median) along with any other information you think will be useful such as ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Your estimates cannot be more precise than their most uncertain component. Thus, your analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Worst-case or conservative analyses are not usually adequate because they do not convey the complete probability distribution of outcomes, and they do not permit calculation of an expected value of net benefits. In many health and safety rules, economists conducting benefit-cost analyses must rely on formal risk assessments that address a variety of risk management questions such as the baseline risk for the affected population, the safe level of exposure or, the amount of risk to be reduced by various interventions. Because the answers to some of these questions are directly used in benefits analyses, the risk assessment methodology must allow for the determination of expected benefits in order to be comparable to expected costs. This means that conservative assumptions and defaults (whether motivated by science policy or by precautionary instincts), will be incompatible with benefit analyses as they will result in benefit estimates that exceed the expected value. Whenever it is possible to characterize quantitatively the probability distributions, some estimates of expected value (e.g., mean and median) must be provided in addition to ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Whenever possible, you should use appropriate statistical techniques to determine a probability distribution of the relevant outcomes. For rules that exceed the $1 billion annual threshold, a formal quantitative analysis of uncertainty is required. For rules with annual benefits and/or costs in the range from 100 million to $1 billion, you should seek to use more rigorous approaches with higher consequence rules. This is especially the case where net benefits are close to zero. More rigorous uncertainty analysis may not be necessary for rules in this category if simpler techniques are sufficient to show robustness. You may consider the following analytical approaches that entail increasing levels of complexity:

- Disclose qualitatively the main uncertainties in each important input to the calculation of benefits and costs. These disclosures should address the uncertainties in the data as well as in the analytical results. However, major rules above the $1 billion annual threshold require a formal treatment.
- Use a numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches. Sensitivity analysis is especially valuable when the information is lacking to carry out a formal probabilistic simulation. Sensitivity analysis can be used to find "switch points" -- critical parameter values at which estimated net benefits change sign or the low cost alternative switches. Sensitivity analysis usually proceeds by changing one variable or assumption at a time, but it can also be done by varying a combination of variables simultaneously to learn more about the robustness of your results to widespread changes. Again, however, major rules above the $1 billion annual threshold require a formal treatment.
- Apply a formal probabilistic analysis of the relevant uncertainties – possibly using simulation models and/or expert judgment as revealed, for example, through Delphi methods.[28] Such a formal analytical approach is appropriate for complex rules where there are large, multiple uncertainties whose analysis raises technical challenges, or where the effects cascade; it is required for rules that exceed the $1 billion annual threshold. For example, in the analysis of regulations addressing air pollution, there is uncertainty about the effects of the rule on future emissions, uncertainty about how the change in emissions will affect air quality, uncertainty about how changes in air quality will affect health, and finally uncertainty about the economic and social value of the change in health outcomes. In formal probabilistic assessments, expert solicitation is a useful way to fill key gaps in your ability to assess uncertainty.[29] In general, experts can be used to quantify the probability distributions of key parameters and relationships. These solicitations, combined with other sources of data, can be combined in Monte Carlo simulations to derive a probability distribution of benefits and costs. You should

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[28] The purpose of Delphi methods is to generate suitable information for decision making by eliciting expect judgment. The elicitation is conducted through a survey process which eliminates the interactions between experts. See Morgan MG and Henrion M (1990), *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Riskand Policy Analysis*, Cambridge University Press.

[29] Cooke RM (1991), *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press.

pay attention to correlated inputs. Often times, the standard defaults in Monte Carlo and other similar simulation packages assume independence across distributions. Failing to correctly account for correlated distributions of inputs can cause the resultant output uncertainty intervals to be too large, although in many cases the overall effect is ambiguous. You should make a special effort to portray the probabilistic results—in graphs and/or tables—clearly and meaningfully.

New methods may become available in the future. This document is not intended to discourage or inhibit their use, but rather to encourage and stimulate their development.

2. Economic Values of Uncertain Outcomes

In developing benefit and cost estimates, you may find that there are probability distributions of values as well for each of the outcomes. Where this is the case, you will need to combine these probability distributions to provide estimated benefits and costs.

Where there is a distribution of outcomes, you will often find it useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of your findings. It is a common practice to compare the "best estimates" of both benefits and costs with those of competing alternatives. These "best estimates" are usually the average or the expected value of benefits and costs. Emphasis on these expected values is appropriate as long as society is "risk neutral" with respect to the regulatory alternatives. While this may not always be the case, you should in general assume "risk neutrality" in your analysis. If you adopt a different assumption on risk preference, you should explain your reasons for doing so.

3. Alternative Assumptions

If benefit or cost estimates depend heavily on certain assumptions, you should make those assumptions explicit and carry out sensitivity analyses using plausible alternative assumptions. If the value of net benefits changes from positive to negative (or vice versa) or if the relative ranking of regulatory options changes with alternative plausible assumptions, you should conduct further analysis to determine which of the alternative assumptions is more appropriate. Because different estimation methods may have hidden assumptions, you should analyze estimation methods carefully to make any hidden assumptions explicit.

F. Specialized Analytical Requirements

In preparing analytical support for your rulemaking, you should be aware that there are a number of analytic requirements imposed by law and Executive Order. In addition to the regulatory analysis requirements of Executive Order 12866, you should also consider whether your rule will need specialized analysis of any of the following issues.

Impact on Small Businesses and Other Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. chapter 6), agencies must prepare a proposed and final "regulatory flexibility analysis" (RFA) if the rulemaking could "have a significant impact on a substantial number of small entities." You should consider posting your RFA on the internet so the public can review your findings.

Your agency should have guidelines on how to prepare an RFA and you are encouraged to consult with the Chief Counsel for Advocacy of the Small Business Administration on expectations concerning what is an adequate RFA. Executive Order 13272 (67 FR 53461, August 16, 2002) requires you to notify the Chief Counsel for Advocacy of any draft rules that might have a significant economic impact on a substantial number of small entities. Executive Order 13272 also directs agencies to give every appropriate consideration to any comments provided by the Advocacy Office. Under SBREFA, EPA and OSHA are required to consult with small business prior to developing a proposed rule that would have a significant effect on small businesses. OMB encourages other agencies to do so as well.

Analysis of Unfunded Mandates

Under the Unfunded Mandates Act (2 U.S.C. 1532), you must prepare a written statement about benefits and costs prior to issuing a proposed or final rule (for which your agency published a proposed rule) that may result in aggregate expenditure by State, local, and tribal governments, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation). Your analytical requirements under Executive Order 12866 are similar to the analytical requirements under this Act, and thus the same analysis may permit you to comply with both analytical requirements.

Information Collection, Paperwork, and Recordkeeping Burdens

Under the Paperwork Reduction Act (44 U.S.C. chapter 35), you will need to consider whether your rulemaking (or other actions) will create any additional information collection, paperwork or recordkeeping burdens. These burdens are permissible only if you can justify the practical utility of the information for the implementation of your rule. OMB approval will be required of any new requirements for a collection of information imposed on 10 or more persons and a valid OMB control number must be obtained for any covered paperwork. Your agency's CIO should be able to assist you in complying with the Paperwork Reduction Act.

Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. The data and analysis that you use to support your rule must meet these agency and OMB quality standards. Your agency's CIO should be able to assist you in assessing information quality. The Statistical and Science Policy

Branch of OMB's Office of Information and Regulatory Affairs can provide you assistance. This circular defines OMB's minimum quality standards for regulatory analysis.

Environmental Impact Statements

The National Environmental Policy Act (42 U.S.C. 4321-4347) and related statutes and executive orders require agencies to consider the environmental impacts of agency decisions, including rulemakings. An environmental impact statement must be prepared for "major Federal actions significantly affecting the quality of the human environment." You must complete NEPA documentation before issuing a final rule. The White House Council on Environmental Quality has issued regulations (40 C.F.R. 1500-1508) and associated guidance for implementation of NEPA, available through CEQ's website (http://www.whitehouse/gov/ceq/).

Impacts on Children

Under Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," each agency must, with respect to its rules, "to the extent permitted by law and appropriate, and consistent with the agency's mission," "address disproportionate risks to children that result from environmental health risks or safety risks." For any substantive rulemaking action that "is likely to result in" an economically significant rule that concerns "an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children," the agency must provide OMB/OIRA "an evaluation of the environmental health or safety effects of the planned regulation on children," as well as "an explanation of why the planned regulation is preferable to other potentially and reasonably feasible alternatives considered by the agency."

Energy Impacts

Under Executive Order 13211 (66 FR 28355, May 22, 2001), agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law. This Statement is to include a detailed statement of "any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)" for the action and reasonable alternatives and their effects. You need to publish the Statement or a summary in the related NPRM and final rule. For further guidance, see OMB Memorandum 01-27 ("Guidance on Implementing Executive Order 13211", July 13, 2001), available on OMB's website.

G. Accounting Statement

You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency. You should use the guidance outlined above to report these estimates. We have included a suggested format for your consideration.

Categories of Benefits and Costs

To the extent feasible, you should quantify all potential incremental benefits and costs. You should report benefit and cost estimates within the following three categories: monetized quantified, but not monetized; and qualitative, but not quantified or monetized.

These categories are mutually exclusive and exhaustive. Throughout the process of listing preliminary estimates of benefits and costs, agencies should avoid double-counting. This problem may arise if more than one way exists to express the same change in social welfare.

Quantifying and Monetizing Benefits and Costs

You should develop quantitative estimates and convert them to dollar amounts if possible. In many cases, quantified estimates are readily convertible, with a little effort, into dollar equivalents.

Qualitative Benefits and Costs

You should categorize or rank the qualitative effects in terms of their importance (e.g., certainty, likely magnitude, and reversibility). You should distinguish the effects that are likely to be significant enough to warrant serious consideration by decision makers from those that are likely to be minor.

Treatment of Benefits and Costs over Time

You should present undiscounted streams of benefit and cost estimates (monetized and net) for each year of the analytic time horizon. You should present annualized benefits and costs using real discount rates of 3 and 7 percent. The stream of annualized estimates should begin in the year in which the final rule will begin to have effects, even if the rule does not take effect immediately. Please report all monetized effects in 2001 dollars. You should convert dollars expressed in different years to 2001 dollars using the GDP deflator.

Treatment of Risk and Uncertainty

You should provide expected-value estimates as well as distributions about the estimates, where such information exists. When you provide only upper and lower bounds (in addition to best estimates), you should, if possible, use the 95 and 5 percent confidence bounds. Although we encourage you to develop estimates that capture the distribution of plausible outcomes for a particular alternative, detailed reporting of such distributions is not required, but should be available upon request.

The principles of full disclosure and transparency apply to the treatment of uncertainty. Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. You may add footnotes to the table as needed to provide documentation and references, or to express important warnings.

In a previous section, we identified some of the issues associated with developing estimates of the value of reductions in premature mortality risk. Based on this discussion, you should present alternative primary estimates where you use different estimates for valuing reductions in premature mortality risk.

Precision of Estimates

Reported estimates should reflect, to the extent feasible, the precision in the analysis. For example, an estimate of $220 million implies rounding to the nearest $10 million and thus a precision of +/-$5 million; similarly, an estimate of $222 million implies rounding to the nearest $1 million and thus, a precision of +/-$0.5 million.

Separate Reporting of Transfers

You should report transfers separately and avoid the misclassification of transfer payments as benefits or costs. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare. To the extent that regulatory outputs reflect transfers rather than net welfare gains to society, you should identify them as transfers rather than benefits or costs. You should also distinguish transfers caused by Federal budget actions -- such as those stemming from a rule affecting Social Security payments -- from those that involve transfers between non-governmental parties -- such as monopoly rents a rule may confer on a private party. You should use as many categories as necessary to describe the major redistributive effects of a regulatory action. If transfers have significant efficiency effects in addition to distributional effects, you should report them.

Effects on State, Local, and Tribal Governments, Small Business, Wages and Economic Growth

You need to identity the portions of benefits, costs, and transfers received by State, local, and tribal governments. To the extent feasible, you also should identify the effects of the rule or program on small businesses, wages, and economic growth.[30] Note that rules with annual costs that are less than one billion dollars are likely to have a minimal effect on economic growth.

[30] The Regulatory Flexibility Act (5 U.S.C. 603(c), 604).

OMB #: **Agency/Program Office:**
Rule Title:
RIN#: **Date:**

Category	*Primary Estimate*	*Minimum Estimate*	*Maximum Estimate*	*Source Citation (RIA, preamble, etc.)*
BENEFITS				
monetized benefits				
Annualized quantified, but unmonetized, benefits				
(unquantified) benefits				
COSTS				
Annualized monetized costs				
Annualized quantified, but unmonetized, costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: "on budget"				
from whom to whom?				
Annualized monetized transfers: "off-budget"				
From whom to whom?				

Category	*Effects*	*Source Citation (RIA, preamble, etc.)*
Effects on State, local, and/or tribal governments		
Effects on small businesses		
Effects on wages		
Effects on growth		

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H. Effective Date

The effective date of this Circular is January 1, 2004 for regulatory analyses received by OMB in support of proposed rules, and January 1, 2005 for regulatory analyses received by OMB in support of final rules. In other words, this Circular applies to the regulatory analyses for draft proposed rules that are formally submitted to OIRA after December 31, 2003, and for draft final rules that are formally submitted to OIRA after December 31, 2004. (However, if the draft proposed rule is subject to the Circular, then the draft final rule will also be subject to the Circular, even if it is submitted prior to January 1, 2005.) To the extent practicable, agencies should comply earlier than these effective dates. Agencies may, on a case-by-case basis, seek a waiver from OMB if these effective dates are impractical.

Regulatory Impact Analysis: Frequently Asked Questions (FAQs)

February 7, 2011

With this document, the Office of Information and Regulatory Affairs (OIRA) is providing answers to frequently asked questions about the regulatory impact analysis that is required by Executive Order 12866 and OMB Circular A-4.[1] In addition, President Obama signed Executive Order 13563, "Improving Regulation and Regulatory Review," on January 18, 2011; that Executive Order incorporates the requirements of Executive Order 12866 and specifically directs agencies "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible."

The purpose of this document is to offer answers to questions often asked with respect to regulatory impact analysis; nothing said here is meant to alter existing requirements in any way. For more complete guidance, please consult Executive 13563, Executive Order 12866, and Circular A-4.

1. <u>When do I need to provide a regulatory impact analysis, and what is the definition of "economically significant"?</u>

Executive Order 12866 provides that agencies must submit a regulatory impact analysis for those regulatory actions that are "significant" within the meaning of Section 3(f)(1) – or what Circular A-4 describes as "economically significant."[2] A regulatory action is economically significant if it is anticipated (1) to "[h]ave [1] an annual effect on the economy of $100 million or more" or (2) to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities."

The $100 million threshold applies to the impact of the proposed or final regulation in *any one year,* and it includes *benefits, costs, or transfers*. (The word "or" is important: $100 million in annual benefits, *or* costs, *or* transfers is sufficient; $50 million in benefits and $49 million in costs, for example, is not.)

The second criterion – whether the rule would "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities" – requires careful consideration of the phrase "adversely affect in a material way." There are no hard-and-fast rules here. Suppose, for example, that a regulation (1) would impose $98 million in first-year costs for pollution control equipment, with lower annual costs thereafter, (2) would disproportionately and adversely affect a small sector of the economy, and (3) would threaten to create significant job loss. This rule would be considered economically significant.

The $100 million threshold is identical to the monetary threshold for determining whether a rule is "major" under the Congressional Review Act (CRA). Under that Act, a "major rule" is one that "has resulted in or is likely to result in . . . an annual effect on the economy of $100,000,000 or more."[3] For both Executive Order 12866 and the CRA, the $100 million threshold is not adjusted for inflation (unlike the expenditure threshold contained in the Unfunded Mandates Reform Act[4]). Under the Congressional Review Act, a rule also qualifies as "major" if it has resulted in or is likely to result in "a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions" or "significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets."[5]

2. How should my regulatory impact analysis be presented to the public?

To inform the public of the expected consequences of regulations, agencies should present their analysis in plain language. To promote transparency and public participation, they should provide a clear executive summary of their central conclusions.[6] They should clearly and prominently include a standardized accounting statement, and are particularly encouraged to do so in the preamble and executive summary.[7] That statement should include one or more tables summarizing their assessment of costs, benefits, and transfers, at both 3% and 7% discount rates.[8] Consistent with the Executive Order 13563 and Executive Order 12866, OMB recommends that the tables provide a transparent statement of both quantitative and qualitative benefits and costs of the proposed or planned action as well as of reasonable alternatives.[9] In addition to providing a clear table of aggregate costs and benefits, agencies are strongly encouraged to provide one or more separate tables disaggregating and showing the components of those figures.[10]

In comparing benefits to costs, agencies should emphasize net benefits rather than ratios. As Circular A-4 states, "[t]he size of net benefits, the absolute difference between the projected benefits and costs, indicates whether one policy is more efficient than another. The ratio of benefits to costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results."[11]

3. Can something other than a "market failure" be identified as the "need" for the regulation?

Yes. Executive Order 13563 states, "Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts." Circular A-4 states that "you should try to explain whether the action is intended to address a significant market failure *or* to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy."[12] The word "or" is once again significant: if a market failure does not exist but there is a compelling public need for regulation, then the agency should clearly identify the problem that it intends to address and explain and assess the significance of that problem.[13]

4. Even if I have identified a market failure or other need for regulation, should I still consider alternatives to Federal regulation?

Yes. In taking into account a range of alternatives, you should begin by asking whether to regulate at all. Even where a market failure clearly exists, there may be alternatives to Federal regulation, including antitrust enforcement, consumer-initiated litigation in the product liability system, and administrative compensation systems.[14]

You should also consider the option of deferring to regulation at the State or local level. To be sure, problems that affect interstate commerce or spill across State lines may best be addressed by Federal regulation. But more localized problems may be more efficiently addressed locally.[15] In such situations, deferring to state and local regulation can encourage regulatory experimentation and innovation while also fostering learning and competition to establish the best regulatory policies.[16]

There are often questions about the proper relationship among Federal, state, and local requirements. Where Federal regulation is warranted, you should avoid imposing conflicting or duplicative requirements wherever possible. Executive Order 13563 states, "Some sectors and industries face a significant number of regulatory requirements, some of which may be redundant, inconsistent, or overlapping. Greater coordination across agencies could reduce these requirements, thus reducing costs and simplifying and harmonizing rules. In developing regulatory actions and identifying appropriate approaches, each agency shall attempt to promote such coordination, simplification, and harmonization."

While some problems are best handled at the state level, others can be handled through simultaneous regulation from different levels of government. In some cases, however, the increased compliance costs required for firms to meet different State and local regulations may exceed any benefits stemming from the diversity of State and local regulation.[17] With close reference to statutory requirements and governing legal principles, you should consider when and whether it is appropriate to retain State and local regulation.

5. After determining that Federal regulation is the best way to proceed, how do I identify and provide an adequate analysis of "potentially effective and reasonably feasible alternatives" as required by Executive Order 12866 ?

Executive Order 12866 requires an "assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation" and "an explanation why the planned regulatory action is preferable to the identified potential alternatives."[18] You should ordinarily consider analyzing at least three options: the preferred option; a more stringent option; and a less stringent one.[19]

In some cases, the relevant alternatives might not line up on a continuum of stringency, but might involve different approaches, with distinct advantages and disadvantages. If, for example, an agency is considering banning the sale of a potentially unsafe product, it might consider instead requiring disclosure of health risks to the public. Executive Order 13563 states, "Where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public." Warnings, appropriate default rules, and disclosure requirements are examples.

In considering which alternatives to discuss, you should explore which approaches are feasible and plausible ways of meeting the regulatory objective. When the preferred option includes a number of distinct provisions, the benefits and costs of different regulatory provisions should be analyzed separately in order to facilitate consideration of the full range of potential alternatives.[20]

6. What is the appropriate time horizon for estimating costs and benefits?

Executive Order 13563 directs agencies "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." When choosing the appropriate time horizon for estimating costs and benefits, agencies should consider how long the regulation being analyzed is likely to have resulting effects. The time horizon begins when the regulatory action is implemented and ends when those effects are expected to cease.[21] Ideally, analysis should include all future costs and benefits. Here as elsewhere, however, a "rule of reason" is appropriate, and the agency should consider for how long it can reasonably predict the future and limit its analysis to this time period. Thus, if a regulation has no predetermined sunset provision, the agency will need to choose the endpoint of its analysis on the basis of a judgment about the foreseeable future. For rules that require large up-front capital investments, the life of the capital is also an option. For most agencies, a standard time period of analysis is 10 to 20 years, and rarely exceeds 50 years.

7. What is a baseline and how do I identify it?

The baseline is the best assessment of how the world would look in the absence of the proposed action during the relevant time horizon. Specifically, the baseline should incorporate the agency's best forecast for how the world will change (if at all) during the identified time horizon, with particular attention to factors such as the evolution of relevant markets; population or economic growth; possible behavioral changes, learning, and adaptation by relevant members of the public; technological changes and advances; and changes in regulations promulgated by the agency or other government entities. Identifying this baseline is necessary to allow assessment of the relative benefits and costs attributable to the proposed action.[22]

For review of an existing regulation or one that simply restates statutory requirements that are self-implementing, a pre-statute baseline, assuming "no change," is appropriate.[23]

Multiple baselines could be appropriate when more than one baseline is reasonable – perhaps because another agency's existing regulation could be implemented in different ways – and the choice would significantly affect estimated benefits and costs.[24]

8. When should I conduct an uncertainty analysis? A sensitivity analysis?

Regulatory analysis requires predictions about the future. What the future holds, both in the baseline and under the regulatory alternative under consideration, is rarely certain. The important uncertainties connected with the regulatory decision should be analyzed and presented as part of the regulatory impact analysis.[25] It is common practice for an agency's uncertainty analysis to present a central "best estimate," which reflects the expected value of the benefits and costs of the rule, as well as a description of the ranges of plausible values for benefits, costs, and net benefits. This description informs the decision-makers and the public of the degree of uncertainty associated with the regulatory decision.[26]

In general, you should also include a "sensitivity analysis" that shows how results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches.[27] The level of detail in the analysis can vary with the expected effects of the rule; you should use more rigorous analytical approaches, and more comprehensive sensitivity analysis, for rules with especially large consequences. For rules that exceed the $1 billion annual threshold, Circular A-4 states that "a formal quantitative analysis of uncertainty is required."

9. What is the difference between a transfer and a cost?

Costs affect the total resources available to society. Transfer payments are monetary payments from one group to another that do not affect total resources.[28] The agency should not include transfer payments in its estimates of the benefits and costs of a regulation. Instead, it should address them in a separate discussion of the distributional effects of the regulation.[29] Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation.

Examples of costs include:

- Expenditures, including goods and services, required to comply with the regulation
- Reductions in consumer and producer well-being resulting from regulation-induced price or quantity changes
- Increases in premature death, illness, or disability (e.g., in the case where a regulation that would reduce certain safety risks would have the consequence of increasing other safety risks).

Examples of transfers include:

- Fees to government agencies for goods or services already provided by the agency (that is, monetary transfers from feepayers to the government—because the goods and services are already counted as government costs, including them as private costs would entail double counting)
- Increases in sales tax revenue as a result of increases in sales (that is, monetary transfers from consumers to government)
- Payments by the Federal government for goods or services provided by the private sector (that is, monetary transfers by the government to service providers, such as reimbursements by the Medicare program)
- Reductions in sales by one business that are matched by increases in sales by another (that is, transfers in economic activity from one business to another)
- Reductions in resources for some consumers that are matched by increases for others (that is, transfers of resources among consumers)[30]

10. Why must I present the estimates using both 3% and 7% discount rates?

The 7 percent rate is a recent estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital in the private sector.[31] The effects of regulation, however, do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the "social rate of time preference," which simply means the rate at which "society" discounts future consumption flows to their present value. If we use the rate that the average saver uses to discount future consumption as our measure, then the real rate of return on long-term government debt provides a fair approximation. Historically, this rate has averaged around 3 percent in real terms on a pre-tax basis.[32]

Special considerations arise when comparing benefits and costs across generations. If the regulatory action will have important intergenerational benefits or costs, the agency should consider a sensitivity analysis, using a lower but positive discount rate, in addition to calculating net benefits using discount rates of 3 percent and 7 percent.[33]

11. How do I value time?

Some regulations require people to spend time on certain activities to comply with their provisions – as, for example, through paperwork or monitoring. The costs of such requirements should be described both in terms of hours and to the extent feasible, in terms of monetary equivalents. In order to value the cost of time, agencies should consider what those people would be doing with their time if they did not need to comply with the regulations.[34] The resulting figures, like all other costs and benefits, should be annualized (see below). As a general rule, workers' hourly wages can be used as a proxy for the value of the time that they could have spent doing other work. If the regulation requires paperwork, it may be appropriate to value the relevant time at the hourly wage for the workers asked to complete the required tasks. If specific expertise is needed to complete those tasks, the average wages of workers with that expertise should be used. If, for example, the regulation will require software changes by computer programmers, it would be appropriate to use the wages of computer programmers.

In some cases, regulations will result in time savings for individuals, and such savings should be described both in terms of hours saved and to the extent feasible, in terms of monetary equivalents. Monetized estimates should include a measure of the value of that time calculated in the same way as costs. If the time saved is not work, it is appropriate to try to estimate people's willingness to pay for the improvement. This estimate attempts to measure what individuals would be willing to pay to enjoy the particular benefit of time saved for the relevant activity.[35]

Sometimes regulations do not save time, but do lead to improvements in the quality of time spent on an activity. An example would be a regulation that requires airlines to provide adequate food and potable water to passengers within two hours of being delayed in an aircraft grounded on the tarmac. The regulation would not shorten people's waiting time, but would improve the quality of that waiting time. In this case, it is appropriate to try to estimate people's willingness to pay for the improvement. Studies or surveys of individuals in similar circumstances may be available to use as a reference point for estimates.

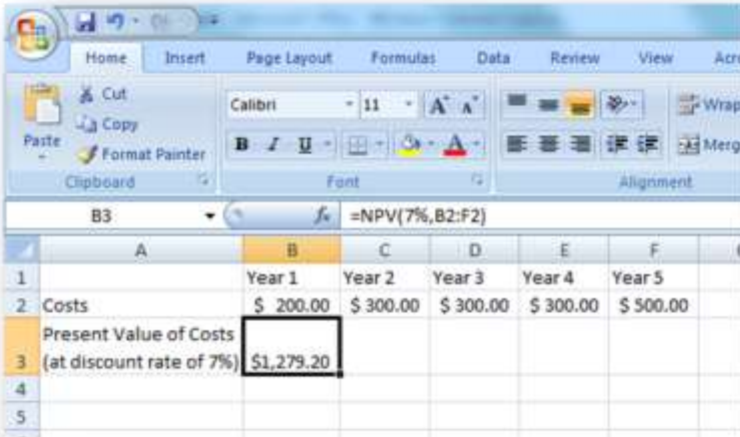
12. <u>How do I annualize?</u>

As part of a regulatory analysis, agencies are asked to provide estimates of the annualized costs and benefits of a regulation.[36] Under this requirement, agencies should take a stream of future benefits and costs of the rule and estimate its approximate yearly costs and benefits. The first step in the annualization of costs is to find the present value of the stream of future costs. To find that value, each year's expected costs should be discounted back to the present using the following formula:

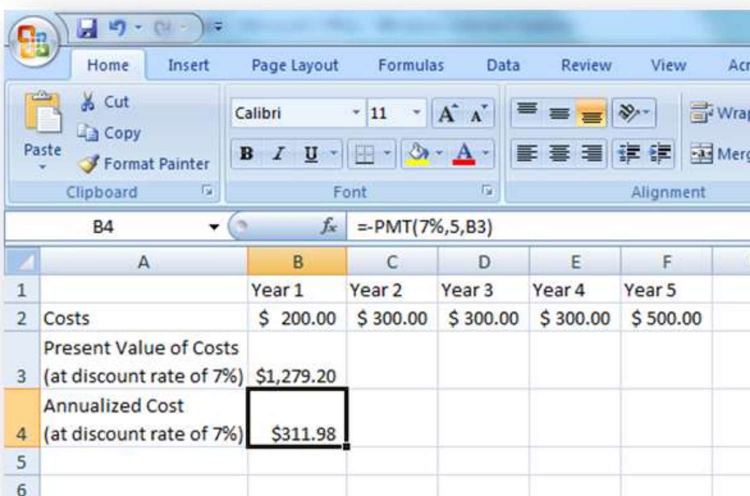
$$Present\ Value\ of\ Year\ T's\ Costs = \frac{C_t}{(1+i)^t}$$

where C_t is the cost t years in the future and i is the discount rate.

Then, each year's discounted costs should be added together to find the present value of costs. If you are using an Excel spreadsheet, you can use the NPV (Net Present Value) function to calculate the present value of costs from a set of future costs, as follows:



The next step is to compute an annualized cost from this present value. This step is akin to spreading the costs equally over each period, taking account of the discount rate. If you are using Excel, an easy way to compute this amount is to use the PMT function, which calculates the annualized amount needed over a number of years to equal a given present value at a particular discount rate. The formula returns a negative number, so the result should be multiplied by -1 to obtain the annualized cost.



Annualized benefits can be computed from a stream of expected future benefits using the same method.

[1] Executive Order 12866 is available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866.pdf. Circular A-4 is available at: http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf.

[2] Executive Order 12866 refers to "those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1)." Circular A-4 states that "Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1)." (P. 1).

[3] 5 U.S.C. § 804(2).

[4] Under the Unfunded Mandates Reform Act, each agency must prepare a benefit-cost analysis "before promulgating any general notice of proposed rulemaking that is likely to result in promulgation of any rule" that "includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." 2 U.S.C. §1532. For such rules, with limited exceptions, the "agency shall identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule, for (1) State, local, and tribal governments, in the case of a rule containing a Federal intergovernmental mandate; and (2) the private sector, in the case of a rule containing a Federal private sector mandate." 2 U.S.C. §1535.

[5] *Id.* See also "Guidance for Implementing the Congressional Review Act," M-99-13, available at http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m99-13.pdf. Note that these alternative tests for a "major rule" under the CRA are not the same as the second criterion under Executive Order 12866 (to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities"); by contrast, the CRA's language is drawn from Executive Order 12291, which was revoked in 1993. See Executive Order 12291, §1(b), available at http://www.archives.gov/federal-register/codification/executive-order/12291.html; Executive Order 12866, §11 ("Executive Order Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.").

[6] Circular A-4 states: "Your analysis should . . . have an executive summary." (P. 3).

[7] Circular A-4 states that "[y]our analysis should . . . have an executive summary, including a standardized accounting statement." (P. 3). It also states that "[y]ou need to provide an accounting statement with tables reporting benefit and cost estimate for each major final rule for your agency." (P. 44). See also OMB's "2010 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," available at http://www.whitehouse.gov/sites/default/files/omb/legislative/reports/2010_Benefit_Cost_Report.pdf. This report states that:

> For all economically significant regulatory actions, we recommend that agencies should clearly and prominently present, in the preamble and in the executive summary of the regulatory impact analysis, one or more tables summarizing the assessment of costs and benefits required under Executive Order 12866 Section 6(a)(3)(C)(i)-(iii). The tables should provide a transparent statement of both quantitative and qualitative benefits and costs of the proposed or planned action as well as of reasonable alternatives. The tables should include all relevant information that can be quantified and monetized, along with relevant information that can be described only in qualitative terms . . . . To the extent feasible in light of the nature of the issue and the relevant data, all benefits and costs should be quantified and monetized. To communicate any uncertainties, we recommend that the table should offer a range of values, in addition to best estimates, and it should clearly indicate impacts that cannot be quantified or monetized. If nonquantifiable variables are involved, they should be clearly identified. Agencies should attempt, to the extent feasible, not merely to identify such variables but also to signify their importance.
> (P. 51).

[8] Under the heading of "Accounting Statement," Circular A-4 states that "[y]ou should present undiscounted streams of benefit and cost estimates (monetized and net) for each year of the analytic time horizon. You should present annualized benefits and costs using real discount rates of 3 and 7 percent." (P. 45).

[9] Circular A-4 states: "The analysis document should discuss the expected benefits and costs of the selected regulatory option and any reasonable alternatives . . . . To present your results, you should: include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs, and express the estimates in this table in constant, undiscounted dollars . . . ; list the benefits and costs you can quantify, but cannot

monetize, including their timing; describe benefits and costs you cannot quantify; and identify or cross-reference the data or studies on which you base the benefit and cost estimates." (P. 18).

[10] See OMB's "2010 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," available at http://www.whitehouse.gov/sites/default/files/omb/legislative/reports/2010_Benefit_Cost_Report.pdf. It states that "[i]t will often be useful to accompany a simple, clear table of aggregated costs and benefits with a separate table offering disaggregated figures, showing the components of the aggregate figures." (P. 51).

[11] See p. 10 of Circular A-4.

[12] See p. 4 of Circular A-4.

[13] Executive Order 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people." Circular A-4 states that "you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy." (P. 4).

[14] Circular A-4 states: "Even where a market failure exists, you should consider other means of dealing with the failure before turning to Federal regulation. Alternatives to Federal regulation include antitrust enforcement, consumer-initiated litigation in the product liability system, or administrative compensation systems. In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate level of governmental level of regulation." (P. 5)

[15] Circular A-4 states: "In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally." (P. 6).

[16] Circular A-4 states: "The advantages of leaving regulatory issues to State and local authorities can be substantial. If public values and preferences differ by region, those differences can be reflected in varying State and local regulatory policies. Moreover, States and localities can serve as a testing ground for experimentation with alternative regulatory policies. One State can learn from another's experience while local jurisdictions may compete with each other to establish the best regulatory policies. You should examine the proper extent of State and local discretion in your rulemaking context." (P. 6).

[17] Circular A-4 states: "Where Federal regulation is clearly appropriate to address interstate commerce issues, you should try to examine whether it would be more efficient to retain or reduce State and local regulation. The local benefits of State regulation may not justify the national costs of a fragmented regulatory system. For example, the increased compliance costs for firms to meet different State and local regulations may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking." (P. 6).

[18] See Section 6(a)(3)(C) of Executive Order 12866.

[19] Circular A-4 states: "In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups." (P. 8).

[20] Circular A-4 states that when "consider[ing] alternative regulatory approaches," there "must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives." (P. 7).

[21] Circular A-4 states: "You should present undiscounted streams of benefit and cost estimates (monetized and net) for each year of the analytic time horizon." (P. 45). A-4 also provides that "you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur. The beginning point for your stream of estimates should be the year in which the final rule will begin to have effects, even if that is expected to be some time in the future. The ending point should be far enough in the future to encompass all the significant benefits and costs likely to result from the rule." (P. 31).

[22] Circular A-4 states that "[y]ou need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action. The choice of an appropriate baseline may require consideration of a wide range of potential factors, including: evolution of the market, changes in external factors affecting expected benefits and costs, changes in regulations promulgated by the agency or other government entities, and the degree of compliance by regulated entities with other regulations." (P. 15).

[23] Circular A-4 states: "It may be reasonable to forecast that the world absent the regulation will resemble the present. If this is the case, however, your baseline should reflect the future effect of current government programs and policies. For review of an existing regulation, a baseline assuming 'no change' in the regulatory program generally provides an appropriate basis for evaluating regulatory alternatives. . . . In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline." (PP. 15-16).

[24] Circular A-4 states: "When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies' regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline." (P. 15).

[25] Circular A-4 states that the "important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis." (P. 38).

[26] Circular A-4 states: "Where there is a distribution of outcomes, you will often find it useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of your findings. It is a common practice to compare the 'best estimate' of both benefits and costs with those of competing alternatives. These 'best estimates' are usually the average or the expected value of benefits and costs." (P. 48).

[27] Circular A-4 states: "Use a numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches." (P. 41).

[28] This general statement does not take into account the potential inefficiencies that may arise from taxation (other than lump-sum taxation). Transfer payments could affect total resources available to society because of the marginal cost of public funds.

[29] Circular A-4 states: "You should report transfers, separately and avoid and misclassification of transfer payments as benefits or costs. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare." (P. 46).

[30] Circular A-4 states: "A regulation that restricts the supply of a good, causing its price to rise, produces a transfer from buyers to sellers. The net reduction in the total surplus (consumer plus producer) is a real cost to society, but the transfer from buyers to sellers resulting from a higher price is not a real cost since the net reduction automatically accounts for the transfer from buyers to sellers." (P. 38).

[31] Circular A-4 states: "The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector." (P. 33).

[32] Circular A-4 provides: "The effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the 'social rate of time preference.' This simply means the rate at which 'society' discounts future consumption flows to their present value. If we take the rate that the average saver uses to discount future consumption as our measure of the social rate of time preference, then the real rate of return on long-term government debt may provide a fair approximation. Over the last thirty years, this rate has averaged around 3 percent in real terms on a pre-tax basis." (P. 33).

[33] Circular A-4 offers a brief relevant background on economic and ethical issues and states: "If your rule will have important intergenerational benefits or costs you might consider a further sensitivity analysis using a lower but positive discount rate in addition to calculating net benefits using discount rates of 3 and 7 percent." (P. 36).

[34] Circular A-4 states: "You should include [other benefit and cost considerations] in your analysis and provide estimates of their monetary values when they are significant: [p]rivate-sector compliance costs and savings; [g]overnment administrative costs and savings; [g]ains or losses in consumers' or producers' surpluses; [d]iscomfort

or inconvenience costs and benefits; and [g]ains or losses of time in work, leisure and/or commuting/travel settings." (P. 37).

[35] According to Circular A-4, "[o]pportunity cost is the appropriate concept for valuing both benefits and costs. The principle of 'willingness-to-pay' (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit." (P. 18). Circular A-4 adds: "In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual's 'willingness-to-accept' (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost." Hence it may be valid for agencies to consider use of WTA. See pp. 18-19 of Circular A-4 for a general discussion of the concept of "willingness to pay."

[36] Circular A-4 states: "As a first step, you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur . . . . Benefits and costs that occur sooner are generally more valuable . . . . To reflect this preference, a discount factor should be used to adjust the estimated benefits and costs for differences in timing. The further in the future the benefits and costs are expected to occur, the more they should be discounted. The discount factor can be calculated given a discount rate." (PP. 31-32). It also states that "[y]ou should present annualized benefits and costs . . ." (P. 45).

Health and Ecological Criteria Division
Office of Science and Technology
Office of Water
United States Environmental Protection Agency
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ARSENIC AND FISH CONSUMPTION

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ARSENIC AND FISH CONSUMPTION

Health and Ecological Effects Division
Office of Science and Technology
Office of Water

ABSTRACT

This report summarizes available data on human intake of inorganic arsenic by consumption of fish and shellfish and arsenic in drinking water. It estimates total exposure to inorganic arsenic from these vehicles under a variety of exposure scenarios.

Much of the arsenic in fish and shellfish is present in the form of organic compounds rather than as inorganic arsenic. For this report, EPA utilized published data on the concentrations of total arsenic and inorganic arsenic in a variety of fish and shellfish species. These data along with data from the U.S. Department of Agriculture Food Consumption Survey on fish/shellfish intake of consumers and non consumers were used to generate estimates for the inorganic arsenic intake for several exposure scenarios. The scenario for the group with the highest potential exposure (90 μg/day) was individuals consuming a diet high in fish and shellfish and having a preference for shellfish. An scenario for the average fish consumer estimated an intake of 4 μg/day and the scenario for the general consumer with only occasional fish/shellfish intake estimated an intake of 0.6 μg/inorganic arsenic per day. Scenarios for consumer groups with other fish/shellfish consumption patterns were evaluated as well.

The evaluation of inorganic arsenic exposure from fish and shellfish provides support for utilizing the existing MCL of 50 ppb for arsenic as an ambient water criterion in some areas until EPA updates its risk assessment for arsenic and revises the MCL. The exposure evaluation also illustrates a need for site specific criterion when high consumption of fish and shellfish is coupled with arsenic contamination of drinking water. Toxicity concern related to the arsenic in marine fish and shellfish is mitigated by the fact that it is largely present as arsenobetaine, a metabolically stable compound that is rapidly excreted. Additional studies of the forms of organic arsenic in fresh water species are needed.

1.0 INTRODUCTION

The U.S. Environmental Protection Agency's (EPA) guidance for arsenic under the Safe Drinking Water Act and the Clean Water Act are different. EPA's drinking water standard, or maximum contaminant level (MCL) for arsenic is 50 ppb and was developed by the Public Health Service in the 1940's. The Ambient Water Quality Criterion under the Clean Water Act is 0.018 ppb based on an estimated one in a million cancer risk (EPA, 1980). EPA has recognized that there is considerable uncertainty in the cancer risk value and is presently in the process of developing a new risk analysis in order to propose a new MCL. Under legislative requirements, the EPA will issue a proposal for an arsenic MCL in the year 2000. Until that time the 50 ppb will remain in effect for public potable water sources.

The question has been raised as to whether the 50 ppb MCL for arsenic in drinking water can also serve as an Ambient Water Quality Criterion for arsenic until the risk assessment revision is complete and whether fish/shellfish consumption from the same waters adds significantly to the inorganic arsenic exposure. According to the Clean Water Act Criteria Document for arsenic (EPA, 1980), trivalent and pentavalent, inorganic, arsenic compounds are the most toxic species. This document accepts that premise and updates the Criteria Document in terms of the forms of arsenic in fish and shellfish.

The following report examines the available quantitative data on arsenic in fish and shellfish as well as its speciation (inorganic vs. organic). Estimates are made for human exposures to inorganic arsenic from fish/shellfish and drinking water under several exposure scenarios that apply to the average and high end of the distribution curve for fish/shellfish consumption. An exposure assessment for the average consumer within the general population (which includes nonconsumers) is also presented. The document is a technical summary of the available data on the arsenic in fish and shellfish as well as an exposure evaluation for inorganic arsenic.

2.0 ARSENIC IN FISH

The quantitative data on arsenic concentrations and speciation in fish are limited but are generally consistent with the hypothesis that most and sometimes all of the arsenic in fish is organic rather than inorganic. The available analytical data on arsenic in fish are presented below. The data are grouped by the source of the fish and the type of arsenic. All data are reported in terms of wet mass. The following presents data on total arsenic in marine species and then freshwater species followed by inorganic arsenic for marine species and then freshwater species.

Total Arsenic in Marine and Estuarine Species. Ballin et al. (1994) analyzed samples of 13 species of marine fish for total arsenic. Average concentrations ranged from 0.6 to 37 ppm. Only two of 20 samples had values greater than 10 ppm, one of three plaice samples and a catfish sample. In cases where samples for a given species originated from different source waters, there was considerable variability in total arsenic concentration. Total arsenic concentrations from three different herring samples ranged from 0.7 to 4 ppm; there was also variability among the results for 5 samples from the same fish. The two species with the highest average levels of total arsenic were plaice from Fladenground (32 ppm; standard deviation 14) and catfish from Gr. Fisherbank (37 ppm; standard deviation 28).

In another study, Lawrence et al. (1986) obtained samples of fish muscle from different areas in Canada. Both Atlantic and Pacific fish species were evaluated. The average total arsenic concentrations for replicate samples ranged from 1.1 ppm (herring) to 13.2 ppm (sole) for Atlantic species and 0.31 (salmon) to 7.4 ppm (cod) for Pacific Species. A total of 6 Atlantic species and 5 Pacific species were evaluated. Slight differences were apparent in the Atlantic versus Pacific samples of the same species. For example the sole sample from the Atlantic had 13.2 ppm while that from the Pacific had 5.2 ppm and the cod sample from the Atlantic had 5.2 ppm while that from the Pacific had 7.4 ppm. Based on the sample variability observed by Ballin et al. (1994), these differences are most likely a reflection of variability in samples rather than differences that result because of the arsenic in the source water. Additional support for this conclusion is provided by analysis of a sample of sole purchased locally in Ottawa which had only 0.10 ppm total arsenic, a value far lower than that for either the Atlantic or Pacific samples. The low value for this sample may represent loss during storage and shipping. Le et al. (1994) found that up to 48% of the total arsenic could be released in defrost liquid.

In order to evaluate microwave assisted distillation with atomic absorption spectrometry as a method for determining inorganic arsenic, Lopes et al. (1994) analyzed commercially purchased canned or frozen samples of anchovies, tuna, sardines, hake and sole for total as well as inorganic arsenic. Total arsenic concentrations ranged from 0.82 ppm (tuna) to 7.76 ppm (sole)

In a report developed for Region 10 of the U.S. EPA, Chew (1996) summarized data from the published literature on the concentrations of total arsenic and inorganic arsenic in fish and shellfish. The data apply primarily to samples from Japan and all but one sample came from the Pacific Ocean. Total average arsenic concentrations ranged from values less than 1 to 10 ppm for fish with two outliers: skate (64 ppm) and stingray (17 ppm).

Total Arsenic in Fresh Water Species. Ballin et al. (1994) examined the total arsenic in fresh water fish from rivers in Northern Germany, the River Elbe or from a fish hatchery. Seven species were examined; the average total arsenic concentrations were lower than those for marine fish and ranged from the detection limit to 1.5 ppm. The highest concentration was present in rainbow trout specimens from a fish hatchery and the lowest concentration was found in perch from a river in Northern Germany. The trout sample was the only one with a concentration of greater than 0.1 ppm.

The lower levels of total arsenic in fresh water fish are substantiated by analysis of the muscle tissue of several species collected in Ontario and Alberta, Canada (Lawrence et al., 1986). Concentrations ranged from 0.007 ppm (yellow perch) to 0.24 ppm (striped perch). Nine replicate samples were analyzed. Among the 23 samples of fresh water fish analyzed by Ballin et al (1994) and Lawrence et al. (1986), the total arsenic was less than 0.3 ppm for 22.

Inorganic Arsenic in Marine and Estuarine Species. In the data summarized by Chew (1996), average inorganic arsenic concentrations ranged from the detection limit to 0.2 ppm. The species with the highest average percentage of arsenic as inorganic arsenic were shark (9.5%), sturgeon (6.9%) and sucker (8.5%). In all other cases the percent of inorganic arsenic was less than 4 %. The two species with the highest average concentrations of total arsenic (skate, stingray) had none of their arsenic present as inorganic arsenic and the species with the highest concentrations of inorganic arsenic (shark, sturgeon, sucker) had low average total arsenic concentrations (2.1, 0.6 and 0.2 ppm respectively). In the study by Lopez et al. (1994), the percent inorganic arsenic in the 5 fish samples analyzed was less than 5% in all samples when analyzed by microwave-assisted distillation and atomic absorption spectrometry.

Ballin et al. (1994) did not analyze the fish for either inorganic arsenic or total organic arsenic. They did analyze the tissues for arsenobetaine and phospholipid arsenic, the major organic forms of arsenic in fish. In marine fish, the arsenobetaine accounted for 96% to 100% of the total arsenic and the phospholipid arsenic for 0.17 to 4.12 % of the total. Assuming, no other organic arsenic forms were present in the fish examined, the maximum amount of inorganic arsenic present was 2%.

Lawrence et al. (1986) analyzed 11 replicate samples of fish muscle for arsenobetaine and arsenocholine using purification by high performance liquid chromatography (HPLC) and identification with atomic absorption spectrometry and fast atom bombardment mass spectrometry. In addition to arsenobetaine and arsenocholine, the method was able to identify two unknown organic compounds containing arsenic. In all fish samples except salmon, the only compound identified was arsenobetaine which accounted for 78 to 88% of the total arsenic. In salmon an unidentified form of organic arsenic was present in addition to arsenobetaine. The arsenobetaine was 41% of the total arsenic and the unknown compound was 42 % of the total arsenic.

Caution must be used in evaluating the Lawrence et al. (1986) data because the percent recovery from samples spiked with arsenobetaine was 80 to 84% quite similar to the percent of arsenic reported to be present as arsenobetaine in most samples. Thus, this method could under report the amount of arsenic present as organic arsenic because of recovery problems. The authors point out that when the results are corrected for recovery they indicate that arsenobetaine accounted for "essentially all of the arsenic present in the marine samples analyzed". It must also be remembered that Lawrence et al. (1986) did not analyze the samples for phospholipid containing arsenic which Ballin et al. (1994) demonstrated to be present in marine fish tissues.

Inorganic Arsenic in Fresh Water Species. In analysis of 9 replicate samples of fresh water fish, Lawrence et al. (1986) did not identify either arsenobetaine or arsenocholine. An unknown organoarsenic compound was present in all samples. This compound accounted for 71 to 85% of the total arsenic. Caution must be used in evaluating these data since it was not possible to quantify the recovery for the unidentified compound. The same unknown compound was present in all fresh fish samples whether they were from Manitoba or Alberta. Elution of the unidentified compound from the HPLC column indicated that it was more hydrophilic than arsenobetaine.

3.0 ARSENIC IN SHELLFISH

Total Arsenic. **Total arsenic concentrations in shellfish tend to be higher than those for finfish. In the data summarized by Chew (1996), average total arsenic concentrations for shellfish ranged from 0.2 to 126 ppm. The highest concentrations were seen in two mollusk samples. However, mollusk values were highly variable among the 20 samples tested (range: 1-126 ppm; Chew, 1996). In the study by Ballin et al. (1994), the total arsenic in 4 species of shellfish ranged from 2.6 to 21 ppm; the highest concentration was found in lobster. The average value from pooled samples of blue mussels (40 samples) was 2.6 ppm (Ballin et al., 1994).** Lawrence et al. (1986) found the total arsenic in replicate lobster, scallop and shrimp samples to be 5.2 ppm, 0.68 ppm and 20.8 ppm respectively. The concentrations of total arsenic in a samples of lobster purchased commercially in Ottawa was 4.7 ppm and in a shrimp sample was 7.2 ppm. Lopez et al. (1994) found values of 4.01 ppm, 0.34 ppm and 2.95 ppm for commercially purchased samples of cockles, prawns, and mussels respectively.

Inorganic Arsenic. The average amount of arsenic present as inorganic arsenic in shellfish was less than 3% in all cases but one among the data summarized by Chew (1996). In the case of *Barnea dilatata*, the one exception, 98% of the arsenic was inorganic but the total arsenic was low (0.2 ppm) making the net exposure to inorganic arsenic low despite the high percentage present. Lopez et al. (1994) found the inorganic arsenic to account for 8% of the total in cockles and 11% in muscles. The amount of inorganic arsenic in the prawns was below the limit of detection (0.023 ppm).

The data by Ballin et al. (1994) are of minimal value for deriving an estimate of the inorganic arsenic in shellfish because samples were not analyzed for inorganic arsenic and the authors felt that two organic forms of arsenic monitored (arsenobetaine and phospholipid arsenic) did not account for all of the organic arsenic.

Ballin et al. (1994) evaluated shrimp, lobster, mussels and oysters for their arsenobetaine and arsenic containing phospholipids. Oysters and blue mussels had the lowest concentrations of arsenobetaine plus phospholipid arsenic (30 and 40%). The authors hypothesized that water soluble arsenocholine, the metabolic precursor to arsenobetaine, accounted for most of the difference between the arsenobetaine and total arsenic concentrations rather than inorganic arsenic. Oysters and muscles had a fair amount of their arsenic present in the fat soluble phospholipid phase (10 to 20%) suggesting that some arsenocholine had been incorporated in the choline-containing phospholipids or sphingolipids.

In shrimp, Ballin et al. (1994) found that 87% of the arsenic was present as arsenobetaine and 4% as phospholipid arsenic while Lawrence et al.(1986) found that 76% was present as arsenobetaine and 15% as arsenocholine. In lobster, 59% of the arsenic was present as arsenobetaine and 2 % as phospholipid arsenic according to Ballin et al. (1994) and Lawrence et al. (1886) found 87% as arsenobetaine and none as arsenocholine. As discussed above, one cannot infer from these data that the remaining arsenic is present in inorganic compounds. Le et al. (1994) found arsenobetaine to be the primary organic arsenic compound in shrimp and prawns.

Table I summarizes the data on total, organic and inorganic concentrations of arsenic in fish and shellfish. The organic arsenic data are extrapolated from either the total arsenic and inorganic arsenic data (Chew, 1996) or the total arsenic plus the arsenobetaine, arsenocholine and/or phospholipid arsenic data (Ballin et al., 1994; Lawrence et al., 1986). In general, the data support the conclusion, that, in fish, less than 10% of the total arsenic is inorganic (Chew, 1996). Indeed, it was 4% or less for all fish species other than shark, sturgeon and sucker evaluated by Chew (1996); a total of 40 species were evaluated.

Table 1
Arsenic in Fish and Shellfish

Genus	Total Arsenic ppm.	Inorganic Arsenic ppm	Organic Arsenic ppm or %.	Reference
Fish	0.6-37	ND	>98%	Ballin et al., 1994
	0.1-64	DL-0.12	0.1-64 ppm	Chew. 1996
	1.1-13.2	NA	78-88 %	Lawrence et al., 1986
	0.82-7.76	<0.023-<5	NA	Lopez et al.. 1994
Shellfish	2.6-21	ND	NA	Ballin et al., 1994
	0.2-126	DL-0.6	<.01-126 ppm	Chew, 1996
	0.68-20.8	NA	87-91%	Lawrence et al., 1986
	0.34-2.95	<0.023-11	NA	Lopez et al., 1994

Weights expressed as ppm wet weight
ND = Not Determined
NA = Not Applicable
DL = Detection Limit

4.0 SPECIATION OF ORGANIC ARSENIC IN FISH AND SHELLFISH

The predominant organic arsenic compounds in marine fish and shellfish are arsenobetaine and arsenocholine (Ballin et al., 1994). Some of the arsenocholine is found in tissue phospholipids. The amount of arsenobetaine exceeds the arsenocholine (Chew, 1996). In both compounds, arsenic has replaced the nitrogen of the natural metabolite (choline; betaine). Arsenic is incorporated into the betaine molecule by microorganisms, phytoplankton, zooplankton and algae (Ballin et al., 1994). The fish obtain arsenobetaine from their food supply. The principle organic form of arsenic in freshwater fish is neither arsenobetaine or arsenocholine according to data collected by Lawrence wt al. (1986). A single compound was isolated from all samples and accounted at least 70 to 85% of all the arsenic present if recovery was complete. The composition of this compound was not identified but it appeared to be more hydrophilic than arsenobetaine.

Betaine is formed metabolically from choline through oxidation and becomes an excretory nitrogen metabolite. Betaine excretions vary between species. In addition, betaine can serve as a methyl donor in biological systems, becoming N,N-dimethyl glycine (Montgomery, 1990). Betaine acts as an osmolyte in marine species (Neufield and Wright, 1996) and as a chemosensory agent (Knutsen, 1992). A study of feeding behavior in North Sea turbot and Dover sole suggest that betaine is one of a number of water-soluble, nitrogen-containing compounds that stimulate feeding behavior in fish larvae and may help to attract the larvae to the plankton layer (Knutsen, 1992). Betaine is probably released to water in plankton-rich areas producing an betaine-enriched microenvironment.

Arsenobetaine is metabolically inert in mammalian systems. Almost all of the radiolabeled arsenic in arsenobetaine administered orally or intravenously to rats, mice or guinea pig was excreted in three days (Vahter et al., 1983; Yamauchi et al. 1986). In rats and mice, more than 99% of the excreted label was found in the urine as arsenobetaine. In comparable studies using arsenocholine, there was greater label retention with 70-80% excreted in three days (Marafante et al., 1984). Extracts from mouse urine showed that more than 90% of the water soluble arsenic excreted was present as arsenobetaine. It can be assumed that some of the retained arsenocholine is incorporated in membranes as phosphatidyl choline compounds or in lipoprotein complexes and, thus, will have little tendency to bioaccumulate as inorganic arsenic.

Small amounts of methylarsonic acid and dimethylarsinic acid have been identified in fish and shellfish (Buchet et al., 1994; Chew 1996). Chew (1996) reported data from a study of fish at the ASARCO Tacoma Smelter Site in Washington state. The amount of methylarsonic acid in striped sea perch was 0.02 ppb and that in rock sole was 0.002 ppb. The dimethylarsinic acid in these two species was 0.02 ppb and $\leq$ 6.6 ppb, respectively. In mussels there was 0.02 ppb for both the methylarsonic and dimethylarsinic acid. The total arsenic concentration was only available for the rock sole and the total arsenic data were not internally consistent with the speciation data. Therefore, it is difficult to evaluate the significance of these results. Buchet et al. (1994) found that the recovery of methylarsonic acid and dimethylarsinic acid varied with the extraction technique and between samples for the same fish.

The data available on the speciation of arsenic in fish and shellfish mitigate some of the concerns generally associated with arsenic exposure. In most cases, more than 95% of the arsenic is present as organic rather than inorganic compounds (Chew, 1996). The most prevalent of the organic species, especially in marine fish, is arsenobetaine (Ballin et al., 1994; Lawrence et al. 1986), a compound with minimal tissue retention in the animals species studied and a compound that is excreted without metabolic alteration. The compound present in the next highest concentration is arsenocholine. The arsenocholine is estimated to be less than 1% of the total arsenic (Edmonds and Francesconi, 1993). Most of the arsenocholine is converted to arsenobetaine and excreted. A small portion may become incorporated in phospholipids and retained; another small amount may be converted to trimethylarsine oxide (Chew, 1996).

Arsenobetaine and arsenocholine and the unidentified organic arsenic compound in freshwater fish are hydrophilic and have little tendency to bioaccumulate in edible fish tissues. They are unlikely to be present in adipose deposits due to their hydrophilic nature although some arsenocholine may be present in membrane phospholipids. Organic arsenicals, especially arsenobetaine, appear to be significantly less toxic than inorganic arsenic species (Edmonds and Francesconi, 1993). Each of these factors diminishes human health concerns related to exposure to organic arsenic compounds in fish and shellfish. Additional support for a conclusion that the organic arsenic compounds from fish and shellfish do not bioconcentrate is provided by data showing that samples of human milk from 88 mothers from the Faroe Islands did not show elevated arsenic in their transition milk despite consumption of diets rich in seafoods (Grandjean et al., 1995).

5.0 ESTIMATED ARSENIC IN FISH AND SHELLFISH FROM WATER CONTAINING 50 PPB ARSENIC

5.1 EPA Bioconcentration Factors for Arsenic

The EPA bioconcentration factor for total arsenic in a fish and shellfish is 44 (EPA, 1980, 1984). It applies to bioconcentration from a mixture of fish and shellfish (roughly 10-15% shellfish). The arsenic concentration by shellfish exceeds that for fish by nearly two orders of magnitude (EPA, 1980). The shellfish value (350) came from a 112 day test of a saltwater oyster species exposed to trivalent arsenic while the bioconcentration factor for bluegill was 4 after a 28 day exposure (EPA, 1980).

The EPA bioconcentration factors were derived from laboratory studies where the water was spiked with trivalent inorganic arsenic. Thus, they may not be representative of what happens in a natural ecosystem where inorganic arsenic is processed through a number of trophic levels before it reaches the fish or shellfish.

The data presented in Sections 2.0 and 3.0 of this report do not include any information on the amount of arsenic in the source waters from which samples were obtained. Thus, it is not possible to evaluate the bioaccumulation that lead to the tissue levels of arsenic measured in the fish or shellfish. In general, the average total arsenic in clean costal and ocean waters is low, about 1 to 3 ug/L. Levels are much higher in estuary systems receiving arsenic discharges (Neff, 1997). The arsenic concentration for most lakes and rivers is less than 5 ug/L (Crecelius, 1997).

A comparison of the amounts of total arsenic in some of the fish and shellfish samples collected from the marine environment with normal background levels of inorganic arsenic in the water, suggests that, for at least the marine environment, arsenic accumulated to a greater extent than suggested by laboratory bioconcentration factor of 4 measured for a freshwater species in a laboratory study. The data on the accumulation of arsenic in fresh water species is conceptually closer to laboratory bioconcentration factors.

5.2 Estimated Total Arsenic

For this report, concentrations of total and inorganic arsenic in edible tissues from fish and shellfish are estimated using the EPA bioconcentration factor for arsenic and the arsenic concentration in ambient water. Deficiencies in the bioconcentration factor are part of the uncertainty for the analysis.

In cases where the fish and shellfish come from water containing 50 ppb arsenic, the estimated total arsenic concentration in edible tissues is 2.2 mg/kg or 2.2 ppm when calculated using the EPA bioconcentration factor.

$$50\ \mu g/L \times 44\ L/kg(BCF) \times 1\ mg/1000\ \mu g = 2.2\ mg/kg \text{ total arsenic}$$

This estimate is within the range observed for fish and shellfish in the most recent USFDA Total Diet Study (0.75 ppm for fish sticks to 2.8 for cod/haddock; MacIntosh, 1997; personal communications). In the data for fish collected by Chew (1996), 70% of the samples had total arsenic concentrations below 2.2 ppm. In the studies by Ballin et al. (1994 and Lawrence et al. (1986) over 60% of the combined marine and fresh water fish data set fell below this value. Because nothing is known concerning the arsenic concentrations in the source water for the field sample data presented by Ballin et al. (1994), Chew (1996) Lawrence et al. (1986) or Lopez et al. (1994), the comparison of the calculated concentration for fish and shellfish with the field data merely supports the calculated value as plausible.

5.3 Estimated Inorganic Arsenic

The maximum inorganic arsenic in fish and shellfish used for this estimate is 4% as discussed in Sections 2.0 and 3.0 above. The median inorganic arsenic value for the fish and shellfish data reported by Chew (1996) is 0.4 %. No inorganic arsenic was detected in 23 of 42 fish samples

and 18 of 50 shellfish samples. Therefore, the median value reflects the higher inorganic arsenic concentrations found in shellfish and is a conservative value.

Using a 4% maximum inorganic arsenic value for a mixed fish and shellfish diet, 2.2 ppm total arsenic in fish/shellfish is equivalent to 0.09 ppm inorganic arsenic.

$$2.2 \text{ mg/kg } As_{total} \times 4 \text{ g } As_{inorganic}/100 \text{ g } As_{total} = 0.09 \text{ mg/kg } As_{inorganic}$$

Using 0.4% as the median inorganic arsenic concentration for a mixed fish and shellfish diet, 2.2 ppm total arsenic in fish/shellfish is equivalent to 0.01 ppm inorganic arsenic.

$$2.2 \text{ mg/kg } As_{total} \times 0.4 \text{ g } As_{inorganic}/100 \text{ g } As_{total} = 0.01 \text{ mg/kg } As_{inorganic}$$

6.0 ESTIMATED INORGANIC ARSENIC EXPOSURE FROM FISH/SHELLFISH CONSUMPTION

Inorganic arsenic exposure estimates for high and average fish and shellfish consumers can be derived using the inorganic arsenic concentrations estimates above and information on population fish/shellfish consumption. The following exposure scenarios are presented for this report based on available data.

High fish/high arsenic - The 99.9th percentile fish/shellfish consumer and the estimated maximum inorganic arsenic concentration for a mixed fish/shellfish diet (4%). This group eats the maximum amount of fish and shellfish on a daily basis and consistently chooses species that have the higher percentages of inorganic arsenic.

High fish/average arsenic -The 99.9th percentile fish/shellfish consumer and the median inorganic arsenic concentration (0.4%). This group eats the maximum amount of fish and shellfish on a daily basis and chooses species with a variety of inorganic arsenic concentrations over a range from low to high.

Average fish/high arsenic - The 50th percentile fish/shellfish consumer and the estimated maximum inorganic arsenic concentration for a mixed fish /shellfish diet. This group has a diet that includes fish and/or shellfish frequently but is not totally dependant on fish/shellfish as a dietary protein source. The group preferences tend towards the fish/shellfish species that have the higher concentrations of inorganic arsenic.

Average fish/ average arsenic - The 50th percentile fish/shellfish consumer and the median inorganic arsenic concentration. This group has a diet that includes fish and/or shellfish frequently but is not totally dependant on fish/shellfish as a dietary protein source.
The group preferences include a variety of fish and shellfish species with inorganic arsenic concentrations that range from low to high.

The fish consumption values used for these calculation were derived from the 1989-1991 dietary records from the USDA Continuing Survey of Food Intake (USEPA, 1995). The USDA food consumption survey collects data on three consecutive days of food intake. Data for one day is provided through a 24-hour recall interview and data for two days through food intake records kept by the respondent. Fish-consumers were segregated from all respondents based on their consumption of fish at least once during the three day survey period. The population data used for the exposure estimates described above apply only to the fish-consuming population rather than the entire population Therefore the data may represent a rather skewed distribution. For the purpose of defining a exposure on the high end of the distribution curve the data are appropriate and useful.

The 99.9th percentile value for females (461 g/day) is used to simulate the eating habits of subsistence fishers such as the Eskimos and other native Indian tribes that consume a diet that is very high in fish and shellfish. This is the highest intake value reported. The 99.9th percentile value or maximum reported value is more than 4 times the 95th percentile value (USEPA, 1995). The 50th percentile value from the USDA data for males was used for the exposure estimate rather than that for females because it is a higher value.

Eskimo's and other native Indian tribes in Alaska have the highest consumption of fish and shellfish within the United States (Wolfe, 1996). In one study of 351 Eskimos, Indians and Aleuts, average fish and shellfish consumption was 109 g/day (Nobmann et al., 1992). This intake lies between the 75th and 95th percentiles of fish consumers in the country as a whole (EPA, 1995). Wolfe (1996) found that the average intake of wild foods by the subsistence populations in Alaska was slightly greater than one pound of wild food per day with 61% of this total contributed by fish and shellfish. In some areas the average consumption of wild foods was two pounds per day. In studies of the Tulalip and Squaxin Island tribes of Puget Sound the mean fish/shellfish consumption for a 70 Kg adult was 71 g/day and the 95% percentile value was 226 g/day (Toy et al., 1995). In a study of the Native Tribes of the Columbia River Basin, the mean value for the adult fish consuming population was 63 g/day and the 99th percentile value was 389 g/day (CRITFC, 1994). These data support the fish/shellfish intake values used for the exposure estimates.

Two addition exposure estimates are also included in this report. These groups are identified as follows:

High fish (shellfish preference)/high arsenic - The 99.9% fish/shellfish consumer who is also at the 99% for shellfish consumption (125 g/day). These individuals consume a high percent of their fish/shellfish in the form of shellfish and select species with the high concentrations of inorganic arsenic.

General population/high arsenic - The average person who consumes fish or shellfish only occasionally but selects species with the high concentrations of inorganic arsenic.

The first of the added groups cover subsistence users of fish and shellfish who have a greater than average intake of shellfish. The arsenic exposure for this group includes separate calculations for the arsenic in fish and shellfish using a fish bioconcentration factor of 4 for fish and a factor of 350 for shellfish (USEPA, 1980, 1985). The 99th percentile shellfish consumption from the USDA data (125 g/day) was used for the shellfish portion of the diet and the difference between the 99.9th percentile fish/shellfish value (461 g/day) and the shellfish value was used for fish consumption (336 g/day).

The first five exposure scenarios defined above apply to those individuals who routinely consume fish and/or shellfish as a dietary protein source. However, most of the general population consumes fish and shellfish only occasionally, and some individuals never eat fish or shellfish. Thus, the general population has a lower exposure averaged over time. The EPA uses a daily fish intake of 6.5 g/day to represent these individuals (EPA, 1989). This is a normalized concentration which recognizes that, on the days that fish and/or shellfish are consumed, the intake will be higher than 6.5 grams but there will also be many days in the course of a year that there is no consumption of either fish or shellfish. This group is identified as "General Population" in subsequent tables. As a worst case, the higher inorganic arsenic concentration was used for the general population arsenic exposure calculation. Individuals who consume fish or shellfish only occasionally tend to have a few species they favor (e.g. tuna, shrimp) and the species of preference may be among the higher arsenic species.

Inorganic arsenic exposures from fish and shellfish under the different exposure scenarios listed above are summarized in Table 2. The fish/shellfish consumption values apply to total fish/shellfish consumption and include marine, estuarine and freshwater species. They are calculated using the following equation:

$$2.2 \text{ mg As}_{total}/\text{ kg fish/shellfish} \times \text{fish/shellfish intake (kg/day)} \times \text{mg As}_{inorganic}/100 \text{ mg As}_{total} = \text{mg As}_{inorganic}/\text{day}$$

Units have been adjusted so that the inorganic arsenic concentrations are expressed in μg/ day in Table 2. The USEPA limitation on arsenic in marine waters is 36 ppb (USEPA, 1992). Therefore, the estimates based on all fish and shellfish being from waters containing 50 ppb is an overestimate in situations where a mixture of marine, estuarine and freshwater species are consumed.

Table 2 Inorganic Arsenic Exposure from Fish and Shellfish Consumption			
Consumer Category	Inorganic Arsenic %	Fish/Shellfish Consumption g/day	Inorganic Arsenic Exposure μg/day
High Fish - High Arsenic	4	461*	41
High Fish - Average Arsenic	0.4	461*	4
Average Fish - High Arsenic	4	42 *	4
Average Fish -Average Arsenic	0.4	42*	0.4
High Fish (shellfish preference)- High Arsenic	4	125 (shellfish) 336 (fish)	87.5 shellfish 2.7 fish 90 total
General Population	4	6.5**	0.6

* 1989-1991 data from the USDA Continuing Survey of Food Intake (USEPA, 1995)

** 1973-1974 data from the National Purchase Dairy Survey (USEPA, 1989)

Other dietary components can have an impact on the net inorganic arsenic exposure for the for all consumer groups. Macintosh et al. (1996) found that other foods in the Total Diet Study such as chicken and rice contributed to the total arsenic exposure. The form of arsenic in food may also contribute to the effect of a given food material on the total body arsenic load.

7.0 INORGANIC ARSENIC EXPOSURE FROM FISH, SHELLFISH AND POTABLE WATER

The data on inorganic arsenic from fish and shellfish from Table 2 can be combined with data on arsenic concentrations in potable water to obtain a profile for net inorganic arsenic exposures in the population groups characterized above. The high estimate for the arsenic concentration in potable water is 20 ppb and the average estimate is 5 ppb. These values were obtained from a study of arsenic in potable water sources conducted by the University of Colorado at Boulder and Malcolm Pirnie, Inc. (1997). Water consumption is estimated as 2 liters/day.

In the University of Colorado at Boulder/ Malcolm Pirnie Study (1997), 88 % or more of the ground water samples analyzed in the Western United States in three separate surveys had concentrations of 20 ppb or less. Concentrations were 5 ppb or less in more than 50% of the ground water systems evaluated. The highest arsenic concentration from ground water sources were in the Western region. None of the surface water systems surveyed in the Western United States contained greater than 5 ppb arsenic. In one survey, there were a few surface water systems in the North Central region of the country that exceeded 20 ppb arsenic (12%). Most arsenic in potable water is inorganic and ground water sources contain higher arsenic concentrations than surface water sources. The highest arsenic concentrations in the country are concentrated on the west coast.

Table 3 presents the estimates for net exposure to inorganic arsenic when the estimates from fish and shellfish consumption are combined with the data on the average and high concentrations of arsenic in Public Water supplies across the country. The value used as the high arsenic concentrations is 20 ppb based on survey data rather than the Arsenic MCL and is exceeded by only about 10% of Public Water Systems. Each of the exposure estimates for inorganic arsenic intakes from fish, shellfish and water is less than the exposure that results from ingesting 2 L of water containing the 50 ppb arsenic except for the High fish/shellfish preference scenarios.

Table 3
Total Inorganic Arsenic Exposures Fish/Shellfish and Water for High and Average Fish Consuming Populations

Consumer Category	Fish/shellfish* μg/day	Water** μg/day	Total μg/day
High Fish - High Arsenic	41	40	81
	41	10	51
High Fish - Average Arsenic	4	40	44
	4	10	14
Average Fish - High Arsenic	4	40	44
	4	10	14
Average Fish - Average Arsenic	0.40	40	40
	0.40	10	10
High Fish (Shellfish Preference)- High Arsenic	90	40	130
	90	10	100
General Population	0.6	40	41
	0.6	10	11

* Based on a maximum 4% of the total arsenic being inorganic arsenic in an mixed fish/shellfish diet

** Water consumption is estimated as 2 liters/ day.

There are some regions in the western part of the country where arsenic levels in potable water from public systems are equal to the MCL and other private systems where the arsenic may exceed the MCL. For Public Water Systems where the potable water concentration is equal to the MCL, fish and shellfish consumption by the general populations does not increase the risk from arsenic exposure since it represents a less than a 1 μg (1%) increase in the net arsenic exposure. However, for regions where high levels of arsenic in the potable water are accompanied by high levels of fish and shellfish consumption the net increase in inorganic arsenic exposure would be greater and site-specific criteria can be developed for surface waters and for fish consumption.

In developing site-specific criteria the state should characterize the size and location of the population of concern and determine their fish/shellfish and water intake rate. The fish and shellfish consumption should consider the species and dietary intake per species. Actual total arsenic and inorganic arsenic values for the species consumed and actual concentrations in drinking water should be used in the exposure calculations wherever possible. Other sources of arsenic exposure should also be considered and quantified.

8.0 UNCERTAINTY

There are a number of uncertainties in the preceding exposure assessment for inorganic arsenic from fish and shellfish originating from water containing 50 ppb arsenic. The exposure estimates assume a mixed fish and shellfish diet in which average inorganic arsenic concentration is no greater than 4% of the total arsenic. This would not apply to any diet with high consumption of shark, sturgeon and sucker. However, these species are not used by the Eskimo and other northern Indian tribes that serve as an example of a 99.9 percentile fish/shellfish-consuming population. Species that constitute the fish component of the diet for Eskimo's and other northern Indians are salmon, halibut, herring, whitefish, sheefish, blackfish and cod (Wolfe, 1996).

The exposure assessments for all but the High Fish (Shellfish Preference) group are also based on a bioconcentration factor that applies to a mixed fish/shellfish diet. It does not apply to a diet that is heavily weighted towards shellfish, particularly mollusks. In the Eskimo and other northern Indian tribes, shellfish is a maximum of 9% of the diet (Wolfe, 1996) a value that is representative of the fish/shellfish biconcentration factor used for the inorganic arsenic exposure calculations. However, shellfish consumption for the Tulalip tribe of Washington State is about 60% of the fish/shellfish intake (Toy et al., 1996). Thus, the inorganic arsenic exposure estimates presented above would not apply to this group.

There is also some uncertainty in the bioconcentration factor since it results from laboratory studies in which the water was spiked with inorganic arsenic. The values obtained may not be representative of natural ecosystems where arsenic can passes through various trophic levels before entry into fish tissues. The data suggest that bioaccumulation through the food chain is more complex in marine species than in fresh water species.

There is some uncertainty in the toxicological assessment for organic arsenic compounds. To the extent that most of the organic arsenic species in the fish are trimethylated species such as arsenobetaine, arsenocholine and trimethylarsine oxide, toxicokinetic data support the conclusion that there is little, if any interaction of the arsenic metabolite with other biomolecules. Thus, the toxicity of these compounds is low. However, in cases where dimethylarsinic acid is found in fish/shellfish species, low toxicity cannot be assumed because there are some data that suggest that dimethylarsinic acid is a tumor promotor (Chew, 1996). If dimethylarsinic acid is a promotor, it could become a risk factor for carcinogenicity. A weight-of -evidence determination for the promoting properties of dimethylarsinic acid has not been established. Lack of data on the nature of the organoarsenic compound or compounds present in freshwater fish contributes additional uncertainty in cases where most fish consumed are freshwater species.

9.0 REFERENCES

Ballin, U., Kruse, R., and H.S. Russel. 1994. Determination of total arsenic and speciation of arseno-betaine in marine fish by means of reaction-headspace gas chromatography utilizing flame-ionization detection and element specific spectrometric detection. Fresenius J Anal Chem 350:54-61.

Buchet, J.P., Pauwels, J., and R. Lauwerys. 1994. Assessment of exposure to inorganic arsenic following ingestion of marine organisms by volunteers. Environ. Res. 66:44-51.

Chew, C. 1996. Toxicity and exposure concerns related to arsenic in seafood: An arsenic literature review for risk assessments. Prepared for USEPA Region 10 ESAT. Seattle Washington as Technical Instruction Document 10-9601-815 under Work Unit document 4038.

Columbia River Inter-Tribal Fish commission (CRITFC). 1994. A fish consumption survey of the Umatilla, Nez Perce, Yakama and Warm Springs Tribes of the Columbia River Basin. CRITFC Technical Report No. 94-3. Portland, OR.

Crecelius, E.A.. 1997. Review of EPA-822-R-97-002 (May 15, 1997) draft report entitled "Arsenic and Fish Consumption"' Letter to Dennis McCauley, Great Lakes Environmental Center, Traverse Center, MI. August 18.

Edmonds, J.S.D. and KA Francesconi. 1993. Arsenic in seafood: human health aspects and regulations. Marine Pollution Bulletin 26:665-674.

Grandjean, P., Weihe, P., Needham, L.L., Burse, V.W., Patterson, D.G., Sampson, E.J., Jorgesen, P.J., and M. Vahter. 1995. Relation of a seafood diet to mercury, selenium, arsenic, and polychlorinated biphenyl and other organochlorine concentrations in human milk. Environ. Res. 71:29-38.

Knutsen, J.A. 1992. Feeding behavior of North Sea turbot (*Scophhalmus maximus*) and Sover sole (*Solea solea*) larvae elicited by chemicals stimuli. Marine Biology 113:543-548.

Lawrence, J.F., Michalik, P., Tam, G., And H.B.S. Conacher. 1986. Identification of arsenobetaine and arsenocholine in candian fish and shellfish by high-performance liquid chromatography with atomic absorption detection and confirmation by fast atom bombardment mass spectrometry. J. Agric. Food Chem. 34:315-319.

Le, Sean X.C., Cullen, W.R., and K.J. Reimer. 1994. Speciation of arsenic compounds in some marine organisms. Environ. Sci. Technol. 28:1598-1604.

Lopez. J.C., Montoro, R., Cervera, M.L. and M. de la Guardia. 1994. Determination of inorganic arsenic in sea food products by microwave-assisted distillation and atomic aabsorption spectrometry. J. Analyt. Atom. Spec. 9:651-656.

MacIntosh, D. L., Spengler, J.D., Ozkaynak, H., Tsai, L, and P.B. Ryan. 1996. Dietary exposures to selected metals and pesticides. Environ Health Perspect 104:202-209.

MacIntosh, D.L. 1997. Personal Communication. Rollins School of Public Health, Emory University, Atlanta, GA 30322.

Marafante, E., Vahter, M., and L. Dencker. 1984. Metabolism of arsenocholine in mice, rats, and rabbits. The Science of the Total Environment 34:223-240.

Montgomery, R., Conway, T.W. and A.A. Spector. 1990. Biochemistry: A Case Oriented Approach. The C.V. Mosby Company. St. Louis, MO.

Neff, J.M.. 1997. Ecotoxicology of arsenic in the marine environment. Environ. Toxicol. Chem. 16:917-927.

Neufield, D.S., and S.H. Wright. 1996. Salinity change and cell volume: the response of tissues from the estuarian mussel Geukensia demissa. J. Exp. Biol. 199:1619-1630.

Nobmann, E.D., Beyers, T., Lanier, A.P., Hankin, J.H, and M.Y. Jackson. 1992. The diet of

Alaska Native adults. 1977-1988. Am. J. Clin. Nut. 55:1024-1032.

Toy, K.A. Polissar, N.L., Liao, S. and G. D. Mittelstaedt. 1996. A fish consumption survey of the Tulalip and Squaxin Island tribes of the Puget Sound region. Tulalip Tribes, Department of Environment, 7615 Totem Beach Road, Marysville, Washington 98271.

University of Colorado at Boulder and Malcolm Pirnie, Inc.1997. National Compliance Assessment and Costs for Regulation of Arsenic in Drinking Water. Water Industry Technical Action Fund.

USEPA. 1980.. Ambient Water Quality Criteria for Arsenic. United States Environmental Protection Agency. Office of Water Regulations and Standards (OWRS). EPA 440/5-80-021.

USEPA. 1984. Ambient Water Quality Criteria for Arsenic. United States Environmental Protection Agency. Office of Water Regulations and Standards (OWRS). EPA 440/5-84-033.

USEPA. 1989. Exposure Factors Handbook. United States Environmental Protection Agency. Office of Health and Environmental Assessment. EPA 600 8-89-043.

USEPA. 1992. National Toxics Rule: Criterion continuous concentration. United States Environmental Protection Agency. Federal Register 57:60848.

USEPA. 1995 Draft. Mercury Study Report to Congress, Volume III: An Assessment of Exposure from Anthropogenic mercury Emissions in the United States. United States Environmental Protection Agency, Office of Air Quality Planning and Standards; Office of Research and Development.

Vahter, M.. Marafante, E., and L. Dencker. 1983. Metabolism of arsenobetaine in mice, rats and rabbits. Sci. Tot. Environ, 30:197-211.

Wolfe, R.J.. 1996. Subsistence-food harvests in rural Alaska and food safety issues. Paper presented to the Institute of Medicine, National Academy of Sciences Committee on Environmental Justice. Spokane, Washington. August 13.

Mann, Laurie

From: Mann, Laurie
Sent: Monday, August 03, 2015 2:49 PM
To: MacIntyre, Mark
Cc: Croxton, Dave; Nickel, Brian
Subject: PCB response to Don

Mark,
Here's our response (reviewed by Dave C, Brian & me)

Don,
We want to make sure there is common understanding regarding the sources of PCBs in the Spokane River. Based on information in the email you sent us, we think that you may have misunderstood the information that was provided to you by members of the Task Force, and we believe that EPA and the Task Force have the same general understanding of the origins of the PCB contamination:

1) There is a mix of past (legacy) and present sources of PCBs contributing to the current PCB impairments in the Spokane river. Many contaminant pathways, like air deposition, contain a mix of legacy PCBs and new, inadvertently generated PCBs.
2) We believe that the relatively high levels of PCBs seen today in the Spokane River are likely the result of legacy contamination from industrial use of PCBs prior to the ban on PCB manufacturing in 1979. Today, those historic sources continue to contribute PCBs to the river through a variety of pathways including PCB contamination in soils (traveling to the river via stormwater and groundwater), building materials (traveling to the river via air deposition and stormwater) and lake and river sediment.
3) One reason we believe that newer consumer products with inadvertently-generated PCBs are a small fraction of the problem is that the PCB impairments in the Spokane River are unusually high relative to other parts of the State. If consumer products were the primary source of PCB contamination in the Spokane River, we would expect to see high levels of PCB contamination throughout Washington – and we don't.
4) The point source dischargers to the Spokane River (excluding stormwater) contribute between 8 and 33% of the loading in the River (varying with river flow). The remainder of the PCB loading comes from a variety of sources, including groundwater, stormwater, air deposition, tributaries, and unidentified sources in Idaho. Inadvertently-generated PCBs likely contribute loading to some of these pathways, especially air deposition, stormwater, and wastewater.

EPA is concerned about all of these potential sources, past and present, and strongly supports the work of the Task Force to further delineate the sources of PCB loading in the Spokane watershed.

If you have any further questions, please feel free to contact us. EPA's response to the remainder of your questions are included below:

Question #1

Why, when production of PCBs is banned in this country, does the EPA still allow a certain percentage of PCBs to occur in products sold here?

While EPA's PCB regulations generally ban the manufacture (defined to include import as well) of PCBs, an exception is made for inadvertently generated PCBs that are unintentional impurities of many common commercial chemical or

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manufacturing processes. EPA's regulations impose an annual average of 25 ppm and a 50 ppm maximum on the concentration of inadvertently generated PCBs manufactured or imported into the United States (see definition of "excluded manufacturing process, 40 CFR §761.3). Imported products and products produced domestically are regulated in the same manner. EPA has concluded that allowing such inadvertent generation has important economic benefits and does not pose an unreasonable risk to human health or the environment (see 49 FR 28172).

Question #2

Does the EPA have a short or long term plan to modify that policy?

Revising current regulations to reduce inadvertently generated PCBs presents both policy and scientific challenges. EPA currently has no plans to modify its policy regarding regulations of inadvertently generated PCBs.

Currently, EPA is considering restricting and/or eliminating many of the remaining authorized uses of higher-concentration liquid PCBs (see "Polychlorinated Biphenyls: Reassessment of Use Authorizations", April 10, 2010; 75 FR 17645). These remaining uses are the largest reservoir of commercial mixtures (Aroclors) that contain the dioxin-like PCBs. While restricting such uses would not address inadvertently generated non-dioxin-like PCBs, EPA believes this effort would help to reduce potential exposure and risk from remaining dioxin-like PCB uses. EPA is in the process of evaluating options for revising current PCB regulations, it has not made any proposed or final decisions.

In addition to potential rulemakings, another activity that may help to address inadvertently generated PCBs in products is EPA's Green Chemistry Program. EPA has provided funding to Washington State Department of Ecology to establish a Green Chemistry Center and is a member of the Advisory Board for the Center. The Green Chemistry Center plans to host a workshop later this year on PCBs inadvertently produced in inks and pigments, perhaps leading to improvements in the production and use of PCB-free inks and pigments.

From: Don Fels [Exemption (6) Personal Information]
Sent: Monday, July 27, 2015 4:43 PM
To: MacIntyre, Mark
Subject: Re: Spokane River

hi Mark- I am writing a two part piece on the PCBs in the Spokane River for crosscut.com. I have interviewed many of the stakeholders there, most of whom have committed a great deal of time to serve

on the Task Force trying to find solutions to the problem of PCBs getting in the tissue of fish in the river. All have told me that they began their work years ago thinking that the issue was legacy polluters who left PCBs in the soil that drains into the river, or who flushed the pollutants into the river directly. But those point sources only account for 8% of the PCBs in the Spokane River. The rest are coming in from common everyday use, that are buried in products used by us all. The EPA allows a certain percentage of PCBs to occur in such products. Why is that when production of PCBs is banned in this country? And does the EPA have a short/long term plan to modify that policy? I would greatly appreciate speaking with someone who can answer my questions.
thanks,
Don Fels

On Mon, Jul 27, 2015 at 12:29 PM, MacIntyre, Mark <Macintyre.Mark@epa.gov> wrote:

> Hey Don! Mark MacIntyre @ EPA....Can you give me a call about your Spokane River Story?
>
> Thanks!
>
> MM
>
> ***Mark A. MacIntyre***
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[Letter to leaders of federally-recognized tribes, signed by Kenneth J. Kopocis, August 11, 2015]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF WATER

Dear Honorable Leader:

The U.S. Environmental Protection Agency is initiating consultation and coordination with federally recognized Indian tribes to consider a potential rulemaking that would establish baseline water quality standards under the Clean Water Act for waters on Indian reservations that currently do not have EPA-approved WQS in place to protect water quality. The EPA's goal is to address the existing gaps in CWA protection of reservation waters where there are no existing EPA-approved WQS. Standards would establish baseline human health and environmental goals as the basis for the CWA protection. This potential rulemaking effort adds to a growing list of initiatives the EPA is undertaking that recognize the importance of tribal waters, tribal sovereignty, and the need to better protect the water resources that tribes rely on.

The potential benefits to tribes and the environment of establishing baseline WQS through a federal rulemaking are significant. WQS define the goals for the quality of reservation waters and serve as the foundation of the water quality-based pollution control program mandated by the CWA to protect human health, recreation, wildlife, aquatic life, and other uses. WQS are the cornerstone to prevent future degradation of waters, and improve water quality in impaired waters, by providing a basis to assess the health of water bodies and impose limits in permits to control pollution discharges, including upstream discharges.

The EPA strongly supports and will continue to encourage eligible tribes to obtain Treatment in a Similar Manner as a State under the CWA in order for tribes to establish their own WQS for approval by the EPA and to administer their own WQS program. The EPA recognizes, however, that not all tribes may seek TAS and some tribes may continue to experience challenges to establishing their own WQS. Out of over 300 tribes with Indian reservations, only 40 have EPA-approved tribal WQS in place. This means those tribal waters without WQS may not have the full suite of protections afforded under the CWA.

Establishing baseline WQS for Indian reservations through a federal rulemaking could ensure a baseline level of protection for tribal waters and a step in supporting tribal interests in protecting their water quality and use of reservation waters. In addition, baseline WQS could provide more protections now than currently exist to address concerns about waters flowing into the reservation from adjacent jurisdictions, until such time that the tribe establishes its own customized WQS and obtains the EPA's approval to make them effective under the CWA.

Working as government-to-government partners with tribes, the EPA seeks to explore this potential effort to establish baseline WQS for Indian reservations, and solicits feedback from tribes on factors to consider to ensure the EPA crafts an effective federal rulemaking that reflects tribes' interests in protecting reservation waters under the CWA. This effort is consistent with the EPA's responsibilities under the CWA and the goals of the EPA's 1984 Indian Policy. Some tribal leaders may recall that between 1999 and 2003, the EPA developed a draft rulemaking of federal WQS for those waters in Indian country that did not have EPA-approved WQS. The EPA is interested in building on elements of that earlier effort to ensure a baseline level of protection exists for reservation waters.

Enclosed is a consultation and coordination plan that includes a description of the action under consultation and the process the EPA intends to follow, including a timeline for the consultation and coordination period, and information on how you can provide input on this action. The EPA's consultation information is also available on EPA's Tribal Portal (http://www.epa.gov/tribal/consultation).

This consultation and coordination process will be conducted in accordance with the *EPA Policy on Consultation and Coordination with Indian Tribes* (http://www.epa.gov/tribal/consultation). The EPA invites you and your designated representative(s) to participate in this process. The EPA's anticipated timeline for the consultation and coordination period is expected to extend from the date of this letter to November 6, 2015.

If you have any questions, please contact Danielle Anderson (anderson.danielle@epa.gov) of my staff. We look forward to hearing from you on this important matter.

Sincerely,

Kenneth J. Kopocis
Deputy Assistant Administrator

Enclosure

Consultation Plan
For Considering a Baseline Water Quality Standards Proposed Rule

August 2015

Background Information

The EPA is exploring a federal rulemaking to establish baseline Water Quality Standards (WQS) for waters on Indian reservations that do not have Clean Water Act (CWA) WQS in place. This adds to a growing list of initiatives that the EPA is undertaking to better protect tribal water quality and uses. For example, the EPA proposed an action to streamline the TAS process for tribes on August 7 (see http://water.epa.gov/scitech/swguidance/standards/wqslibrary/tribal.cfm), and is planning to propose a process later this year for tribes to apply for the section 303(d) program for listing impaired waters and developing total maximum daily loads (TMDLs) (see http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/policy.cfm).

This baseline WQS action is focused on establishing baseline federal WQS for Indian reservations that are not currently covered by EPA-approved WQS. Such WQS could be used in water quality permitting decisions that impact reservation waters, including permits directly upstream from reservation waters. At any time, tribes, with assistance from the EPA, could still seek to obtain TAS authority (under CWA section 518) to adopt and administer their own tribal-specific WQS for EPA approval. Tribe-adopted, EPA-approved WQS would supersede any baseline WQS established by this potential rulemaking.

The EPA is considering including a combination of CWA 101(a)(2) designated uses, numeric criteria, narrative "free from" criteria, and general WQS provisions in the baseline WQS. The EPA may also consider providing some very limited regional adjustments for consistency with other federal actions. However, the EPA recognizes that fully customized standards are best achieved by a tribe with TAS that develops its own WQS for approval by the EPA. Tribe-adopted, EPA-approved WQS best reflect tribal-specific circumstances and uses that are not feasible for national baseline WQS. Nonetheless, baseline WQS could be developed to be fully protective of water quality, and may be critical for those tribes that may never seek TAS or adopt their own WQS. This rulemaking could impact the EPA's direct implementation of the CWA on Indian reservations including facilitating the use of approved WQS in EPA-issued permits, providing water quality certifications, and other protective actions.

Tribal leaders may recall that in 1999-2003, the EPA initiated the process of promulgating federal WQS for Indian reservations that did not have EPA-approved WQS. The EPA is interested in your feedback on how we might build on elements of that earlier effort to better ensure Indian reservations have EPA-approved WQS and the full slate of protections under the CWA.

Potential Benefits for Tribes

The potential benefits of establishing baseline WQS through a federal rulemaking are significant given that WQS define the goals for a waterbody and serve as the foundation of the water quality-based pollution control program mandated by the CWA to protect human health, recreation, wildlife, aquatic life, and other uses.

In this potential rulemaking, the EPA would be providing a set of WQS that the EPA, states, and tribes would use on a consistent basis for water quality management decisions where there are currently no EPA-approved WQS in place. The benefits of having federal WQS in place for reservation waters where no EPA-approved WQS exist include:

- Facilitating tribal participation with states and the federal government to inform water quality management decisions impacting those waters on the reservation;
- Establishing goals for the quality of reservation waters that are recognized under the CWA;
- Providing a basis for enforceable National Pollutant Discharge Elimination System (NPDES) permits to require controls beyond basic technology-based controls. (Water discharges allowed by NPDES permits must meet WQS set under the CWA for those receiving waters);
- Providing a mechanism to control discharges through other federal licenses and permits (CWA section 401 certification); and
- Protecting reservation water quality from upstream discharges flowing into reservation waters from other jurisdictions.

Areas for Consultation and Coordination

Consistent with the EPA's Policy on Consultation and Coordination with Tribes, the EPA seeks to consult and coordinate with federally recognized tribes to solicit feedback on all aspects of this potential rulemaking, including input on how best to structure and develop baseline WQS for Indian reservations which currently do not have EPA-approved WQS. The EPA is particularly interested in hearing from tribes on the following questions:

Questions relating to tribes' interests in protecting water quality:

(1) What would an effective federal rulemaking look like to you and your tribe?

(2) What water quality protection issues (or issues specifically related to WQS) are you and your tribe facing that should be considered in this potential rulemaking?

   a. Concerns for reservation water quality and degradation of water quality?
   b. Concerns for upstream sources of water pollution?
   c. Concerns for neighboring state WQS?
   d. Concerns for water uses relating to equity, safety, drinking water, treaty rights, or economic interests?

(3) Do tribes have examples of situations they are facing regarding water quality that could help inform, or that should be addressed, by this potential rulemaking?

Questions relating to the EPA's CWA implementation responsibilities:

(4) What approaches in a potential rulemaking should the EPA consider to implement CWA WQS on reservations and be most effective for you and your tribe?

(5) Do you have any concerns about this action? Are there any sensitivities or unintended consequences that the EPA should consider before moving forward on this action?

(6) If the EPA provided baseline standards, would this change your tribe's interest in pursuing TAS?

   a. Would your tribe be more likely to pursue TAS? If yes, would your tribe be interested in using baseline standards as a starting point to develop more specific standards for reservation waters?
   b. Would your tribe be more likely **not** to pursue TAS?
   c. No effect?

Tribes may submit written consultation comments by email or mail to:

Danielle Anderson, anderson.danielle@epa.gov
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 4305T
Washington, DC 20460

Tribal Consultation and Coordination Process and Time Frame
Consultation and coordination with tribes on a proposed rulemaking will occur according to the table below. If the EPA decides to move forward with a proposed rulemaking, tribes will have the opportunity to further consult with the EPA once the rule is proposed. In addition, tribes may provide input as part of the public comment period that immediately follows the publication of a proposed rule.

The table on the next page describes the process and timeline for consultation and coordination on this action. Tribes may access this letter through the Tribal Consultation Opportunities Tracking System (TCOTS), located at: http://tcots.epa.gov/oita/TConsultation.nsf/TC?OpenView.

Tribal Consultation and Coordination Process and Timeline	
Date	**Event**
Date of this letter through November 6, 2015.	Consultation and coordination period
August 17-20, 2015	Information presentation and discussion at the Tribal Lands and Environment Forum, Minneapolis, MN EPA's Office of Water will participate in this conference, and is available for consultation discussions during the conference. For more information, see http://www7.nau.edu/itep/main/Conferences/confr_tlef/. Session: USEPA Major Initiatives Discussion with Senior USEPA Staff, Tuesday, August 18, 10:30 a.m. to 12:00 p.m.
September 9-11, 2015	Information presentation and discussion at the Region 10 Region Tribal Operations Committee meeting. EPA's Office of Water will participate in this conference by telephone. Details will be announced via TCOTS and email, "Time-Sensitive U.S. EPA Office of Water Information and Tribal Participation Opportunities"
September 23, 2015 Time: 2:00 – 4:00 p.m. EDT	Tribes-only information, coordination and consultation webinar* Details will be announced via TCOTS and email, "Time-Sensitive U.S. EPA Office of Water Information and Tribal Participation Opportunities"
October 18, 2015 Time: Afternoon	72nd Annual Meeting, National Congress of American Indians, San Diego, CA. Session details to be determined. EPA officials will participate in this conference, and will be available for consultation discussions during the conference. For more information, see http://www.ncai.org/events/2015/10/18/72nd-annual-convention-and-marketplace.
October 26, 2015	Information presentation and discussion at the Region 9 Region Tribal Operations Committee meeting in Reno, NV. EPA's Office of Water will participate in the accompanying Annual Tribal/EPA conference, and is available for consultation discussions during the conference. Details will be announced via TCOTS and email, "Time-Sensitive U.S. EPA Office of Water Information and Tribal Participation Opportunities"

*The webinar will include two segments: The first segment will be used to coordinate and share information, and provide an opportunity for input and questions on the proposal. The second segment will provide an opportunity for consultation comments from tribal consultation officials.

Contact information for all events:

Danielle Anderson, anderson.danielle@epa.gov
EPA Office of Water
(202) 564-1631

For additional information regarding the prior federal core WQS rulemaking effort for Indian Country, please visit:
http://water.epa.gov/scitech/swguidance/standards/wqsregs.cfm

EPA has additional resources available that explain the Clean Water Act and Water Quality Standards, please visit:
http://www2.epa.gov/laws-regulations/summary-clean-water-act
http://water.epa.gov/scitech/swguidance/standards/

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Acquisition of Polychlorinated Biphenyls (PCBs) By Pacific Chinook Salmon: An Exploration of Various Exposure Scenarios

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ABSTRACT

In 2011, as part of an update to its state water quality standards (WQS) for protection of human health, the State of Oregon adopted a fish consumption rate of 175 g/day for freshwater and estuarine finfish and shellfish, including anadromous species. WQS for the protection of human health whose derivation is based in part on anadromous fish, create the expectation that implementation of these WQS will lead to lower contaminant levels in returning adult fish. Whether this expectation can be met is likely a function of where and when such fish are exposed. Various exposure scenarios have been advanced to explain acquisition of bioaccumulative contaminants by Pacific salmonids. This study examined 16 different scenarios with bioenergetics and toxicokinetic models to identify those where WQS might be effective in reducing polychlorinated biphenyls (PCBs)—a representative bioaccumulative contaminant—in returning adult Fall chinook salmon, a representative salmonid. Model estimates of tissue concentrations and body burdens in juveniles and adults were corroborated with observations reported in the literature. Model results suggest that WQS may effect limited (< approximately 2 ×) reductions in PCB levels in adults who were resident in a confined marine water body or who transited a highly contaminated estuary as out-migrating juveniles. In all other scenarios examined, WQS would have little effect on PCB levels in returning adults. Although the results of any modeling study must be interpreted with caution and are not necessarily applicable to all salmonid species, they do suggest that the ability of WQS to meet the expectation of reducing contaminant loadings in anadromous species is limited. Integr Environ Assess Manag 2012;8:553–562. © 2012 SETAC

Keywords: Anadromous fish Pacific salmonids Chinook Water quality standards PCBs

Environmental Policy & Regulation

INTRODUCTION

In 2011, as part of the update of its state water quality standards (WQS) for protection of human health (USEPA 2000), the State of Oregon adopted a fish consumption rate (FCR) of 175 g/day for freshwater and estuarine finfish and shellfish. This value is the highest among all US states and 10 times higher than the US Environmental Protection Agency's (USEPA) national default FCR of 17.5 g/day for the general population (Matzke and Wigal 2011; USEPA 2000). Fish consumption surveys among 4 Native American tribes in the Columbia River basin demonstrated that they consume fish, primarily anadromous, at higher rates than the general population. When Oregon's WQS for organic chemicals and trace metals were calculated using the national FCR, these criteria likely afforded less protection to such high-end consumers of fish and shellfish. Raising the FCR was assumed to offer added protection to populations, such as Native Americans, that consume greater quantities of fish or shellfish on a regular basis and also to specific subpopulations, such as children and women of childbearing age, who may be more susceptible to any chemical contaminants in fish and shellfish. One aspect of increasing the FCR was deciding whether to include consumption of anadromous fish, such as salmon, in the total ingestion rate. USEPA typically does not include salmon in ingestion rate estimates ''...on the assumption that adult salmon spend most of their lives in the open ocean and take up bioaccumulative and persistent contaminants almost exclusively via the food chain in that environment.'' (USEPA 2007). Nonetheless, as a matter of policy, these species were ultimately included in the data sets used to derive the Oregon FCR because they are of special interest and concern to Northwest Native American tribes (Matzke and Wigal 2011).

Water quality standards for protection of human health that are more stringent, because they are based in part on anadromous fish consumption data, create the expectation that their implementation will lead to lower contaminant levels in such fish. If exposure occurs in waters within the State's jurisdiction (''waters of the state''), then more stringent WQS generated by a higher FCR may reduce both contaminant loads in anadromous fish and risk to humans from subsequent consumption of these fish. This benefit of lower risk, and thus increased availability for consumption, would partially offset regulatory costs associated with what are significantly more stringent WQS. If, however, anadromous species are primarily contaminated in waters beyond the State's jurisdiction (e.g., in the open ocean), then more stringent WQS may simply impose economic and legal costs on the State's economy without the offsetting benefits of reductions in contaminant loads and associated risk. Thus the decision to include anadromous fish in a FCR calculation should be informed by some knowledge of where and when anadromous fish are most likely to be exposed to, and uptake, the majority of their contaminant burden.

All Supplemental Data may be found in the online version of this article.
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Conceptually, contaminant concentration and body burden are a function of where and for how long the specific life stage of a fish and a contaminant are colocated relative to one another in the environment. Because of their anadromous life history, Pacific salmonids occupy 3 distinct habitat types during their lifetimes, each of which may present a different opportunity for exposure to a contaminant: a) freshwater habitats, where eggs hatch and fry develop, b) estuary habitats, where smolts enter marine waters to feed and reside for some time during migration to c) ocean habitats, where the fish spend the majority of their lives. An exposure scenario is defined by where a fish is in space (exposure location), the time it spends in each location (exposure duration), and the contaminant concentration in prey at that location (exposure concentration). A number of exposure scenarios have been advanced, in both the published literature and in anecdotal accounts, to explain the circumstances under which Pacific Northwest salmonids may acquire a contaminant load. Frequently discussed scenarios have contaminant uptake occurring when: a) juveniles are reared in a hatchery (Johnson et al. 2009), b) juveniles (fry, subyearling, yearling) are out-migrating through fresh or estuarine waters (Johnson, Ylitalo, Sloan, et al. 2007; Johnson, Ylitalo, Arkoosh, et al. 2007), particularly if they transit areas with known contamination (Meador et al. 2010), c) adults are in near-shore marine waters (Missildine et al. 2005; O'Neill and West 2009; O'Neill et al. 1998), d) adults are in the open ocean (Cullon et al. 2009; Ewald et al. 1998; Krümmel et al. 2003, 2005; Rice and Moles 2006), e) adults partake of a final ''feeding frenzy'' in marine waters just before entering freshwater to spawn (anecdotal), or f) adults migrate upriver to spawn (anecdotal). Note that scenario (f) differs from one where exposure is to a contaminant body burden, acquired elsewhere, that is mobilized during spawning (Debruyn et al. 2004). Because the FCR is only relevant to calculation of WQS for protection of human health, this study focused on where fish could acquire tissue residues that could pose a health risk if consumed by humans. It did not address either the protection of aquatic life or the effect of contaminant burdens on the health of anadromous fish, important issues that have been studied by others (Arkoosh et al. 1998; Spromberg and Meador 2005).

The primary objective of this study was to corroborate model estimates of contaminant tissue concentrations and body burdens for specific exposure scenarios with those observed in returning adult Pacific salmonids. Model corroboration considered both the magnitude and lifetime trajectories of both contaminant concentrations and body burdens. A scenario (or scenarios) corroborated by observations might be one that offers a possible explanation for the genesis of those observations. A secondary objective of this study was to identify exposure scenarios within which implementation of a WQS inclusive of anadromous fish might reasonably be expected to reduce contaminant levels in such fish. Because life histories of these anadromous fish are complex and varied, it did not seem possible to test the absolute plausibility of an exposure scenario for all combinations of salmon species, types, evolutionarily significant units (i.e., a population of organisms that is considered distinct for purposes of conservation), or individuals. It did appear feasible, however, to identify a plausible scenario (or scenarios) based on corroboration between scenario-specific model estimates and observed tissue concentrations and body burdens in a representative species of salmonid. Bioenergetics and toxicokinetic (bioaccumulation) models were used to estimate contaminant concentrations and body burdens at locations (spatial dimension) typically occupied by juvenile and adult life stages (temporal dimension) of an idealized individual salmonid.

METHODS

Overview

Figure 1 illustrates the conceptual approach to this study. For each simulated day {d} postemergence, a bioenergetics model was used to estimate the mass of invertebrate and vertebrate prey consumed by a fish on that day, for a total lifetime of 2040 d ($\approx$5.5 y). This is likely an overestimate of lifespan, as most Fall chinook return at 3–4 y of age. The model runs for 2040 d to show the potential trajectory of bioaccumulation should a fish live for its theoretical maximum lifespan. Concurrently, the spatial location {y} of the fish on day {d} was estimated based on an individual's idealized life history. The contaminant concentration in prey was quantified at specific locations based on observed levels. A toxicokinetic (bioaccumulation) model was then used to combine estimates of contaminant concentrations in prey with estimates of prey consumption rates to make an estimate of contaminant levels (as both concentration and body burden) in a fish on day {d} at location {y} (Drouillard et al. 2009). Model estimates of tissue concentrations were then compared with those reported in the literature to assess the explanatory power of various exposure scenarios.

Representative salmonid

Pacific salmon have evolved many diverse strategies for juvenile migration, estuarine rearing, and adult migration and spawning (Allen and Hassler 1986; Groot and Margolis 1991; Healy 1991; Quinn 2004). Life histories of anadromous salmonids do, however, have some common traits. Adult fish spawn in freshwater streams, usually in late summer or fall. Their large yolky eggs are buried in the substrate, where embryonic development occurs. Juveniles emerge from the substrate the following spring as fry and are dependent on external food sources on emerging. Species life histories diverge at this point, with some species migrating to the estuary and others delaying their migration for months or years. After passing through the estuary, the fish carry out most of the growth in the ocean, spending, depending on the species and stock, between 1 and 6 years there. Adults then return to their natal streams or lakes to spawn and die shortly thereafter.

Fall chinook salmon (*Oncorhynchus tshawytscha*) were selected as the representative salmonid species because it is highly valued commercially, likely represents an important exposure pathway in the diet of peoples with subsistence lifestyles and high salmon consumption rates, is spiritually and culturally prized among certain Native American tribes, and is known to accumulate contaminants (Carlson and Hites 2005). With chinook, 2 distinct ''types'' have evolved. A ''stream-type'' (or Spring) is found most commonly in headwater streams of large river systems. This type has a longer freshwater residency and carries out extensive offshore migrations in the central North Pacific ocean before returning

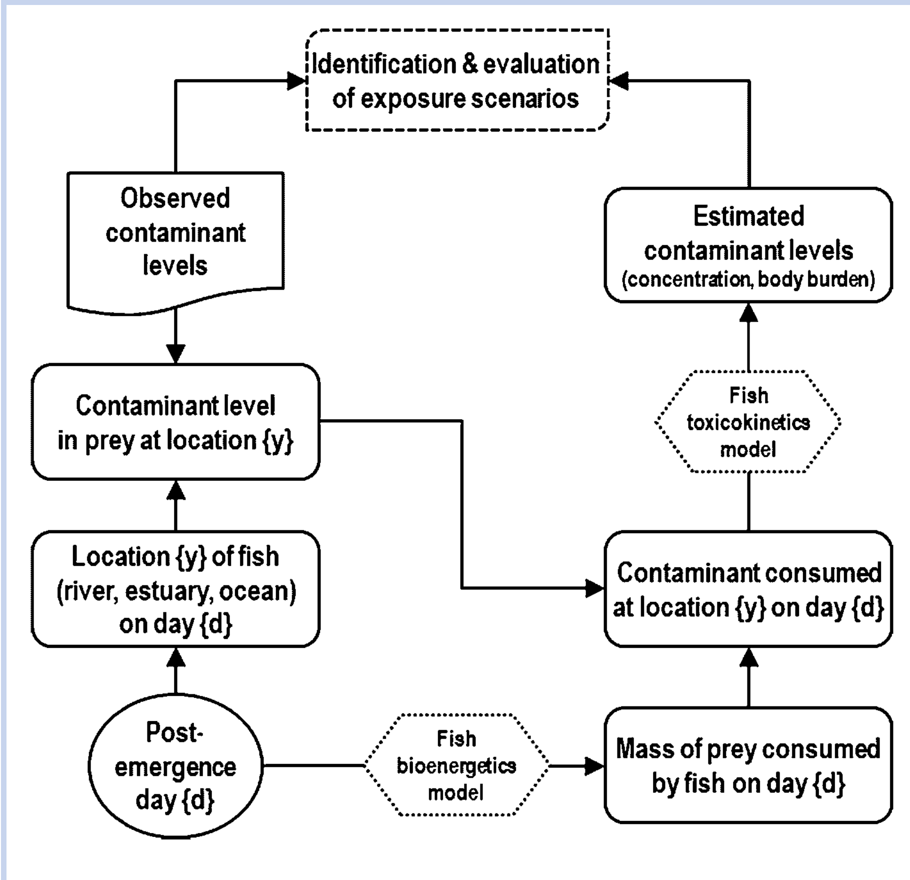

Figure 1. Conceptual model for conduct of this study.

to its natal streams in the spring or summer months. Juveniles migrate as yearlings after overwintering in the river environment. Stream-type juveniles are much more dependent on freshwater stream ecosystems because of their extended residence in these areas, but they spend little time in estuaries before moving to the ocean. They typically spend their first year at sea in near-shore waters before moving into the Gulf of Alaska and Northern Pacific Ocean for 2–4 years. An ''ocean-type'' (or Fall) is found commonly in coastal streams. Juveniles typically migrate to sea within the first 3 months of life, but timing of migration is quite variable (Reimers and Loeffel 1967). Some disperse to estuaries as fry immediately after emergence, some spend additional time in freshwater before entering the estuary, and some rapidly transit the estuary after short or long periods of residence in freshwater. Ocean-type spend more time in estuaries as juveniles than any other Pacific salmon but variation in timing and duration of estuarine residence is considerable (Hering 2009). After entering ocean waters, they tend to migrate along the coast, spend their ocean life in coastal waters (≈5–8 km offshore), and return to their natal streams or rivers principally as summer and fall runs. After 1–6 years in marine waters, both types return to their natal waters to spawn, the difference being that the ocean-type spawns almost immediately after reaching their natal stream whereas the stream-type typically spends several months in freshwater before spawning. Chinook from Alaska are almost entirely stream-type, whereas those from northern British Columbia are mixed stream- and ocean-types, and those further south in Puget Sound and Oregon waters are predominantly ocean-type (Healy 1991).

Representative contaminant

Polychlorinated biphenyls (PCBs) were selected as the representative persistent, bioaccumulative, and toxic (PBT) contaminant because their physicochemical behavior is well characterized, they have been detected in fresh and marine waters, in the tissues of various salmonid species, and in the tissues of salmonid invertebrate and vertebrate prey (Carlson and Hites 2005; O'Neill and West 2009). Empirical data on PCB concentrations in fresh and marine waters, in chinook salmon, and in their dietary items at various life stages, were drawn from the literature and are summarized in Table S1 (Supplemental Data). These data, although extensive and of good quality, nonetheless had some limitations. Ready comparisons between studies were challenged by PCB concentrations, particularly total concentrations, being reported as differing summations of various aroclors or congeners. Studies did not always report both wet weight and lipid-normalized concentrations, or data needed to convert from one to the other. Body burden estimates, an important adjunct to concentration measurements, were also rarely reported. There were also few measurements of PCB concentrations in adult fish caught at sea at known locations and apparently none of PCBs levels in the stomach contents of such fish. Many studies did not report ancillary data, such as type of salmon (Fall or Spring), weight, length, age, or lipid content, that would have been useful for comparative purposes.

A metaanalysis of the observations listed in Table S1 (Supplemental Data) suggested groups based on sampling location and tissue concentration. Wild fish in headwater (1st–3rd order) streams, including fish in headwater reaches of Puget Sound rivers and large rivers discharging to the ocean, and hatchery fish formed distinct groups, with wild fish in headwater streams having the lowest reported prey and tissue concentrations of all groups. Three groups were evident for Puget Sound: fish collected in the Sound itself, fish collected from contaminated estuaries, and fish taken from presumably un- or less contaminated, estuaries. Fish entering the ocean directly (i.e., not through Puget Sound) from large rivers and those that entered directly from small rivers formed 2 additional groups. Fish caught in the open ocean (e.g., Gulf of Alaska) or in coastal waters outside of Puget Sound (e.g., Johnstone Strait) formed a final group.

From the perspective of observed mean tissue concentrations in returning adults, fish could be placed, seemingly without regard to their type or exposure experience as out-migrating juveniles, into 1 of 3 concentration ranges: 1) a higher ''Sound'' range (mean tissue concentrations from 35 to 90 μg/kg, w/w) for returning adults whose natal river discharged into Puget Sound, 2) a middle ''Large River'' range (mean tissue concentrations from 10 to 40 μg/kg, w/w) for returning adults whose natal river discharged directly to the ocean from a watershed with significant urban land use and other anthropogenic impacts (e.g., Columbia River, Fraser River), or 3) a lower ''Ocean'' range (mean tissue concentrations from 10 to 20 μg/kg, w/w) for returning adults whose natal river also discharged directly to the ocean but from a watershed with few anthropogenic impacts (e.g., Salmon River, OR). This low range also included adults caught in the open waters of the North Pacific, Gulf of Alaska, or Bering Sea on the assumption that their natal rivers were also lightly impacted. Data for returning adults were sufficient to identify 2 ranges based on observed mean body burdens: a high range (200–400 μg/fish, w/w) for adults caught within Puget Sound and in the Duwamish, Deschutes, and Lower Fraser Rivers and a low range (30–100 μg/fish, w/w) for fish caught in the North Pacific Ocean, Gulf of Alaska, or Bering Sea. The differences between these high and low ranges for concentration (6–7-fold) and burden (7–10-fold) may be explained in part by the hydrology of Puget Sound, which is a deep, fjord-like estuary with a narrow connection to oceanic waters through the Strait of Juan de Fuca and shallow sills at Admiralty Inlet. These hydrological features tend to isolate its waters from less contaminated open ocean waters, reduce summer flushing time relative to that of the Strait of Georgia, and allow for contaminants to become entrained within it (Friebertshauser and Duxbury 1972; O'Neill and West 2009; Thomson 1994). This hydrology, combined with considerable urbanization on its surrounding lands, and the presence of several federal Superfund sites, may make the Sound a unique upper bound case for PCB contamination in Pacific Northwest coastal waters. These 5 ranges were used for corroboration purposes, in that a potentially explanatory exposure scenario would be one that placed its model estimates for both tissue concentration and body burden within either the higher or lower ranges observed in returning adult salmon.

Exposure Scenarios

Locations. In general, anadromous fish may be exposed to a contaminant while out-migrating as a juveniles through freshwater or estuarine environments, as adults in the marine environment, or in all 3 environments at different times. Within this general context, measurements summarized in Table S1 (Supplemental Data) were used to identify 16 specific exposure scenarios (Table 1). Because of the known ubiquity of PCBs in aquatic environments, a constant dissolved phased PCB concentration of 10 pg/L in both fresh and marine waters was assumed for all scenarios (Iwata et al. 1993). Seven scenarios (Scenarios 1–8) assumed that exposure occurred via water and prey consumption in only 1 specific location. Scenario 1 had exposure occurring only when wild juveniles out-migrate through river reaches with few, if any, significant anthropogenic impacts (e.g., Salmon River, OR), whereas Scenario 2 assumed exposure only when fish were reared on contaminated food in hatcheries. Exposures in estuaries within Puget Sound could occur when transiting (Scenario 3) a contaminated estuary (e.g., Duwamish Waterway) or another estuary that connects with the Sound (Scenario 4). Estuaries that enter open marine waters directly could be those for large rivers (Scenario 5) with urbanization in their watersheds (e.g., Columbia River, Fraser River), or small rivers (Scenario 6) with little urbanization in their watersheds (e.g., coastal rivers in Washington, Oregon, or Alaska). Exposures could also take place only in Puget Sound (Scenario 7) or only in unconfined coastal or the open marine waters (e.g., Gulf of Alaska) (Scenario 8). Although exposure in just 1 location is possible (e.g., only when transiting a contaminated estuary), fish have the potential, particularly with globally ubiquitous contaminants like PCBs, to be exposed in multiple locations. Eight scenarios (Scenarios 9–16) allowed for combined exposures via water and prey in multiple locations (Table 1). For example, Scenario 15 assumes that an out-migrating wild juvenile (Scenario 1) enters the open ocean (+ Scenario 8) through the estuary of a small river (+ Scenario 6), whereas Scenario 10 assumes that a hatchery-raised fish (Scenario 2) takes up residency in Puget Sound (+ Scenario 7) after entering it through an estuary with known contamination (+ Scenario 4). Although there is no empirical evidence to suggest that Pacific salmon indulge in a prespawning ''feeding frenzy'' (Higgs et al. 1995), the effect of any such behavior was evaluated by assuming that the consumption rate increased by 10 times for 30 days before the start of the spawning migration. Because Pacific salmon cease feeding during the spawning migration (Higgs et al. 1995), the only uptake of a contaminants during this portion of a salmon's life cycle would be from water via the gills.

Duration. Chinook in Puget Sound and Oregon waters are predominantly Fall or ocean-type (Healy 1991). Fall chinook may spend approximately 60–210 d postemergence in freshwater and approximately 10 and 90 d in an estuary. For this study, an idealized Fall chinook was assumed to have an exposure duration in freshwater for 130 d postemergence (median of the freshwater range), then in an estuary environment for 50 d (median of the estuary range), and the remaining 1860 d in the marine environment (Table 1), for a total lifetime of 2040 d (≈5.5 y). Median values were selected to explore what happens to a ''typical'' individual. Here the

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Table 1. Summary of exposure scenarios, durations, and concentrations in Fall chinook

Scenario[a]	Exposure location	Exposure duration[c]	Exposure concentration (C_D, μg/kg, w/w)[b]	
			Juveniles[d]	Adults[d]
1	Freshwater: Wild (upstream of most anthropogenic stressors)	130	5 (5–23)	—
2	Freshwater: Hatchery	130	12 (10–14)	—
3	Estuary: Contaminated (Puget Sound)	50	450 (57–760)	—
4	Estuary: Other (Puget Sound)	50	34 (22–59)	—
5	Estuary: Large river	50	62 (20–115)	—
6	Estuary: Small river	50	10	—
7	Ocean: Puget Sound	1860	—	28[e]
8	Ocean: Open water	1860	—	6[e]
9 (1 + 3 + 7)	Wild > contaminated > Sound	Fall chinook resident in Puget Sound		
10 (2 + 3 + 7)	Hatchery > contaminated > Sound			
11 (1 + 4 + 7)	Wild > other > Sound			
12 (2 + 4 + 7)	Hatchery > other > Sound			
13 (1 + 5 + 8)	Wild > urban > Ocean	Fall chinook outside Puget Sound		
14 (2 + 5 + 8)	Hatchery > urban > Ocean			
15 (1 + 6 + 8)	Wild > non-urban >Ocean			
16 (2 + 6 + 8)	Hatchery > non-urban > Ocean			

[a]All scenarios assume a constant dissolved phase PCB concentration of 10 pg/L.
[b]Concentration as grand mean of means in Table 1 (minimum–maximum range of means).
[c]Days postemergence.
[d]Concentration in stomach contents.
[e]PCB concentration in Pacific herring, assuming contaminated herring is 20% of total adult diet.

marine environment was either Puget Sound or the open ocean. A lifetime of this length is expected to overestimate exposure, as returns typically occur within 3–4 years of entering the marine environment.

PCB concentrations in prey. A key input to the toxicokinetic model is the PCB concentration in salmonid invertebrate and vertebrate prey (C_D), which is typically the PCB concentration in salmonid stomach contents. Each individual exposure scenario was assigned a different representative value for C_D, based on available dietary data as detailed in Table S1 (Supplemental Data) and summarized in Table 1. Its value in all scenarios was a point estimate representing a grand mean. For wild juveniles (Scenario 1), C_D was that for fish from the Salmon River (Oregon). For hatchery juveniles (Scenario 2), C_D was the mean PCB concentration in feed from various Oregon, Washington, Columbia River, and Columbia Basin fish hatcheries, exclusive of concentrations measured before 2000, as these appeared unusually high relative to more recent measurements. The C_D point estimate for a contaminated estuary (Scenario 3) was the mean of data from the Commencement Bay and Duwamish Waterway Superfund sites. That for a large river estuary (Scenario 5) was the mean of data from uncontaminated rivers entering Puget Sound, plus those for the lower Columbia and Fraser Rivers. All of these watersheds include urban lands subject to a variety of anthropogenic stressors, including chemical stressors. The Lower Columbia River, for example, is likely impacted at its confluence with the Willamette River by the Portland metropolitan area (Johnson, Ylitalo, Sloan, et al. 2007; Johnson, Ylitalo, Arkoosh, et al. 2007) and the Fraser River in Canada by its passage through the Vancouver (BC) metropolitan area. For a small river estuary (Scenario 6), C_D was the mean in the diet of fish in small, coastal rivers whose estuaries enter the ocean directly, without an intervening sound. Because of a paucity of data on PCB concentrations in adult stomach contents, the C_D for adults, in both Puget Sound (Scenario 7) and the open ocean (Scenario 8), was inferred from measured PCB concentrations in Pacific herring (*Clupea pallasi*), prey comprising 20%–60% of an adult's diet (Healy 1991; West et al. 2008).

Bioenergetic Model (Daily Consumption Rate)

As out-migrating juveniles in freshwater, wild chinook salmon typically feed on pelagic, drifting, and epibenthic larval and adult insects. In estuaries, their diet shifts toward pelagic zooplankton, epibenthic amphipods, and, as they grow larger, small fishes. In the marine environment, the diet of adult chinook is largely comprised of larval and juvenile

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fishes (principally Pacific herring [*Clupea*]), pelagic amphipods, and crab megalopa (Healey 1991; Schabetsberger et al. 2003). The Wisconsin bioenergetics model 3.0 (Hanson et al. 1997; Madenjian et al. 2004) was used, unmodified, to estimate the feeding rate (G_D), fecal egestion rate (G_F), and body weight (W) for juvenile (J) and adult (A) chinook salmon cohorts for each day of a 2040 d lifetime. The model's default values for chinook salmon were used to parameterize its physiological variables (Hanson et al. 1997; Stewart and Ibarra 1991). These included the allometric parameters for dependence of consumption and respiration on body mass, the most sensitive variables (i.e., those with the greatest influence on model predictions). Values for user-specified variables were: weight range (J: 0.1–80 g, A: 80–15 000 g), indigestible fraction of prey (J, A: 20%), prey energy content (J: 2000 J/g, A: 4000 J/g, wet body mass; energy densities of typical prey items (Hanson et al. 1997: see Appendix B), prey dietary fraction (1, unitless; because all prey had the same energy content and digestibility), predator energy content (4000 J/g, wet body mass), and water temperature (10° C, midpoint of optimal growth range [Allen and Haster 1986]).

Toxicokinetic Model (Contaminant Uptake and Retention)

Uptake from prey items and elimination via feces are the major pathways by which fish accumulate and eliminate persistent hydrophobic ($\log K_{OW} \approx 6$) organic contaminants such as PCBs (Qiao et al. 2000). Uptake of such contaminants from water via the gills is of less importance due to their generally low concentrations (pg/L) in fresh or marine waters (Gobas and Mackay 1987; Iwata et al. 1993). A mass balance contaminant accumulation model was implemented in STELLA™ (Isee Systems) using variables and algorithms developed by Arnot and Gobas (2003, 2004) and Gobas and Arnot (2010). The 2 most sensitive variables in this model are $\log K_{OW}$ (that was a fixed value) and the concentration of a contaminant in prey items (C_D). Values for C_D (Table 1), as well as the day or days on which a fish is exposed, were varied to match the exposure scenario being evaluated. Table S2 (Supplemental Data) summarizes model variables and equations; relationships for these are shown in Figure S1 (Supplemental Data). This model provided estimates of tissue concentration and body burden resulting for uptake of PCBs from both surface water (via gill exchange) and prey (via consumption) for all, or any portion, of a fish's lifespan. Both estimates were necessary because for non- or poorly metabolized contaminants (such as PCBs) in a fast-growing species, decreases in concentration due mainly to growth dilution may be misinterpreted as reductions in burden (i.e., as a loss of contaminant mass). Burden is a better indicator of the difficult-to-reverse consequences of long term exposure to a recalcitrant contaminant.

RESULTS AND DISCUSSION

Scenarios

Observed and model estimated tissue concentrations are listed in Table 2; body burdens in Table 3. Scenario-specific model results, in relation to ranges observed in returning adults after 3–4 years in seawater, are shown in Figure 2 for concentrations and Figure 3 for body burdens. Trajectories through time of tissue concentrations, again in relation to observed ranges, are shown in Figures S2–S8 (Supplemental Material).

Individual scenarios. Exposures only in upstream freshwater habitats (Scenario 1 [Figure S2]) or only in a hatchery (Scenario 2 [Figure S2]), or only while transiting uncontaminated estuaries (Scenarios 4 and 6 [Figure S3]) all failed to produce estimates for returning adult fish within any of the observed concentration ranges. With the unusually high dietary concentrations reported before 1993 set aside, hatchery fish exposed to contaminated food (Scenario 2) would be indistinguishable from those exposed only in the open ocean (Scenario 8 [Figure S4]), which suggests that hatcheries may be an unlikely sole source of PCB loads in returning adults. Exposure only in Puget Sound (Scenario 7 [Figure S4]) or only in the open ocean (Scenario 8) was sufficient to generate concentrations and burdens within the Sound and Ocean ranges, respectively, for fish with 3–4 years in seawater and also at end-of-life (Figures 2 and 3). Exposure only in a large river estuary (Scenario 5 [Figure S3]) yielded

Table 2. Comparison of observed and modeled tissue concentrations (μg/kg, w/w)[a]

	Out-migrating juveniles		Returning adults
Scenario	River at 130 d	Estuary at 180 d	3–4 y[b]
1	8 5 (4–8)[c]	6	2
2	18 24 (10–50)[c]	15	3
3	0.4	196 197 (24–725)[c]	38 49 (35–57)[d]
4	0.4	15 45 (40–50)[c]	3 51 (37–83)[d]
5	0.4	27 57 (49–70)[c]	6 34 (11–47)[d]
6	0.4	8 17 (4–46)	2 12 (7–19)
7	0.4	0.4	65 67 (40–86)[d]
8	0.4	0.4	14 11 (9–14)[d]
9	8 5 (4–8)[c]	202 197 (24–725)[c]	103 67 (40–86)[d]
10	18 24 (10–50)[c]	211 197 (24–725)[c]	104 67 (40–86)[d]
11	8 5 (4–8)[c]	21 45 (40–50)[c]	69 67 (40–86)[d]
12	18 24 (10–50)[c]	30 45 (40–50)[c]	70 67 (40–86)[d]
13	6 5 (4–8)[c]	32 57 (49–70)[c]	20 11 (9–14)[d]
14	18 24 (10–50)[c]	42 57 (49–70)[c]	22 11 (9–14)[d]
15	8 5 (4–8)[c]	11 17 (4–46)[c]	16 11 (9–14)[d]
16	18 24 (10–50)[c]	19 17 (4–46)[c]	18 11 (9–14)[d]

[a]Single and upper values are model estimates; lower values are observed concentrations.
[b]Three to four winters in seawater, as average of postemergence Days 1145–1510.
[c]Observed tissue concentration, grand mean (range of means).
[d]Observed tissue concentration, grand mean (range of means), age of fish not specified.

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Table 3. Comparison of observed and model estimated body burdens (μg/fish, w/w)

	Out-migrating juveniles		Returning adults
Scenario	River at 130 d	Estuary at 180 d	3–4 y[k]
1	0.2	0.4	9
	0.2[g]	0.4[a]	
2	1	1 2.0 (1.5)[f]	18
3	0.01	12	212
		2.1 (9.2)[d]	350 (800)[e]
		4.8 (0.8)[h]	218–333[i]
4	0.01	1	19
5	0.01	2	32
6	0.01	0.5	11
7	0.01	0.02	372
			260–340[b]
			280–390[c]
8	0.01	0.02	82
			29–98[j]
9	0.2	12	587
10	0.5	12	596
11	0.2	1	394
12	0.5	2	403
13	0.2	2	116
14	0.5	2	126
15	0.2	1	93
16	1	1	102

[a]Estimated value in 10 g out-migrating smolts (O'Neill and West 2009).
[b]Puget Sound adult chinook after 1–2 winters in saltwater (O'Neill and West 2009).
[c]Puget Sound adult chinook after 3–4 winters in saltwater (O'Neill and West 2009).
[d]Out-migrating smolts in the Duwamish River, mean (95th percentile) (O'Neill and West 2009).
[e]Adults returning to the Duwamish River, mean (95th percentile) (O'Neill and West 2009).
[f]Out-migrating hatchery fish in 1989, 1993, and 2000, mean (1 SD) (Meador et al. 2002).
[g]Out-migrating wild juveniles collected in 2000 in the Duwamish River upstream of major urban impacts, mean (Meador et al. 2002).
[h]Out-migrating juveniles collected in 1989, 1993, 2000 in the Duwamish River estuary, mean (1 SD) (Meador et al. 2002).
[i]Adults returning to the Lower Fraser River (BC) and Duwamish and Deschutes Rivers (WA) (Cullon et al. 2009).
[j]Adults collected in the Gulf of Alaska and North Pacific Ocean (Carlson and Hites 2005; Easton et al. 2002), in Johnstone Strait (Cullon et al. 2009), and off Vancouver Island (BC) (Ikonomou et al. 2007).
[k]3 to 4 winters in seawater, as average of post-emergence days 1145 to 1510.

concentration estimates just below, but burden estimates at, the lower range, whereas short, intense exposures not unlike those achieved by passage through an estuary containing an in-water contaminated site (Scenario 3 [Figure S3]) generated concentration and burden estimates at the higher range. An estuary fed by a large river flowing through areas impacted by anthropogenic chemical stressors (e.g., the Columbia River at its confluence with the Willamette River is affected by the urban areas of Portland [OR] and Vancouver [WA], as well as a large in-water Superfund site) could produce such exposures.

Scenario 3, a single large exposure when out-migrant juveniles transit a contaminated estuary, produced tissue and burden estimates at the lower bound of those observed in 3–4-year-old adults (Figures 2 and 3). Tissue concentrations slowly declined but body burdens were recalcitrant, indicating that even a relatively brief ($\leq$50 d) exposure to elevated prey concentrations may have lasting consequences in terms of increased PCB burdens carried by adults. Average and adjusted average contaminant concentrations in adults taken from Puget Sound after 1–4 years in salt water (O'Neill and West 2009) were compared to model estimated concentrations. Scenario 3 provided the closest approximation to these observations in terms of both magnitude of, and rate of decline in, concentration (Figure S9). Colloquially, a juvenile transiting a contaminated location appears to ''jump-start'' acquisition of a body burden of highly bioaccumulative contaminants such as PCBs. Scenario 7 did not suggest declines in tissue concentrations, suggesting that apparent declines, particularly in burdens, result from samples composed of individual fish with differing exposure experiences.

Absent a short, intense exposure to chemical stressors (e.g., Scenarios 3 and 5), simple residence in, or extended transit through, contaminated marine waters may be sufficient to generate the majority of the observed loads. The degree of loading may be a function of the extent of the time spent is residence or transit. Thus exposures before entering marine waters that do not involve intense exposures are unlikely to be the principal source of PCB loads observed in returning adults. This finding of a dominant role for exposure in open marine waters is consistent with reports by others (O'Neill and West 2009) and with the USEPA rationale for not including anadromous fish in exposure estimates (USEPA 2007).

Multiple scenarios. Exposure upstream, then in a contaminated estuary, then in Puget Sound (Scenarios 9 and 10 [Figure S5]), approximately doubled concentration and burden estimates over those for the Sound (Scenario 7) alone. Conversely, exposures upstream, then in an uncontaminated Puget Sound estuary, then in Puget Sound (Scenarios 11 and 12 [Figure S6]) did not produce concentration and burden estimates different than those in the Sound (Scenario 7) alone. This emphasizes the role played by short but intense exposures associated with a contaminated estuary. Exposure upstream, then in an large river estuary, then in open marine waters (Scenarios 13 and 14 [Figure S7]), also approximately doubled concentration and burden estimates over those for the open ocean (Scenario 8) alone. An initial spike in concentration (Figure S7) due to the large river estuary was subsequently ameliorated by a longer exposure to less contaminated prey in the open ocean, causing concen-

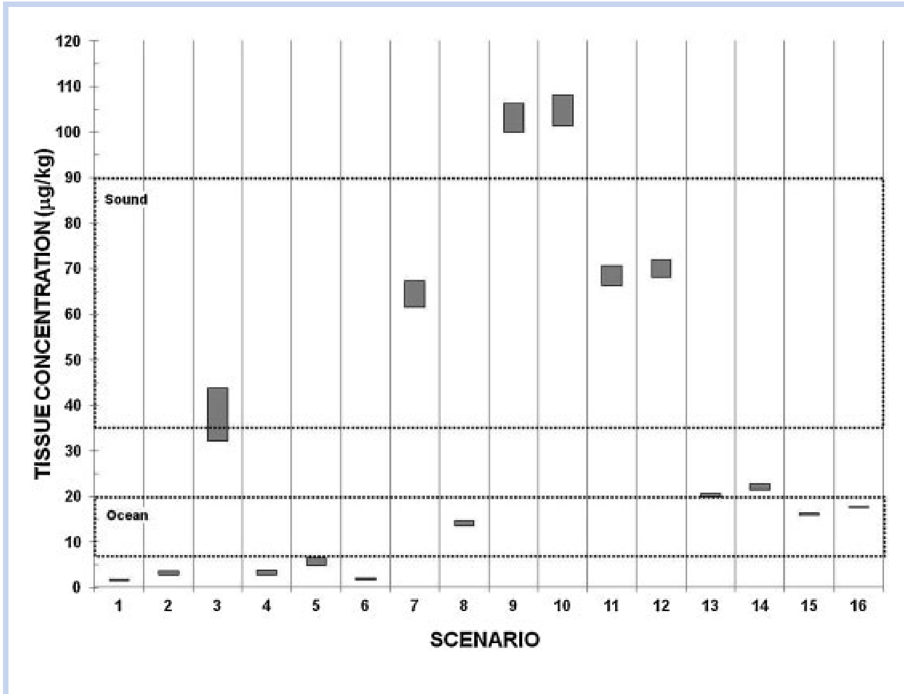

Figure 2. Comparison of tissue concentration estimates (µg/kg, w/w) by scenario (vertical bars) to observed tissue concentration ranges (boxes with dotted line borders) in adult fish at 3–4 y in marine waters.

tration and burden estimates to settle into the large river range between the Sound and Ocean ranges. However, exposures upstream, then in a small river estuary, then in the open ocean (Scenarios 15 and 16 [Figure S8]) did not produce concentration and burden estimates different than those in the open ocean (Scenario 8) alone.

Miscellaneous scenarios. Uptake from water was a small and comparatively inconsequential source of PCB concentrations and burdens, indicating that observed adult burdens could not be obtained only during the upstream spawning migration in freshwater. However, the ubiquity and persistence of legacy PCBs (and other legacy chemicals with similar

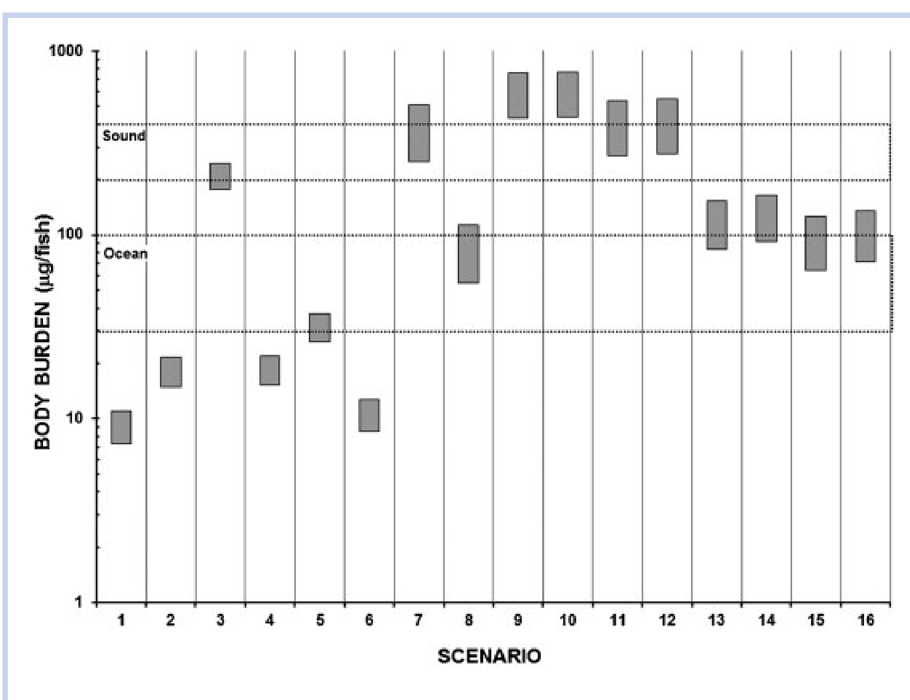

Figure 3. Comparison of body burden estimates (µg/fish) by scenario (vertical bars) to observed body burden concentration ranges (boxes with dotted line borders) in adult fish at 3–4 y in marine waters.

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physicochemical properties) virtually guarantees that any fish, whether anadromous or resident, will have some small PCB burden (CTUIR 2007; Henny et al. 2003). The ''feeding frenzy'' scenario (a 10-fold increase in the consumption rate in the 30 d before the start of spawning) had no discernible effect on either concentrations or burdens estimated for any scenario. It is thus highly unlikely that an adult fish could acquire concentrations or burdens on the order of observed levels simply by sharply increasing its feeding near the end of its life.

Implications for WQS

This study focused on 1 type (Fall) of 1 species (chinook) of salmonid and on 1 PBT contaminant (PCBs), corroborated by a metaanalysis of available data on tissue concentrations and body burdens of that contaminant collected in the Pacific Northwest and Alaska by a number of researchers. It applied these data to models that are well established and whose behavior, including sensitive inputs, is well understood. However, these species, data, and models all embed uncertainties of various types, not all of which are readily identifiable or quantifiable. As a result, the results of this (or any) modeling study must be interpreted with caution; however, it may still provide insights into the efficacy of WQS for reducing contaminant loads in Fall chinook salmon. Note, however, that the specific applicability of these results to other salmonid species was not determined here. At a minimum, these results may be useful for dispelling assertions about exposure scenarios that are physiologically improbable and whose pursuit is unlikely to result in protective outcomes.

Results suggest that using WQS as waterbody target concentrations may yield only small ($\leq 2\times$) reductions in PCB levels (or of other ubiquitous legacy contaminants with similar PBT properties) in returning adult Fall chinook salmon because the majority of uptake likely occurs while adults are in marine waters beyond the state's jurisdiction. WQS would also have little effect on hatchery fish whose PCB load stems from consumption of contaminated feed (Scenario 2). Scenario 8 results suggest, as have others (O'Neill and West 2009), that PCB loads in fish either resident outside of Puget Sound or not in contact with a contaminated estuary likely stem primarily from exposure in open marine waters. Because states do not have jurisdiction over the open ocean, implementation of WQS will not occur in such waters.

Puget Sound is unique marine water body in that it is both poorly flushed and subject to contaminant loading from surrounding urban landscapes, which have been shown to be disproportionate contributors of chemical stressors (Black et al. 2000; Paul and Meyer 2001). It is also host to several major in-water contaminated sites, where WQS are currently being used to guide remediation efforts. Although addressing these sites is likely to eliminate excesses in concentrations and burdens (e.g., Scenarios 9 and 10), doing so is unlikely to result in large reductions in bioaccumulative contaminants in anadromous fish. Because of the known relationship between urban land use and chemical stressors (Black et al. 2000), use of WQS in controlling or reducing contaminants from nonpoint sources (e.g., runoff from impervious surfaces, nonpermitted stormwater flows, runoff of air deposition [Hope 2008]) will also be required (McCarthy et al. 2008). Because permitted and properly managed point sources (e.g., industrial, wastewater treatment, permitted stormwater) are no longer significant contributors of PCBs to watersheds, use of WQS to regulate such sources would not reduce chemical loadings throughout the Sound. Although implementation of WQS for all waters entering the Sound may, over time, yield lower contaminant levels within the Sound, there are likely to be practical limits on the affect WQS can have on globally distributed legacy contaminants such as PCBs.

Including anadromous fish in the FCR used for developing WQS for protection of human health creates the expectation that implementation of this WQS will significantly reduce bioaccumulative contaminants (e.g., PCBs, PBDEs, dioxins/furans) in such fish. Based on these model results, meeting WQS may lead to small reductions ($\leq 2\times$) only for returning Fall chinook salmon adults that were resident in a confined water body (e.g., Puget Sound) or who transited a highly contaminated estuary (e.g., Duwamish Waterway) as out-migrating juveniles. Otherwise, it may be unrealistic to expect attainment of WQS to result in reduced contaminant burdens in species who receive these burdens as adults in unconfined coastal or open marine waters. Where attainment of WQS can be physically linked to reductions in contaminant loads, benefits will typically out-weigh costs associated with its attainment. Conversely, any physical disconnects between attainment of WQS and expected reductions in contaminant loads creates a situation with costs but few, if any, off-setting benefits. Such a cost-benefit disparity can frustrate those seeking the protection of WQS and those legally required to implement controls designed to attain it.

SUPPLEMENTAL DATA

Supporting Tables S1–S9.
Supporting Figure S1.
Supporting Figure S2.

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REFERENCES

Allen MA, Hassler TJ. 1986. Species profiles: Life histories and environmental requirements of coastal fishes and invertebrates (Pacific Southwest)—Chinook salmon. Biological Report 82 (11.49). Washington (DC): US Fish and Wildlife Service.

Arkoosh MR, Casillas E, Clemons E, Kagley AN, Olson R, Reno P, Stein JR. 1998. Effect of pollution on fish diseases: Potential impacts on salmonid populations. *J Aq Animal Health* 10:182–190.

Arnot JA, Gobas FAPC. 2003. A generic QSAR for assessing the bioaccumulation potential of organic chemicals in aquatic food webs. *QSAR Comb Sci* 22:337–345.

Arnot JA, Gobas FAPC. 2004. A food web bioaccumulation model for organic chemicals in aquatic ecosystems. *Environ Toxicol Chem* 23:2343–2355.

Black RW, Haggland AL, Voss FD. 2000. Predicting the probability of detecting organochlorine pesticides and polychlorinated biphenyls in stream systems on the basis of land use in the Pacific Northwest, USA. *Environ Toxicol Chem* 19:1044–1054.

Carlson DL, Hites RA. 2005. Polychlorinated biphenyls in salmon and salmon feed: Global differences and bioaccumulation. *Environ Sci Technol* 39:7389–7395.

[CTUIR] Confederated Tribes of the Umatilla Indian Reservation. 2007. Umatilla River Fish Toxicant Studies. Confederated Tribes of the Umatilla Indian Reservation, Pendleton, OR. Report prepared by Jones and Stokes, Portland, OR.

Cullon DL, Yunker MB, Alleyne C, Dangerfield NJ, O'Neill S, Whiticar MJ, Ross PS. 2009. Persistent organic pollutants in chinook salmon (*Oncorhynchus tshawytscha*): Implications for resident killer whales of British Columbia and adjacent waters. *Environ Toxicol Chem* 28:148–161.

Debruyn AMH, Ikonomou MG, Gobas FAPC. 2004. Magnification and toxicity of PCBs, PCDDs, and PCDFs in upriver-migrating Pacific salmon. *Environ Sci Technol* 38:6217–6224.

Drouillard KG, Paterson G, Haffner GD. 2009. A combined food web toxicokinetic and species bioenergetic model for predicting seasonal PCB elimination by yellow perch (*Perca flavescens*). *Environ Sci Technol* 43:2858–2864.

Easton MDL, Luszniak D, Von der Geest E. 2002. Preliminary examination of contaminant loadings in farmed salmon, wild salmon and commercial salmon feed. *Chemosphere* 46:1053–1074.

Ewald G, Larsson P, Linge H, Okla L, Szarzi N. 1998. Biotransport of organic pollutants to an inland Alaska lake by migrating Sockeye salmon (*Oncorhynchus nerka*). *Arctic* 51:40–47.

Friebertshauser MA, Duxbury AC. 1972. A water budget study of Puget Sound and its subregions. *Am Soc Limnol Oceanog* 17:237–247.

Gobas FAPC, Arnot JA. 2010. Food web bioaccumulation model for polychlorinated biphenyls in San Francisco Bay, California, USA. *Environ Toxicol Chem* 29:1385–1395.

Gobas FAPC, Mackay D. 1987. Dynamics of hydrophobic organic chemical concentration in Fish. *Environ Toxicol Chem* 6:495–504.

Groot C, Margolis L. 1991. Pacific salmon life histories. Vancouver (BC): University of British Columbia Press. 564 p.

Hanson PC, Johnson TB, Schindler DE, Kitchell JF. 1997. Fish Bioenergetics 3.0 for Windows. WISCU-T-97-001. Madison Center for Limnology and Sea Grant Institute, University of Wisconsin, Madison, WI.

Healy MC. 1991. Life history of chinook salmon (*Oncorhynchus tshawytscha*). In: Groot C, Margolis L, editors. Pacific salmon life histories. Vancouver (BC): University of British Columbia Press. p 311–391.

Henny CJ, Kaiser JL, Grove RA, Bentley VR, Elliott JE. 2003. Biomagnification factors (fish to osprey eggs from Willamette River, Oregon, U.S.A.) for PCDDs, PCDFs, PCBs, and OC pesticides. *Environ Monitor Assess* 84:275–315.

Hering DK. 2009. Growth, residence, and movement of juvenile chinook salmon within restored and reference estuarine marsh channels in Salmon River, Oregon [MS thesis]. Corvallis (OR): Oregon State Univ.

Higgs DA, Macdonald JS, Levings CD, Dosannjh BS. 1995. Nutrition and feeding habits in relation to life history stage. In: Groot C, Margolis L, Clarke WC, editors. Physiological ecology of Pacific salmon. Vancouver (BC): University of British Columbia Press. p 174–176.

Hope BK. 2008. A model for the presence of polychlorinated biphenyls (PCBs) in the Willamette River Basin (Oregon). *Environ Sci Technol* 42:5998–6006.

Ikonomou MG, Higgs DA, Gibbs M, Oakes J, Skura B, McKinley S, Balfry SK, Jones S, Withler R, Dubetz C. 2007. Flesh quality of market-size farmed and wild British Columbia Salmon. *Environ Sci Technol* 41:437–443.

Iwata H, Tanabe S, Sakai N, Tatsukawa R. 1993. Distribution of persistent organochlorines in the oceanic air and surface seawater and the role of ocean on their global transport and fate. *Environ Sci Technol* 27:1080–1098.

Johnson LL, Willis ML, Olson OP, Pearce RW, Sloan CA, Ylitalo GM. 2009. Contaminant concentrations in juvenile fall Chinook salmon from Columbia River hatcheries. *N Am J Aquaculture* 72:73–92.

Johnson LL, Ylitalo GM, Arkoosh MR, Kagley AN, Stafford C, Bolton JL, Buzitis J, Anulacion BF, Collier TK. 2007. Contaminant exposure in outmigrant juvenile salmon from Pacific Northwest estuaries of the United States. *Environ Monitor Assess* 124:167–194.

Johnson LL, Ylitalo GM, Sloan CA, Anulacion BF, Kagley AN, Arkoosh MR, Lundrigan TA, Larson K, Siipola M, Collier TK. 2007. Persistent organic pollutants in outmigrant chinook salmon from the Lower Columbia Estuary, USA. *Sci Tot Environ* 374:342–366.

Krümmel EM, Gregory-Eaves I, Macdonald RW, Kimpe LE, Demers MJ, Smol JP, Finney B, Blais JM. 2005. Concentrations and fluxes of salmon-derived polychlorinated biphenyls (PCBs) in lake sediments. *Environ Sci Technol* 39:7020–7026.

Krümmel EM, Macdonald RW, Kimpe LE, Gregory-Eaves I, Demers MJ, Smol JP, Finney B, Blais JM. 2003. Delivery of pollutants by spawning salmon. *Nature* 415:255–256.

Mandenjian CP, O'Connor DV, Chernyak SM, Rediske RR, O'Keefe JP. 2004. Evaluation of a chinook salmon (*Oncorhynchus tshawytscha*) bioenergetics model. *Can J Fish Aq Sci* 61:627–635.

Matzke A, Wigal J. 2011. Issue paper: Human Health toxics criteria, human health toxics rulemaking, 2008-2011. Portland (OR): Water Quality Division, Oregon Department of Environmental Quality.

McCarthy SG, Incardona JP, Scholz NL. 2008. Coastal storms, toxic runoff, and the sustainable conservation of fish and fisheries. *Am Fish Soc Symp* 64: 7–27.

Meador JP, Collier TK, Stein JE. 2002. Use of tissue and sediment-based threshold concentrations of polychlorinated biphenyls (PCBs) to protect juvenile salmonids listed under the U.S. Endangered Species Act. *Aq Conser Mar Fresh Ecosys* 12:493–516.

Meador JP, Ylitalo GM, Sommers FC, Boyd DT. 2010. Bioaccumulation of polychlorinated biphenyls in juvenile chinook salmon (*Onchorhynchus tshwytscha*) outmigrating through a contaminated estuary: dynamics and application. *Ecotoxicology* 19:141–152.

Missildine BR, Peters RJ, Chin-Leo G, Houck D. 2005. Polychlorinated biphenyl concentrations in adult Chinook salmon (*Oncorhynchus tshawytscha*) returning to coastal and Puget Sound hatcheries of Washington State. *Environ Sci Technol* 39:6944–6951.

O'Neill SM, West JE, Hoeman JC. 1998. Spatial trends in the concentration of polychlorinated biphenyls (PCBs) in Chinook (*Oncorhynchus tshawytscha*) and Coho salmon (*O. kisutch*) in Puget Sound and factors affecting PCB accumulation: Results from the Puget Sound Ambient Monitoring Program. Olympia (WA): Puget Sound Research Proceedings. p 312–328.

O'Neill SM, West JE. 2009. Marine distribution, life history traits, and the accumulation of polychlorinated biphenyls in Chinook salmon from Puget Sound, Washington. *Trans Am Fish Soc* 138:616–632.

Paul MJ, Meyer JL. 2001. Streams in the urban landscape. *Ann Rev Ecol Syst* 32:333–365.

Qiao P, Gobas FAPC, Farrell AP. 2000. Relative contributions of aqueous and dietary uptake of hydrophobic organic chemicals to the body burden in juvenile trout. *Arch Environ Contam Toxicol* 39:369–377.

Quinn TP. 2004. The behavior and ecology of Pacific salmon and trout. Seattle (WA): University of Washington Press. 320 p.

Reimers PE, Loeffel RE. 1967. The length of residence of juvenile fall chinook salmon in selected Columbia River tributaries. *Res Briefs Fish Comm Oregon* 13:5–19.

Rice S, Moles A. 2006. Assessing the potential for remote delivery of persistent organic pollutants to the Kenai River in Alaska. *Alaska Fish Res Bull* 12:153–157.

Schabetsberger R, Morgan CA, Brodeur RD, Potts CL, Peterson WT, Emmett RL. 2003. Prey selectivity and diel feeding chronology of juvenile chinook (*Oncorhynchus tshawytscha*) and coho (*O. kisutch*) salmon in the Columbia River plume. *Fish Oceanog* 12:523–540.

Spromberg JA, Meador JP. 2005. Relating results of chronic toxicity responses to population-level effects: Modeling effects on wild chinook salmon populations. *Integr Environ Assess Manag* 1:9–21.

Stewart DJ, Ibarra M. 1991. Predation and production by salmonine fishes in Lake Michigan, 1978-88. *Can J Fish Aq Sci* 48:909–922.

Thomson RE. 1994. Physical oceanography of the Strait of Georgia-Puget Sound-Juan de Fuca Strait system. *Can Tech Rep Fish Aq Sci* 1948:36–48.

[USEPA] US Environmental Protection Agency. 2007. Framework for selecting and using tribal fish and shellfish consumption rates for risk-based decision making at CERCLA and RCRA cleanup sites in Puget Sound and the Strait of Georgia (Working Document). Office of Environmental Cleanup, Office of Air, Waste, and Toxics, Office of Environmental Assessment, Seattle (WA): USEPA, Region 10.

[USEPA] US Environmental Protection Agency. 2000. Methodology for deriving ambient water quality criteria for the protection of human health. Washington DC: USEPA. EPA-822-B-00-004.

ES&T FEATURES

Cancer risk management

A review of 132 federal regulatory decisions

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Various federal agencies are responsible for promulgating regulations and standards to protect the public from exposure to environmental carcinogens. Although many factors are considered in the decision to regulate a carcinogen, one important issue concerns the probability that individuals in an exposed population will develop cancer.

What has not been clear, however, is the level of cancer risk that triggers regulation, or whether there is consistency within and between agencies in arriving at the risk decisions that underpin regulatory action. We have retrospectively reviewed the use of cancer risk estimates in prevailing federal standards and in withdrawn regulatory initiatives to determine whether any simple patterns emerge to correlate risk level with regulatory action. Our results show that there are definite patterns and a surprising degree of consistency in the federal regulatory process.

The sources of the data reviewed are notices of proposed or final regulations found in the *Federal Register* and in published and unpublished regulatory support documents, all of which are in the public domain. Three measures of risk are considered: *Individual risk* is measured as an upper-limit estimate of the probability that the most highly exposed individual in a population will develop cancer as a result of a lifetime of exposure. The *size of the population* exposed to the hazards is considered. Finally, *population risk* is measured as an upper-limit estimate of the number of additional incidences of cancer in the exposed population. Federal agencies compute population risks (as measured by the number of cancer deaths per year) by one of two methods: by multiplying maximum individual risk by population size or by accounting for variations in individual exposure levels and adding up the resulting figures for an entire population. Almost one-third of the population risk estimates reviewed here were calculated using the first method, although the second method is preferable.

Knowledge of two additional terms, de manifestis and de minimis, is important to understanding the patterns that emerge from the data. *De manifestis* risk, literally a risk of obvious or evident concern, has its roots in the legal definition of an "obvious risk"; one that is instantly recognized by a person of ordinary intelligence. *De minimis* risk has been used for a number of years by regulators to define an acceptable level of risk that is below regulatory concern. This term stems from the legal principle, *de minimis non curat lex;* "the law does not concern itself with trifles."

Table 1 lists 132 regulatory decisions for which at least one of these measures of risk was estimated prior to regulation of the substance in question. The methods used by federal agencies for estimating individual risk are generally considered to overestimate risk; they assume maximum exposure and a linear no-threshold dose–response function. For example, the population risk estimate for saccharin (Number 100 in Table 1) is listed as 1200 cancer deaths annually, although the Food and Drug Administration (FDA) states that this is an upper-limit risk estimate and the actual risk is between zero and 1200.

The published maximum risk estimates have been taken at face value; any errors in the estimates or interagency differences in the approach to risk analysis are not considered impor-

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