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State of Washington

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

Overview of key decisions in rule amendment

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For more information contact:

Water Quality Program
P.O. Box 47600
Olympia, WA 98504-7600

Phone: 360-407-6600

Washington State Department of Ecology - www.ecy.wa.gov

- Headquarters, Olympia 360-407-6000
- Northwest Regional Office, Bellevue 425-649-7000
- Southwest Regional Office, Olympia 360-407-6300
- Central Regional Office, Yakima 509-575-2490
- Eastern Regional Office, Spokane 509-329-3400

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Water Quality Program
Washington State Department of Ecology
Olympia, Washington

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Overview

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

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

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

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

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

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

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

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

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

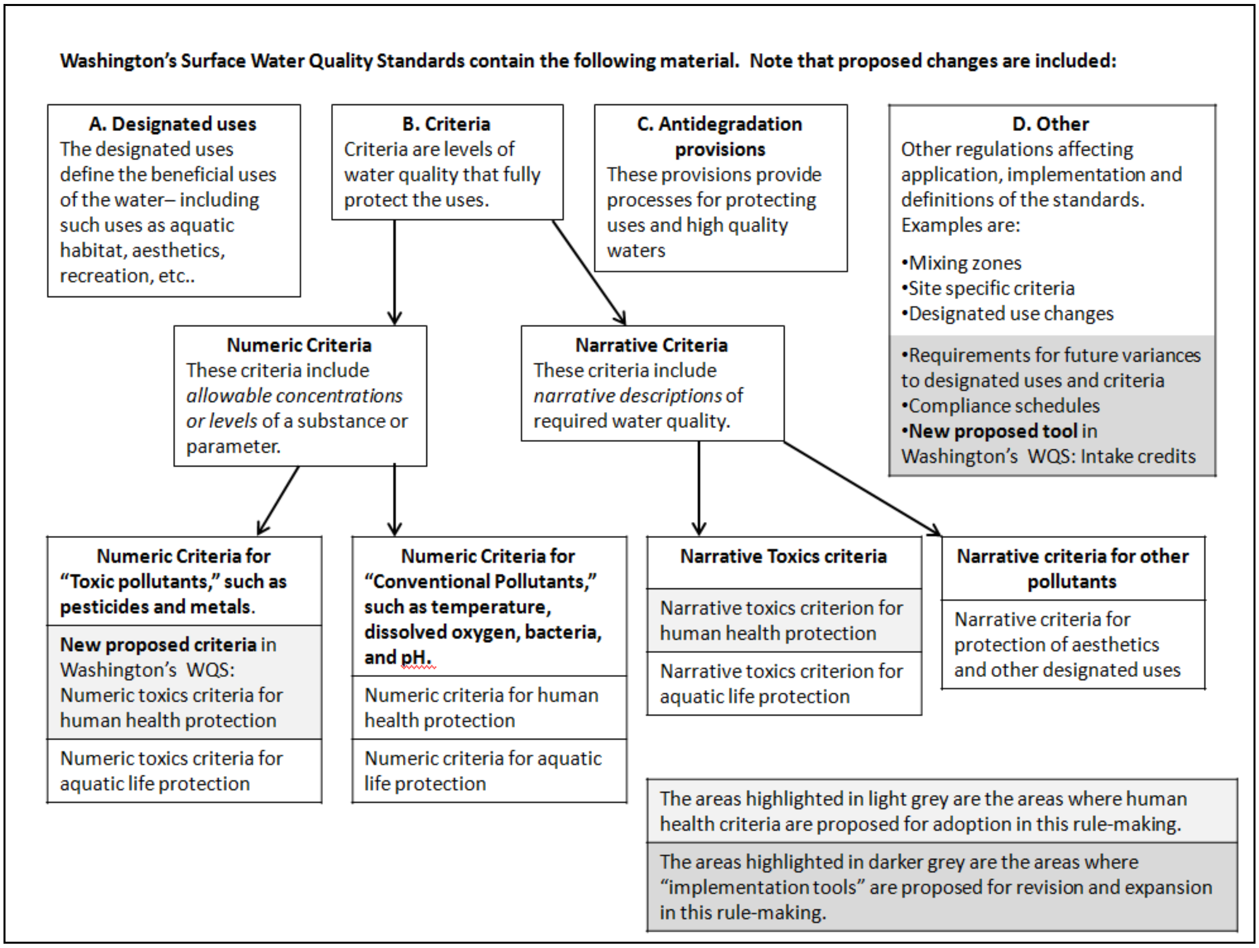

Figure 1: Water quality standards proposed changes

How are water quality standards revised?

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

An important part of the state's rule revision process, and in determining which revisions are most important to make, is public review and discussion about the water quality standards. Federal regulations require that states hold public hearings at least once every three years to review applicable surface water quality standards and, as appropriate, adopt new or modified standards. This process is called a *triennial review*.

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

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

Selection of rulemaking topics

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

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

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

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

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

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

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

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

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

Variances: Variances are WQS changes that temporarily waive water quality standards for a specific chemical and designated use for either a single discharge or for multiple discharges, or for specified stretches of surface waters (e.g., for a specific tributary, a lake, a watershed, etc.). Variances are used in situations where it can be demonstrated that: (1) a discharge can meet the permit limit or a water body can meet the criteria and designated use, but needs a longer time frame than allowed in a compliance schedule, or, (2) it is not known whether the discharge will ever be able to meet the permit limit or a receiving water body's criteria and designated use. Because a variance is a temporary change to a criteria and use, variances are considered changes to the WQS and must go through a rulemaking and subsequent EPA CWA approval to be effective. The current WQS give a brief list of the requirements for granting variances, including a maximum five-year time frame. The federal and state requirements for variances are brief, and demonstrating the need for a variance could be very labor intensive, depending on the specific situation. More detailed specifications in the WQS will help set clearer expectations for both discharges and the state, and will result in more predictable outcomes for dischargers.

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

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

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

Public Discussion

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

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

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

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

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

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

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

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

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

What Chemicals and Criteria will be included

Proposal

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

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

Background

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

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

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

> **Priority pollutants (CWA 303(c)(2)(B) requirements).** Excerpts of guidance from EPA's *Water Quality Standards Handbook: Second Edition* (EPA, 2012, Chapter 3.4.1) are copied below:
>
> > **Excerpt 1**
> > "*Section 303(c)(2)(B) addresses only pollutants listed as "toxic" pursuant to section 307(a) of the Act, which are codified at 40 CFR 131.36(b). The section 307(a) list contains 65 compounds and families of compounds, which potentially include thousands*

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

Excerpt 2

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

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

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

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

Basis for Ecology's Proposal

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

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

This proposal:

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

Additional Resources

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

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

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

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

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Human Health Criteria Equations and Variables

Proposal

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

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

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

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

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

Background

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

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

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

HHC equations and types of variables considered in the equations

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

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

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

Why are these variables important? Each variable in the equations affects the final calculated HHC concentrations. Some variables make significant differences in the calculated values, while other variables make smaller changes. For instance, the additional lifetime cancer risk level for carcinogens can make a large difference in some criteria concentrations. If the risk level increases, the criteria become less stringent. Fish consumption rates also affect the calculation considerably. Higher fish consumption rates result in lower criteria concentrations. An example of a variable that has much less effect on the calculated value is body weight. Higher body weight results in only slightly higher criteria concentrations.

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

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

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

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

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

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

Basis for Ecology's Proposal:

Variables in the equation

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

Variables where the values vary among states:

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

Variables where the values generally do not vary among states:

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

Variables implicit in the HHC equations:

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

1. Fish Consumption Rate (FCR)

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

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

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

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

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

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

<u>EPA's use of a revised FCR in *draft* national criteria</u>

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

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

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

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

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

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

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

Decision for draft rule:

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

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

2. Risk level (RL)

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

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

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

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

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

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

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

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

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

Table 3: CWA regulatory programs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Relative Source Contribution (RSC)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"*Human Exposure Considerations*

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

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

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

4. Body Weight (BW)

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

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

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

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

Table 4: Summary of guidance and studies on body weight		
Date	**Source**	**BW input**
1992	National Toxics Rule (40CFR131.36)	70 kg = average adult body weight
2000	EPA 2000 HHC Methodology (EPA -822-B-00-004)	EPA recommends using 70 kg = average adult body weight as "a representative average value for both male and female adults:" "EPA recommends maintaining the default body weight of 70 kg for calculating AWQC as a representative average value for both male and female adults."
2007	Tribal FCR studies – as summarized in: USEPA Reg. 10, 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, To Be Applied in Consultation with Tribal Governments on a Site-specific Basis, Revision 00.2007 (EPA, 2007, Tables B-1 and B-2 in Appendix B).	Tulalip Tribe = 81.8 kg average adult Suquamish Tribe = 79 kg average adult
2011	EPA Exposure Factors Handbook - 2011 edition. EPA 600/R-090/052F. (EPA, 2011)	EPA recommends 80 kg for average adult body weight

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

5. Drinking Water Intake (DI)

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

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

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

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

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

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

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

Below is information on this exposure factor:

Table 5: Exposure factor

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

Decision for draft rule: At this time, Ecology proposes to continue to use the EPA 2000 recommended DI value of 2 liters/day to calculate criteria for the draft rule. Washington state-specific information has not been obtained, so consideration of local data in comparison with national data has not been possible thus far in the rulemaking process. However, a different value will be considered if data or information is brought forward that compels Ecology to consider whether data from the newer *Exposure Factors Handbook* (EPA, 2011), EPA's new 2014 OSWER Directive, or the DI value used to calculate EPA's new draft national recommended human health surface water criteria should be used.

6. Reference Dose (RfD)

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

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

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

7. Cancer Slope Factor (CSF)

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

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

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

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

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

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

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IRISTrack Detailed Report

Arsenic, inorganic Assessment Milestones and Dates

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

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

** To be determined.

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

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Figure 2: Integrated risk information system

_II. CARCINOGENICITY ASSESSMENT FOR LIFETIME EXPOSURE

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

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

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

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

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

__II.A. EVIDENCE FOR HUMAN CARCINOGENICITY

Not applicable

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

Not applicable

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

Not applicable

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

___II.D.1. EPA DOCUMENTATION

Not applicable

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

Figure 3: Carcinogenicity assessment

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

http://www.epa.gov/iris/subst/1024.htm — 2,3,7,8-Tetrachlorodibenzo-...

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

File First On-Line 02/17/2012

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

_I. HEALTH HAZARD ASSESSMENTS FOR NONCARCINOGENIC EFFECTS

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

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

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

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

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

__I.A.1. Chronic Oral RfD Summary

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

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

Figure 4 Health hazard assessments for noncarcinogenic effects

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

__II.B.1. Summary of Risk Estimates

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

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

EPA published draft national recommended human health surface water criteria for chloroform on May 13, 2014. They used a point of departure-based criteria formula based on cancer effects. This formula is virtually identical to the non-cancer criteria equation, with the RfD replaced with a POD/uncertainty factor. The POD/uncertainty factor used by EPA in the draft criteria is equal to the reference dose of 0.01 mg/kg/day. Based on this new science and on the equivalence of the criteria calculation whether calculated for cancer or non-cancer effects, Ecology is calculating the draft criteria for chloroform, based on non-cancer effects, using the new 2001 RfD in IRIS.

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

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

8. Bioconcentration Factor (BCF)

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

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

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

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

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

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

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

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

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

Decision for draft rule: Because the geographic and regulatory scope of the CWA addresses contaminant discharge directly to waters of the state (not other sources or areas), Ecology is making a state-specific policy decision to use BCFs (not BAFs) as developed by EPA and incorporated into the 1992 NTR and the EPA recommended 304(a) national criteria (as of March 17, 2014) to calculate the criteria in the draft rule. Given the limited ability of the Clean Water Act to control sources outside its jurisdiction, Ecology thinks this is a sound and prudent decision.

9. Lifespan and duration of exposure:

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

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

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

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

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

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

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

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

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

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

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

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

Although the duration of exposure for the HHC can be up to 70 years, the EPA recommended criteria do not contain specific durations of exposure in either a chemical-specific or overall approach. The duration of exposure is an important characteristic needed to most effectively implement the criteria to reflect the variables and assumptions in the criteria. Because the EPA criteria and equations do not *explicitly* include a lifetime value or a duration of exposure factor, and because these factors are needed to effectively implement the criteria in a manner consistent with their implicit presence in the calculation, these implicit factors are acknowledged in the draft rule language accompanying the numeric criteria values, and will be considered by Ecology in development of permit limits and water quality assessments. The preliminary draft rule includes language that explicitly states that the criteria are calculated using durations of exposure that can be up to 70 years. Ecology will draft implementation guidance to address how this information could be used in permit limit development. This information is most likely to affect discharge limits for episodic discharges where the short term nature of some discharges may make calculation of limits that are based on the longer exposure durations that are in the HHC infeasible. In these cases discharge limits, if needed, could be based on best management practises, as per 40CFR122.44(k).

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

10. Hazard quotient (HQ)

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

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

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

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

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Challenging Chemicals: Polychlorinated Biphenyls (PCBs)

Proposal

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

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

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

Background

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

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

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

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

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

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

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

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

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

These PCB characteristics make them particularly difficult to control, and efforts to address PCBs are multimedia, including contaminated site clean-up, regulation of PCBs in products, and reductions of PCBs from airborne sources. Disposal of PCBs requires specifically designed equipment. Ecology is currently developing a Chemical Action Plan for PCBs to address additional multi-media approaches to control PCBs entering the environment (Ecology, 2014).

Basis for Ecology's proposal

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

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

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

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

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

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Challenging Chemicals: Arsenic

Proposal

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

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

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

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

Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Basis for Ecology's proposal

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

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

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

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

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

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

Pollution prevention requirements

Adopting new arsenic criteria that reflect both a change in the chemical form (a change from inorganic arsenic to total arsenic) and a higher concentration has prompted Ecology to address implementation to ensure that unforeseen industrial discharges of arsenic are controlled and reduced. The following draft language was developed to address discharges of arsenic, from industrial sources, to waters with the designated use of "domestic water supply."

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

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Challenging Chemicals: Methylmercury

Proposal

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

The background and basis for this decision are described below.

Background

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

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

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

Table 8: **Washington's Current Water Quality Standards for mercury**					
National Toxics Rule (NTR)-Human Health Criteria (1992)		Washington State water quality standards (WAC 173-201A) Aquatic Life Criteria			
Organism + Water (µg/L)	Organism Only (µg/L)	Acute Marine (µg/L)	Chronic Marine (µg/L)	Acute Freshwater (µg/L)	Chronic Freshwater (µg/L)
0. 14 (total)	0. 15 (total)	1.8 (dissolved)	(1) 0.025 (total)	2.1 (dissolved)	(1) 0.012 (total)

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

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

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

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

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

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

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

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

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

Basis for Ecology's proposal

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

Ecology based this decision on the following factors:

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

References

USEPA. 2010. *Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion*. EPA 823-R-10-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC. Available online at: http://water.epa.gov/scitech/swguidance/standards/criteria/aqlife/methylmercury/upload/mercury2010.pdf

USEPA. 2002. U.S. Environmental Protection Agency. *National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix*. EPA-822-R-02-012

USEPA. 2001. U.S. Environmental Protection Agency. Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury. 66 *Federal Register* 1344. https://www.federalregister.gov/articles/2001/01/08/01-217/water-quality-criteria-notice-of-availability-of-water-quality-criterion-for-the-protection-of-human

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Implementation Tools: Intake Credits

Proposal

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

Background

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

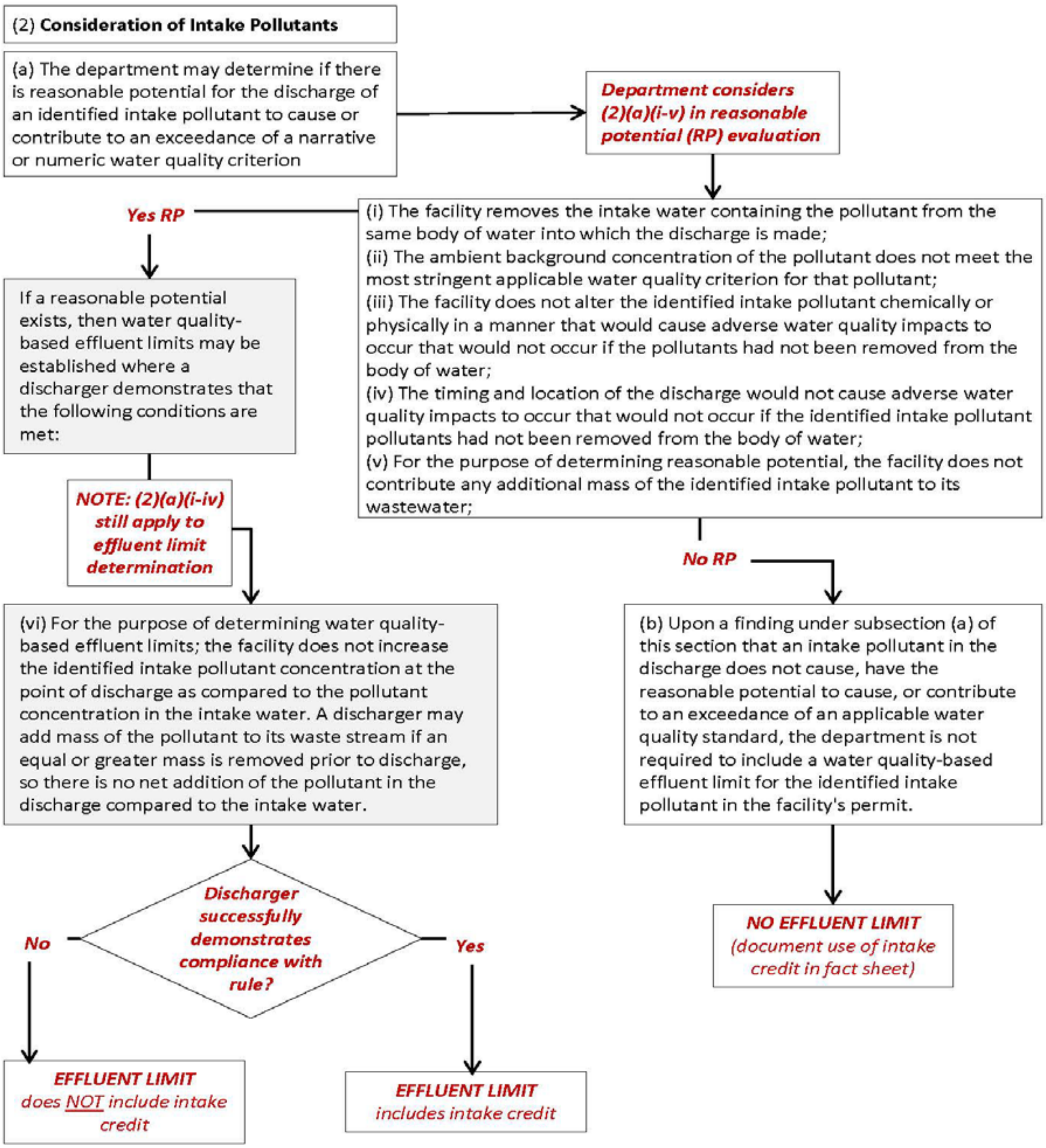
An intake credit is a procedure that allows permitting authorities to conclude that the return of unaltered intake water pollutants to the same body of water under identified circumstances does not cause, have the reasonable potential to cause, or contribute to an exceedance above water quality standards.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

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

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

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

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



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

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

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

Basis for Ecology's proposal

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

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

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

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

Additional information

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

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

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Implementation Tools: Compliance Schedules

Proposal

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

Background

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

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

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

The use and limitations of compliance schedules for NPDES permits in Washington are described at WAC 173-220-140. For purposes of water quality standards, compliance schedules may be used only where there is a finding that a permittee cannot immediately comply with a new, or newly revised, water-quality based effluent limit (WQBEL). Compliance schedules lasting longer than one year must include interim milestones, along with dates for their achievement, with no more than one year between dates. Interim milestones might relate, for example, to purchase and installation of new equipment, modification of existing facilities, construction of new facilities, and/or development of new programs. Compliance schedules also must include specific numeric or narrative effluent limits that will be met during the compliance schedule period.

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

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

Basis for Ecology's Proposal

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

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

Ecology has also added language that takes into consideration circumstances where a TMDL does not exist, but a compliance schedule would be the most appropriate tool to bring the permittee into compliance with the standard in the shortest timeframe possible. In this case, the actions must be identified that will bring the discharger into compliance with the effluent limits, but more time is needed than the term of the permit.

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

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

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

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

Additional Information

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

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Implementation Tools: Variances

Proposal

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

- A public process, including tribal notification, rulemaking, and EPA approval.
- The time period for when a variance would be in effect, generally not to exceed the term of the permit but under certain circumstances can be longer, as long as the time is "as short as possible."
- Requirements for a pollutant reduction plan that identifies specific schedule of actions that are set forth to achieve compliance with the original criteria.
- Requirements for interim numeric and narrative requirements that reflect the highest achievable water quality, as soon as possible, during the term of the variance.
- Requirements for a mandatory five-year review if the variance extends beyond the term of a permit.
- For variances that apply more broadly than individual variances, require a watershed assessment or total maximum daily load (TMDL) to identify responsible sources.
- Conditions under which a variance would be shortened or terminated, and when renewal would be considered.

Background

A variance is a temporary change to the water quality standards for a single discharger, a group of dischargers, or stretch of waters. Variances establish a time-limited set of temporary requirements that apply instead of the otherwise applicable water quality standards and related water quality criteria. Variances may be used where attaining the designated use and criteria is not feasible immediately, but might be, or will be, feasible in the longer term (versus a compliance schedule where it is clear water quality standards can be met once specific implementation action occur). They can be targeted to specific pollutants, sources, and/or stretches of waters.

The U.S, Environmental Protection Agency (EPA) has dictated that state variance procedures, as part of state water quality standards, must be consistent with the substantive requirements of 40 CFR 131. EPA has approved state-adopted variances in the past and has indicated that it will continue to do so if:

- Each variance is included as part of the water quality standard.

- The state demonstrates that meeting the standard is unattainable based on one or more of the grounds outlined in 40 CFR 13 1.10(g) for removing a designated use.
- The justification submitted by the state includes documentation that treatment more advanced than that required by sections 303(c)(2)(A) and (B) has been carefully considered, and that alternative effluent control strategies have been evaluated.
- The more stringent state criterion is maintained and is binding upon all other dischargers on the stream or stream segment.
- The discharger who is given a variance for one particular constituent is required to meet the applicable criteria for other constituents.
- The variance is granted for a specific period of time and must be re-justified upon expiration.
- The discharger either must meet the standard upon the expiration of this time period or must make a new demonstration of "unattainability."
- Reasonable progress is being made toward meeting the standards.
- The variance was subjected to public notice, opportunity for comment, and public hearing. The public notice should contain a clear description of the impact of the variance upon achieving water quality standards in the affected stretch of waters.

The temporary requirements established through a variance are only effective for the life of the variance. Because a variance establishes a temporary set of requirements that apply instead of the otherwise applicable water quality criteria, EPA has specified that variances are appropriate only under the same circumstances required in federal rule to undertake a Use Attainability Analysis (UAA), used to change a designated use for a water body. Regulations found in 40 CFR 131.10(g) establish six circumstances under which a UAA, or a variance, might be appropriate. They are:

1. Naturally occurring pollutant concentrations prevent attainment of the use.
2. Natural, ephemeral, intermittent or low flow conditions or water levels prevent attainment of the use, unless these conditions may be compensated for by discharge of sufficient volume of effluent discharges without violating state water conservation requirements to enable uses to be met.
3. Human caused conditions or sources of pollution prevent attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place.
4. Dams, diversions or other types of hydrologic modifications preclude attainment of the use, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in attainment of the use.
5. Physical conditions related to the natural features of the water body, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to water quality, preclude attainment of aquatic life protection uses.
6. Controls more stringent than those required by Sections 301(b) and 306 of the Clean Water Act would result in substantial and widespread economic and social impact.

Recent EPA guidance offered two examples of the circumstances under which variances may be particularly appropriate to consider:

> (1) When attaining the designated use and criteria is not feasible under current conditions (e.g., water quality-based controls required to meet the numeric nutrient criterion would result in substantial and widespread social and economic impact) but achieving the standards could be feasible in the future if circumstances related to the attainability determination change (e.g., development of less expensive pollution control technology or a change in local economic conditions).
>
> (2) When it is not known whether the designated use and criteria may ultimately be attainable, but feasible progress toward attaining the designated use and criteria can be made by implementing known controls and tracking environmental improvements (e.g., complex use attainability challenges involving legacy pollutants).

EPA has not established a specific time limit for variances. Proposed changes to the federal water quality standards rule, recently released by EPA in September 2013, include changes to address variances with a proposed timeframe not to exceed ten years. These federal rules have not been finalized and are still in draft form.

Variances have not been issued in Washington to date but are allowed under WAC 173-201A-420. The current language states that a variance is subject to a public and intergovernmental involvement process and a variance does not go into effect until it is incorporated into WAC 173-201A and approved by EPA. The current duration of a variance is for up to five years and variances may be renewed after providing another opportunity for public and intergovernmental involvement and review.

Basis for Ecology's proposal

Ecology is currently developing human health criteria for Washington's water quality standards. Changes to the variables that go into the human health criteria equation, such as an updated fish consumption rate, will generally result in more protective criteria. Ecology recognizes that these new, more protective criteria may be difficult to meet in situations where technology is not yet available or feasible to remove the pollutant, or in cases where either a persistent pollutant resides and is cycling within the aquatic ecosystem of the water body and cannot be removed without degrading the system, or when the main sources of the pollutant are not within the scope of the state's jurisdiction to control through water quality protection.

EPA has advised states that a variance should be used instead of removal of a use where the state believes the standard can ultimately be attained. By maintaining the beneficial use rather than changing it, the state will ensure that further progress is made in improving water quality and attaining the standard. With a variance, NPDES permits may be written such that reasonable progress is made toward attaining the standards without violating section 402(a)(l) of the Clean Water Act, which requires that NPDES permits must meet the applicable water quality standards.

With these factors in mind, Ecology is proposing revisions to the variance section of the water quality standards at WAC 173-201A-420, as part of the rulemaking for developing human health criteria. The key goals of these revisions are:

- **Provide accountability** that the discharger cannot feasibly meet the original criteria and that they continually strive to make reasonable progress to meet the original criteria during the life of the variance. Build in checks and balances to ensure that variance information is reviewed on a regular basis, new technology and science is taken into account, and benchmarks are required to ensure that implementation of the variance is occurring and that the variance continues to be necessary.
- **Extend timeframe** of a variance where necessary to allow time to deal with difficult, complex toxics compounds, such as legacy pollutants or those that come from sources outside of Clean Water Act jurisdiction. Include mandatory reviews to ensure that the variance is still necessary. Provide framework for renewing, shortening, and revoking a variance.
- **Efficiency of Resources**. Where possible, reduce resource intensity of regulating agencies in issuing variances.

The proposed language at WAC 173-201A-420 includes general provisions, and specific requirements that would apply for variances for individual dischargers, stretches of waters, and multiple dischargers. Requirements are intended to be consistent with federal guidance and also provide the necessary tools for implementing state water quality standards.

Besides requirements for issuing an individual variance, new language also provides requirements for issuing a variance to multiple dischargers for circumstances where multiple permittees cannot attain a designated use or criteria for the same pollutant(s) for the same reason, regardless of whether or not they are located on the same water body. In these cases, Ecology proposes to streamline the variance process by adopting one variance that applies to all the permittees. These are generally known as “multiple discharger variances.” Multiple discharger variances may be considered under the same circumstances, and must meet the same standards, as single discharger variances. A permittee that could not qualify for an individual variance should not qualify for a multiple discharger variance. Ecology is following EPA guidance, which recommends that justifications for multiple discharger variances should:

> (1) Apply only to permittees experiencing the same challenges in meeting water quality based effluent limits for the same pollutant(s), criteria, and designated uses.
>
> (2) Group permittees based on specific characteristics or technical and economic scenarios that they share, and conduct a separate analysis for each group. The more homogenous a group is in terms of factors affecting attainability of the designated use and criteria, the more credible a multiple discharger variance will be. For example: type of discharger (public or private); industrial classification; permittee size and/or effluent quality; pollutant treatability; whether or not the permittee can achieve a level of effluent quality comparable to the other permittees in the group; and water body or watershed characteristics.
>
> (3) Collect sufficient information from each individual permittee to support the assignment of each individual permittee to the designated group of multiple dischargers. The justification for a multiple discharger variance should account for as much individual permittee information as possible. When a permittee does not fit with any of the group characteristics, an individual variance should instead be considered.

Ecology is also proposing new language that will allow a variance for stretches of waters, such that the variance would apply to an entire stretch of water or portions of water body segments. Other states have used water body variances where the problems in a stretch of waters are significantly impacting water quality and habitat, are widespread, and involve numerous sources of point and nonpoint pollution; that is, where waters are significantly impaired by multiple sources, not just a few point sources. For example, where historic mining practices have impaired both water quality and habitat throughout a headwater basin, states have applied temporary standards with specific expiration dates for certain pollutants related to the historic mining practices rather than downgrading these waters through a use change. In this way, states have maintained designated uses and underlying criteria for other pollutants, while recognizing that existing ambient conditions for certain pollutants are not correctable in the short-term.

The temporary standards provide a basis for permit limits in the shorter term that will in turn lead to remediation of damaged water resources to the point that they will once again provide protection for the underlying designated use and criteria. By doing a variance instead of a UAA the underlying use and criteria are preserved, allowing them to actively drive water quality improvements in the longer-term. A water body variance provides time for the state to work with both point and nonpoint sources to determine and implement adaptive management approaches on a water body or watershed scale to achieve pollutant reductions and strive toward attaining the water body’s designated use and associated criteria.

Additional information

- Ecology, 2013. WA Dept. of Ecology Supplemental Material from Policy Forum #3 (Feb. 8, 2013) - Application of variances and compliance schedules to existing, new, and expanding dischargers/discharges: *http://www.ecy.wa.gov/programs/wq/swqs/SupMaterialVariancesComplianceSched.pdf*.
- EPA, 2013. Office of Water. EPA-820-F-13-012. Discharger-specific Variances on a Broader Scale: Developing Credible Rationales for Variances that Apply to Multiple Dischargers: Frequently Asked Questions. Found online at: *http://water.epa.gov/scitech/swguidance/standards/upload/Discharger-specific-Variances-on-a-Broader-Scale-Developing-Credible-Rationales-for-Variances-that-Apply-to-Multiple-Dischargers-Frequently-Asked-Questions.pdf*.
- EPA, 2014. Water Quality Standards Handbook - Chapter 5: General Policies (40 CFR 131.12) - Section 5.3 Variances from Water Quality Standards. Found online at: *http://water.epa.gov/scitech/swguidance/standards/handbook/chapter05.cfm#section3*.
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Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)

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Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)

Final

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NOTICE

The policies and procedures set forth in this document are intended solely to describe EPA methods for developing or revising ambient water quality criteria to protect human health, pursuant to Section 304(a) of the Clean Water Act, and to serve as guidance to States and authorized Tribes for developing their own water quality criteria. This guidance does not substitute for the Clean Water Act or EPA's regulations; nor is it a regulation itself. Thus, it does not impose legally-binding requirements on EPA, States, Tribes or the regulated community, and may not apply to a particular situation based upon the circumstances.

This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

FOREWORD

This document presents EPA's recommended Methodology for developing ambient water quality criteria as required under Section 304(a) of the Clean Water Act (CWA). The Methodology is guidance for scientific human health assessments used by EPA to develop, publish, and from time to time revise, recommended criteria for water quality accurately reflecting the latest scientific knowledge. The recommended criteria serve States and Tribes' needs in their development of water quality standards under Section 303(c) of the CWA.

The term "water quality criteria" is used in two sections of the Clean Water Act, Section 304(a)(1) and Section 303(c)(2). The term has a different program impact in each section. In Section 304, the term represents a scientific assessment of ecological and human health effects that EPA recommends to States and authorized Tribes for establishing water quality standards that ultimately provide a basis for controlling discharges or releases of pollutants. Ambient water quality criteria associated with specific stream uses when adopted as State or Tribal water quality standards under Section 303 define the maximum levels of a pollutant necessary to protect designated uses in ambient waters. The water quality criteria adopted in the State or Tribal water quality standards could have the same numerical limits as the criteria developed under Section 304. However, in many situations States and authorized Tribes may want to adjust water quality criteria developed under Section 304 to reflect local environmental conditions and human exposure patterns before incorporation into water quality standards. When adopting their water quality criteria, States and authorized Tribes have four options: (1) adopt EPA's 304(a) recommendations; (2) adopt 304(a) criteria modified to reflect site-specific conditions; (3) develop criteria based on other scientifically defensible methods; or (4) establish narrative criteria where numeric criteria cannot be determined.

EPA will use this Methodology to develop new ambient water quality criteria and to revise existing recommended water quality criteria. It also provides States and authorized Tribes the necessary guidance to adjust water quality criteria developed under Section 304 to reflect local conditions or to develop their own water quality criteria using scientifically defensible methods consistent with this Methodology. EPA encourages States and authorized Tribes to use this Methodology to develop or revise water quality criteria to appropriately reflect local conditions. EPA believes that ambient water quality criteria inherently require several risk management decisions that are, in many cases, better made at the State, Tribal, or regional level. Additional guidance to assist States and authorized Tribes in the modification of criteria based on the Methodology will accompany this document in the form of three companion Technical Support Documents on Risk Assessment, Exposure Assessment, and Bioaccumulation Assessment.

Geoffrey H. Grubbs
Director
Office of Science and Technology

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Project Leader

Denis Borum	U.S. EPA Office of Science and Technology

Coauthors

Risk Assessment

Joyce M. Donohue, Ph.D.*	U.S. EPA Office of Science and Technology
Julie T. Du, Ph.D.*	U.S. EPA Office of Science and Technology
Charles O. Abernathy, Ph.D.	U.S. EPA Office of Science and Technology

Exposure

Denis Borum *	U.S. EPA Office of Science and Technology
Helen Jacobs, M.S.	U.S. EPA Office of Science and Technology
Henry Kahn, D.Sc.	U.S. EPA Office of Science and Technology

Bioaccumulation

Keith G. Sappington, M.S.*	U.S. EPA Office of Science and Technology
Lawrence P. Burkhard, Ph.D.	U.S. EPA Office of Research and Development
Philip M. Cook, Ph.D.	U.S. EPA Office of Research and Development
Erik L. Winchester, M.S.	U.S. EPA Office of Science and Technology

U.S. EPA Technical Reviewers

William Beckwith	U.S. EPA Region 1
Jeff Bigler	U.S. EPA Office of Science and Technology
Sally Brough	U.S. EPA Region 10
Karen Clark	U.S. EPA Office of General Counsel
Gregory Currey	U.S. EPA Office of Wastewater Management
Vicki Dellarco	U.S. EPA Office of Prevention, Pesticides, and Toxic Substances
Charles Delos	U.S. EPA Office of Science and Technology
Arnold Den	U.S. EPA Region 9
Catherine Eiden	U.S. EPA Office of Prevention, Pesticides, and Toxic Substances
Michael Firestone	U.S. EPA Office of Prevention, Pesticides, and Toxic Substances
Steven Galson	U.S. EPA Office of Prevention, Pesticides, and Toxic Substances
Sue Gilbertson	U.S. EPA Office of Science and Technology
Denise Hakowski	U.S. EPA Region 3
Joel Hansel	U.S. EPA Region 4
Wayne Jackson	U.S. EPA Region 2
Annie Jarabek	U.S. EPA Office of Research and Development
William Jordan	U.S. EPA Office of Prevention, Pesticides, and Toxic Substances

Margaret Kelly	U.S. EPA Office of Children's Health Protection
Henry Lee	U.S. EPA Office of Research and Development
Sharon Lin	U.S. EPA Office of Wetlands, Oceans, and Watersheds
Roseanne Lorenzana	U.S. EPA Region 10
Gregory McCabe	U.S. EPA Region 7
Jennifer Mclain	U.S. EPA Office of Ground Water and Drinking Water
Bruce Mintz	U.S. EPA Office of Research and Development
Dave Moon	U.S. EPA Region 8
William Morrow	U.S. EPA Office of Science and Technology
Jacqueline Moya	U.S. EPA Office of Research and Development
Deirdre Murphy	U.S. EPA Office of Air Quality Planning and Standards
Joseph Nabholz	U.S. EPA Office of Prevention, Pesticides, and Toxic Substances
Russell Nelson	U.S. EPA Region 6
Jennifer Orme-Zavaleta	U.S. EPA Office of Research and Development
Lynn Papa	U.S. EPA Office of Research and Development
Robert Pepin	U.S. EPA Region 5
David Pfeifer	U.S. EPA Region 5
Rita Schoeny	U.S. EPA Office of Science and Technology
Charles Stephan	U.S. EPA Office of Research and Development
Linda Teuschler	U.S. EPA Office of Research and Development
David Tomey	U.S. EPA Region 1
Fritz Wagener	U.S. EPA Region 4
Jennifer Wigal	U.S. EPA Office of Science and Technology
Jeanette Wiltse	U.S. EPA Office of Scence and Technology
Gary Wolinsky	U.S. EPA Region 9
Philip Woods	U.S. EPA Region 9
William Wuerthele	U.S. EPA Region 8

* Principal U.S. EPA Author and Contact

EXTERNAL
PEER REVIEW WORKGROUP

The following professionals were part of the External Peer Review Workgroup that provided technical and scientific review regarding the content and technical approach in the July 1998 *Draft Ambient Water Quality Criteria Derivation Methodology: Human Health*. Their comments were reviewed and incorporated where appropriate to develop this final document.

Kenneth T. Bogen, Ph.D.	Lawrence Livermore National Laboratory
Paul E. Brubaker, Ph.D.	P.E. Brubaker Associates
Peter L. DeFur, Ph.D.	Virginia Commonwealth University
Karen Erstfeld, Ph.D.	Rutgers University
Bob Fares, Ph.D.	Environmental Standards, Inc.
Laura Green, Ph.D.	Cambridge Environmental, Inc.
Robert Hales, Ph.D.	Virginia Institute of Marine Science
Brendan Hickie, Ph.D.	Trent University
Ernest Hodgson, Ph.D.	North Carolina State University
Paul Locke, Ph.D.	Johns Hopkins University
Lynn S. McCarty, Ph.D.	LS McCarty Scientific Research and Consulting
Erik Rifkin, Ph.D.	Rifkin and Associates, Inc.
Damian Shea, Ph.D.	North Carolina State University
Nga Tran, Ph.D.	Johns Hopkins University
Curtis Travis, Ph.D.	Project Performance Corp.

Potential areas for conflict of interest were investigated via direct inquiry with the peer reviews and review of their current affiliations. No conflicts of interest were identified.

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LIST OF ACRONYMS

ADI	Acceptable Daily Intake
ARAR	Applicable or Relevant and Appropriate Requirements
ASTM	American Society of Testing and Materials
AWQC	Ambient Water Quality Criteria
BAF	Bioaccumulation Factor
BAF_{ℓ}^{fd}	Baseline Bioaccumulation Factor
BCF	Bioconcentration Factor
BCF_{ℓ}^{fd}	Baseline Bioconcentration Factor
BCF_{T}^{t}	Bioconcentration Factor Based on Total Concentrations in Tissue and Water
BMD	Benchmark Dose
BMDL	Lower-Bound Confidence Limit on the BMD
BMF	Biomagnification Factor
BMR	Benchmark Response
BSAF	Biota-Sediment Accumulation Factors
BW	Body Weight
C_{ℓ}	Lipid-normalized Concentration
C_{soc}	Organic Carbon-normalized Concentration
C_{t}	Concentration of the Chemical in the Specified Wet Tissue
C_{w}	Concentration of the Chemical in Water
CDC	U.S. Centers for Disease Control and Prevention
CSFII	Continuing Survey of Food Intake by Individuals
CWA	Clean Water Act
DDT	1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane
DDE	1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene
DDD	1,1-dichloro-2,2-bis(p-chlorophenyl)ethane
DI	Drinking Water Intake
DNA	Deoxyribonucleic Acid
DNOC	2,4-dinitro-o-cresol
DOC	Dissolved Organic Carbon
ED_{10}	Dose Associated with a 10 Percent Extra Risk
EPA	Environmental Protection Agency
f_{fd}	Fraction Freely Dissolved
f_{ℓ}	Fraction Lipid
FCM	Food Chain Multiplier
FEL	Frank Effect Level
FI	Fish Intake
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GLI	Great Lakes Water Quality Initiative
HCBD	Hexachlorobutadiene
IARC	International Agency for Research on Cancer
II	Incidental Ingestion
ILSI	International Life Sciences Institute

IRIS	Integration Risk Information System
kg	kilogram
K_{ow}	Octanol-Water Partition Coefficient
L	Liter
LAS	Linear Alkylbenzesulfonate
LED_{10}	The Lower 95 Percent Confidence Limit on a Dose Associated with a 10 Percent Extra Risk
LMS	Linear Multistage Model
LOAEL	Lowest Observed Adverse Effect Level
M_ℓ	Mass of Lipid in Specified Tissue
M_t	Mass of Specified Tissue (Wet Weight)
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MF	Modifying Factor
mg	Milligrams
ml	Milliliters
MOA	Mode of Action
MOE	Margin of Exposure
NCHS	National Center for Health Statistics
NCI	National Cancer Institute
NFCS	Nationwide Food Consumption Survey
NHANES	National Health and Nutrition Examination Survey
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
NPDES	National Pollutant Discharge Elimination System
PAH	Polycyclic Aromatic Hydrocarbon
PCB	Polychlorinated Biphenyls
POD	Point of Departure
POC	Particulate Organic Carbon
RDA	Recommended Daily Allowance
RfC	Reference Concentration
RfD	Reference Dose
RfD_{DT}	Reference Dose for Developmental Effects
RPF	Relative Potency Factor
RSC	Relative Source Contribution
RSD	Risk-Specific Dose
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
SF	Safety Factor
STORET	Storage Retrieval
TEAM	Total Exposure Assessment Methodology
TEF	Toxicity Equivalency Factor
TMDL	Total Maximum Daily Load
TSD	Technical Support Document
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency

UF	Uncertainty Factor
WQBEL	Water Quality-Based Effluent Limits

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1. INTRODUCTION

1.1 WATER QUALITY CRITERIA AND STANDARDS

Pursuant to Section 304(a)(1) of the Clean Water Act (CWA), the U.S. Environmental Protection Agency (EPA) is required to publish, and from time to time thereafter revise, criteria for water quality accurately reflecting the latest scientific knowledge on the kind and extent of all identifiable effects on human health which may be expected from the presence of pollutants in any body of water.

Historically, the ambient water quality criteria (AWQC or 304(a) criteria) provided two essential types of information: (1) discussions of available scientific data on the effects of the pollutants on public health and welfare, aquatic life, and recreation; and (2) quantitative concentrations or qualitative assessments of the levels of pollutants in water which, if not exceeded, will generally ensure adequate water quality for a specified water use. 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. The 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting the criteria in ambient water. These 304(a) criteria may be used as guidance by States and authorized Tribes to establish water quality standards, which ultimately provide a basis for controlling discharges or releases of pollutants into ambient waters.

In 1980, AWQC were derived for 64 pollutants using guidelines developed by the Agency for calculating the impact of waterborne pollutants on aquatic organisms and on human health. Those guidelines consisted of systematic procedures for assessing valid and appropriate data concerning a pollutant's acute and chronic adverse effects on aquatic organisms, nonhuman mammals, and humans.

1.2 PURPOSE OF THIS DOCUMENT

The *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (hereafter the "2000 Human Health Methodology") addresses the development of AWQC to protect human health. The Agency intends to use the 2000 Human Health Methodology both to develop new AWQC for additional pollutants and to revise existing AWQC. Within the next several years, EPA intends to focus on deriving AWQC for chemicals of high priority (including, but not limited to, mercury, arsenic, PCBs, and dioxin). Furthermore, EPA anticipates that 304(a) criteria development in the future will be for bioaccumulative chemicals and pollutants considered highest priority by the Agency. The 2000 Human Health Methodology is also intended to provide States and authorized Tribes flexibility in establishing water quality standards by providing scientifically valid options for developing their own water quality criteria that consider local conditions. States and authorized Tribes are strongly encouraged to use this Methodology to derive their own AWQC. However, the 2000 Human Health Methodology also defines the default factors EPA intends to use in evaluating and determining consistency of State water quality standards with the requirements of the CWA. The Agency intends to use these default factors to calculate national water quality criteria under

Section 304(a) of the Act. EPA will also use this Methodology as guidance when promulgating water quality standards for a State or Tribe under Section 303(c) of the CWA.

This Methodology does not substitute for the CWA or EPA's regulations; nor is it a regulation itself. Thus, the 2000 Human Health Methodology cannot impose legally-binding requirements on EPA, States, Tribes or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA and State/Tribal decision-makers retain the discretion to use different, scientifically defensible, methodologies to develop human health criteria on a case-by-case basis that differ from this Methodology where appropriate. EPA may change the Methodology in the future through intermittent refinements as advances in science or changes in Agency policy occur.

The 2000 Human Health Methodology incorporates scientific advancements made over the past two decades. The use of this Methodology is an important component of the Agency's efforts to improve the quality of the Nation's waters. EPA believes the Methodology will enhance the overall scientific basis of water quality criteria. Further, the Methodology should help States and Tribes address their unique water quality issues and risk management decisions, and afford them greater flexibility in developing their water quality programs.

There are three companion Technical Support Document (TSD) volumes for the 2000 Human Health Methodology: a Risk Assessment TSD; an Exposure Assessment TSD; and a Bioaccumulation TSD. These documents are intended to further support States and Tribes in developing AWQC to reflect local conditions. The Risk Assessment TSD (USEPA, 2000) is being published concurrently with this Methodology. Publication of the Exposure Assessment and Bioaccumulation TSDs are anticipated in 2001.

1.3 HISTORY OF THE AMBIENT WATER QUALITY CRITERIA (AWQC) METHODOLOGY

In 1980, EPA published AWQC for 64 pollutants/pollutant classes identified in Section 307(a) of the CWA and provided a methodology for deriving the criteria (USEPA, 1980). These 1980 AWQC National Guidelines (or the "1980 Methodology") for developing AWQC for the protection of human health addressed three types of endpoints: noncancer, cancer, and organoleptic (taste and odor) effects. Criteria for protection against noncancer and cancer effects were estimated by using risk assessment-based procedures, including extrapolation from animal toxicity or human epidemiological studies. Basic human exposure assumptions were applied to the criterion equation.

The risk assessment-based procedures used to derive the AWQC to protect human health were specific to whether the endpoint was cancer or noncancer. When using cancer as the critical risk assessment endpoint (which had been assumed not to have a threshold), the AWQC were presented as a range of concentrations associated with specified incremental lifetime risk levels[1]. When using noncancer effects as the critical endpoint, the AWQC reflected an assessment of a “no-effect” level, since noncancer effects were assumed to have a threshold. The key features of each procedure are described briefly in the following paragraphs.

Cancer effects. If human or animal studies on a contaminant indicated that it induced a statistically significant carcinogenic response, the 1980 AWQC National Guidelines treated the contaminant as a carcinogen and derived a low-dose cancer potency factor from available animal data using the linearized multistage model (LMS). The LMS, which uses a linear, nonthreshold assumption for low-dose risk, was used by the Agency as a science policy choice in protecting public health, and represented a plausible upper limit for low-dose risk. The cancer potency factor, which expresses incremental, lifetime risk as a function of the rate of intake of the contaminant, was then combined with exposure assumptions to express that risk in terms of an ambient water concentration. In the 1980 AWQC National Guidelines, the Agency presented a range of contaminant concentrations corresponding to incremental cancer risks of 10^{-7} to 10^{-5} (that is, a risk of one additional case of cancer in a population of ten million to one additional cancer case in a population of one hundred thousand, respectively).

Noncancer effects. If the pollutant was not considered to have the potential for causing cancer in humans (later defined as a known, probable, or possible human carcinogen by the 1986 *Guidelines for Carcinogen Risk Assessment*, USEPA, 1986d), the 1980 AWQC National Guidelines treated the contaminant as a noncarcinogen; a criterion was derived using a threshold concentration for noncancer adverse effects. The criteria derived from noncancer data were based on the Acceptable Daily Intake (ADI) (now termed the reference dose [RfD]). ADI values were generally derived using a no-observed-adverse-effect level (NOAEL) from animal studies, although human data were used whenever available. The ADI was calculated by dividing the NOAEL by an uncertainty factor to account for uncertainties inherent in extrapolating limited toxicological data to humans. In accordance with the National Research Council recommendations of 1977 (NRC, 1977), safety factors (SFs) (later redefined as uncertainty factors) of 10, 100, or 1,000 were used, depending on the quality of the data.

Organoleptic effects. Organoleptic characteristics were also used in developing criteria for some contaminants to control undesirable taste and/or odor imparted by them to ambient water. In some cases, a water quality criterion based on organoleptic effects would be more stringent than a criterion based on toxicologic endpoints. The 1980 AWQC National Guidelines emphasized that criteria derived for organoleptic endpoints are not based on toxicological information, have no direct relationship to adverse human health effects and, therefore, do not necessarily represent approximations of acceptable risk levels for humans.

[1]Throughout this document, the term “risk level” regarding a cancer assessment using linear approach refers to an upper-bound estimate of excess lifetime cancer risk.

1.4 RELATIONSHIP OF WATER QUALITY STANDARDS TO AWQC

Under Section 303(c) of the CWA, States have the primary responsibility for establishing water quality standards, defined under the Act as designated beneficial uses of a water segment and the water quality criteria necessary to support those uses. Additionally, Native American Tribes authorized to administer the water quality standards program under 40 CFR 131.8 establish water quality standards for waters within their jurisdictions. This statutory framework allows States and authorized Tribes to work with local communities to adopt appropriate designated uses and to adopt criteria to protect those designated uses. Section 303(c) provides for EPA review of water quality standards and for promulgation of a superseding Federal rule in cases where State or Tribal standards are not consistent with the applicable requirements of the CWA and the implementing Federal regulations, or where the Agency determines Federal standards are necessary to meet the requirements of the Act. Section 303(c)(2)(B) specifically requires States and authorized Tribes to adopt water quality criteria for toxics for which EPA has published criteria under Section 304(a) and for which the discharge or presence could reasonably be expected to interfere with the designated use adopted by the State or Tribe. In adopting such criteria, States and authorized Tribes must establish numerical values based on one of the following: (1) 304(a) criteria; (2) 304(a) criteria modified to reflect site-specific conditions; or, (3) other scientifically defensible methods. In addition, States and authorized Tribes can establish narrative criteria where numeric criteria cannot be determined.

It must be recognized that the Act uses the term “criteria” in two different ways. In Section 303(c), the term is part of the definition of a water quality standard. Specifically, a water quality standard is composed of designated uses and the criteria necessary to protect those uses. Thus, States and authorized Tribes are required to adopt regulations which contain legally enforceable criteria. However, in Section 304(a) the term criteria is used to describe the scientific information that EPA develops to be used as guidance by States, authorized Tribes and EPA when establishing water quality standards pursuant to 303(c). Thus, two distinct purposes are served by the 304(a) criteria. The first is as guidance to the States and authorized Tribes in the development and adoption of water quality criteria which will protect designated uses, and the second is as the basis for promulgation of a superseding Federal rule when such action is necessary.

1.5 NEED FOR THE AWQC METHODOLOGY REVISIONS

Since 1980, EPA risk assessment practices have evolved significantly in all of the major Methodology areas: that is, cancer and noncancer risk assessments, exposure assessments, and bioaccumulation. When the 1980 Methodology was developed, EPA had not yet developed formal cancer or noncancer risk assessment guidelines. Since then, EPA has published several risk assessment guidelines. In cancer risk assessment, there have been advances in the use of mode of action (MOA) information to support both the identification of potential human carcinogens and the selection of procedures to characterize risk at low, environmentally relevant exposure levels. EPA published *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA, 1996a, hereafter the “1996 proposed cancer guidelines”). These guidelines presented revised procedures to quantify cancer risk at low doses, replacing the current default use of the LMS model. Following review by the Agency’s Science Advisory Board (SAB), EPA published the revised *Guidelines for Carcinogen Risk Assessment–Review Draft* in July 1999 (USEPA, 1999a, hereafter the "1999 draft revised cancer guidelines"). In noncancer risk assessment, the Agency is moving toward the use of the benchmark dose (BMD) and other dose-response approaches in place of the traditional NOAEL approach to estimate an RfD or Reference Concentration (RfC). *Guidelines for Mutagenicity Risk Assessment* were published in 1986 (USEPA, 1986b). In 1991, the Agency published *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991), and it issued *Guidelines for Reproductive Toxicity Risk Assessment* in 1996 (USEPA, 1996b). In 1998, EPA published final *Guidelines for Neurotoxicity Risk Assessment* (USEPA, 1998), and in 1999 it issued the draft *Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 1999b).

In 1986, the Agency made available to the public the Integrated Risk Information System (IRIS). IRIS is a database that contains risk information on the cancer and noncancer effects of chemicals. The IRIS assessments are peer reviewed and represent EPA consensus positions across the Agency's program and regional offices.

New studies have addressed water consumption and fish tissue consumption. These studies provide a more current and comprehensive description of national, regional, and special-population consumption patterns that EPA has reflected in the 2000 Human Health Methodology. In addition, more formalized procedures are now available to account for human exposure from multiple sources when setting health goals such as AWQC that address only one exposure source. In 1986, the Agency published the *Total Exposure Assessment Methodology (TEAM) Study: Summary and Analysis, Volume I, Final Report* (USEPA, 1986c), which presents a process for conducting comprehensive evaluation of human exposures. In 1992, EPA published the revised *Guidelines for Exposure Assessment* (USEPA, 1992), which describe general concepts of exposure assessment, including definitions and associated units, and provide guidance on planning and conducting an exposure assessment. The *Exposure Factors Handbook* was updated in 1997 (USEPA, 1997a). Also in 1997, EPA developed *Guiding Principles for Monte Carlo Analysis* (USEPA, 1997b) and published its *Policy for Use of Probabilistic Analysis in Risk Assessment* (see http://www.epa.gov/ncea/mcpolicy.htm). The Monte Carlo guidance can be applied to exposure assessments and risk assessments. The Agency has recently developed the Relative Source Contribution (RSC) Policy for assessing total human exposure to a contaminant and apportioning the RfD among the media of concern, published for the first time in this Methodology.

The Agency has moved toward the use of a bioaccumulation factor (BAF) to reflect the uptake of a contaminant from all sources (e.g., ingestion, sediment) by fish and shellfish, rather than just from the water column as reflected by the use of a bioconcentration factor (BCF) in the 1980 Methodology. The Agency has also developed detailed procedures and guidelines for estimating BAF values.

Another reason for the 2000 Human Health Methodology is the need to bridge the gap between the differences in the risk assessment and risk management approaches used by EPA's Office of Water for the derivation of AWQC under the authority of the CWA and Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act (SDWA). Three notable differences are the treatment of chemicals designated as Group C, possible human carcinogens under the 1996 proposed cancer guidelines, the consideration of non-water sources of exposure when setting an AWQC or MCLG for a noncarcinogen, and cancer risk ranges. Those three differences are described in the three subsections below, respectively.

1.5.1 Group C Chemicals

Chemicals were typically classified as Group C–i.e., possible human carcinogens–under the existing (1986) EPA cancer classification scheme for any of the following reasons:

1) Carcinogenicity has been documented in only one test species and/or only one cancer bioassay and the results do not meet the requirements of "sufficient evidence."

2) Tumor response is of marginal statistical significance due to inadequate design or reporting.

3) Benign, but not malignant, tumors occur with an agent showing no response in a variety of short-term tests for mutagenicity.

4) There are responses of marginal statistical significance in a tissue known to have a high or variable background rate.

The 1986 *Guidelines for Carcinogen Risk Assessment* (hereafter the "1986 cancer guidelines") specifically recognized the need for flexibility with respect to quantifying the risk of Group C, possible human carcinogens. The 1986 cancer guidelines noted that agents judged to be in Group C, possible human carcinogens, may generally be regarded as suitable for quantitative risk assessment, but that case-by-case judgments may be made in this regard.

The EPA Office of Water has historically treated Group C chemicals differently under the CWA and the SDWA. It is important to note that the 1980 AWQC National Guidelines for setting AWQC under the CWA predated EPA's carcinogen classification system, which was proposed in 1984 (USEPA, 1984) and finalized in 1986 (USEPA, 1986a). The 1980 AWQC National Guidelines did not explicitly differentiate among agents with respect to the weight of evidence for characterizing them as likely to be carcinogenic to humans. For all pollutants judged as having adequate data for quantifying carcinogenic risk–including those now classified as Group C–AWQC were derived based on data on cancer incidence. In the1980 AWQC National Guidelines, EPA emphasized that the AWQC for carcinogens should state that the recommended concentration for maximum protection of human health is zero. At the same time, the criteria published for specific carcinogens presented water concentrations for these pollutants corresponding to individual lifetime excess cancer risk levels in the range of 10^{-7} to 10^{-5}.

In the development of national primary drinking water regulations under the SDWA, EPA is required to promulgate a health-based MCLG for each contaminant. The Agency policy has been to set the MCLG at zero for chemicals with strong evidence of carcinogenicity associated with exposure from water. For chemicals with limited evidence of carcinogenicity, including many Group C agents, the MCLG was usually obtained using an RfD based on the pollutant's noncancer effects with the application of an additional uncertainty factor of 1 to 10 to account for carcinogenic potential of the chemical. If valid noncancer data for a Group C agent were not available to establish an RfD but adequate data are available to quantify the cancer risk, then the MCLG was based upon a nominal lifetime excess cancer risk in the range of 10^{-6} to10^{-5} (ranging from one case in a population of one million to one case in a population of one hundred thousand). Even in those cases where the RfD approach has been used for the derivation of the MCLG for a Group C agent, the drinking water concentrations associated with excess cancer risks in the range of 10^{-6} to 10^{-5} were also provided for comparison.

It should also be noted that EPA's pesticides program has applied both of the previously described methods for addressing Group C chemicals in actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and finds both methods applicable on a case-by-case basis. Unlike the drinking water program, however, the pesticides program does not add an extra uncertainty factor to account for potential carcinogenicity when using the RfD approach.

In the 1999 draft revised cancer guidelines, there are no more alphanumeric categories. Instead, there will be longer narratives for hazard characterization that will use consistent descriptive terms when assessing cancer risk.

1.5.2 Consideration of Non-water Sources of Exposure

The 1980 AWQC National Guidelines recommended that contributions from non-water sources, namely air and non-fish dietary intake, be subtracted from the Acceptable Daily Intake (ADI), thus reducing the amount of the ADI "available" for water-related sources of intake. In practice, however, when calculating human health criteria, these other exposures were generally not considered because reliable data on these exposure pathways were not available. Consequently, the AWQC were usually derived such that drinking water and fish ingestion accounted for the entire ADI (now called RfD).

In the drinking water program, a similar "subtraction" method was used in the derivation of MCLGs proposed and promulgated in drinking water regulations through the mid-1980s. More recently, the drinking water program has used a "percentage" method in the derivation of MCLGs for noncarcinogens. In this approach, the percentage of total exposure typically accounted for by drinking water, referred to as the relative source contribution (RSC), is applied to the RfD to determine the maximum amount of the RfD "apportioned" to drinking water reflected by the MCLG value. In using this percentage procedure, the drinking water program also applies a ceiling level of 80 percent of the RfD and a floor level of 20 percent of the RfD. That is, the MCLG cannot account for more than 80 percent of the RfD, nor less than 20 percent of the RfD.

The drinking water program usually takes a conservative approach to public health by applying an RSC factor of 20 percent to the RfD when adequate exposure data do not exist, assuming that the major portion (80 percent) of the total exposure comes from other sources, such as diet.

In the 2000 Human Health Methodology, guidance for the routine consideration of non-water sources of exposure [both ingestion exposures (e.g., food) and exposures other than the oral route (e.g., inhalation)] is presented. The approach is called the Exposure Decision Tree. Relative source contribution estimates will be made by EPA using this approach, which allows for use of either the subtraction or percentage methods, depending on chemical-specific circumstances, within the 20 to 80 percent range described above.

1.5.3 Cancer Risk Ranges

In addition to the different risk assessment approaches discussed above for deriving AWQC and MCLGs for Group C agents, there have been different risk management approaches by the drinking water and surface water programs on lifetime excess risk values when setting health-based criteria for carcinogens. The surface water program has derived AWQC for carcinogens that generally corresponded to lifetime excess cancer risk levels of 10^{-7} to 10^{-5}. The drinking water program has set MCLGs for Group C agents based on a slightly less stringent risk range of 10^{-6} to 10^{-5}, while MCLGs for chemicals with strong evidence of carcinogenicity (that is, classified as Group A, known, or B probable, human carcinogen) are set at zero. The drinking water program is now following the principles of the 1999 draft revised cancer guidelines to determine the type of low-dose extrapolation based on mode of action.

It is also important to note that under the drinking water program, for those substances having an MCLG of zero, enforceable Maximum Contaminant Levels (MCLs) have generally been promulgated to correspond with cancer risk levels ranging from 10^{-6} to 10^{-4}. Unlike AWQC and MCLGs which are strictly health-based criteria, MCLs are developed with consideration given to the costs and technological feasibility of reducing contaminant levels in water to meet those standards.

With the 2000 Human Health Methodology, EPA will publish its national 304(a) water quality criteria at a 10^{-6} risk level, which EPA considers appropriate for the general population. EPA is increasing the degree of consistency between the drinking water and ambient water programs, given the somewhat different requirements of the CWA and SDWA.

1.6 OVERVIEW OF THE AWQC METHODOLOGY REVISIONS

The following equations for deriving AWQC include toxicological and exposure assessment parameters which are derived from scientific analysis, science policy, and risk management decisions. For example, values for parameters such as a field-measured BAF or a point of departure from an animal study [in the form of a lowest-observed-adverse-effect level (LOAEL)/no-observed -adverse-effect level (NOAEL)/lower 95 percent confidence limit on a dose associated with a 10 percent extra risk (LED_{10})] are empirically measured using scientific methods. By contrast, the decision to use animal effects as surrogates for human effects involves judgment on the part of the EPA (and similarly, by other agencies) as to the best practice to follow when human data are lacking. Such a decision is, therefore, a matter of science policy. The choice of default fish consumption rates for protection of a certain percentage (i.e., the 90^{th} percentile) of the general population is clearly a risk management decision. In many cases, the Agency has selected parameter values using its best judgment regarding the overall protection afforded by the resulting AWQC when all parameters are combined. For a longer discussion of the differences between science, science policy, and risk management, please refer to Section 2 of this document. Section 2 also provides further details with regard to risk characterization for this Methodology, with emphasis placed on explaining the uncertainties in the overall risk assessment.

The generalized equations for deriving AWQC based on noncancer effects are:

Noncancer Effects[2]

$$AWQC = RfD \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 1-1)}$$

Cancer Effects: Nonlinear Low-Dose Extrapolation

$$AWQC = \frac{POD}{UF} \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 1-2)}$$

[2] Although appearing in this equation as a factor to be multiplied, the RSC can also be an amount subtracted. Refer to the explanation key below the equations.

Cancer Effects: Linear Low-Dose Extrapolation

$$AWQC = RSD \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 1-3)}$$

where:

AWQC	=	Ambient Water Quality Criterion (mg/L)
RfD	=	Reference dose for noncancer effects (mg/kg-day)
POD	=	Point of departure for carcinogens based on a nonlinear low-dose extrapolation (mg/kg-day), usually a LOAEL, NOAEL, or LED_{10}
UF	=	Uncertainty Factor for carcinogens based on a nonlinear low-dose extrapolation (unitless)
RSD	=	Risk-specific dose for carcinogens based on a linear low-dose extrapolation (mg/kg-day) (dose associated with a target risk, such as 10^{-6})
RSC	=	Relative source contribution factor to account for non-water sources of exposure. (Not used for linear carcinogens.) May be either a percentage (multiplied) or amount subtracted, depending on whether multiple criteria are relevant to the chemical.
BW	=	Human body weight (default = 70 kg for adults)
DI	=	Drinking water intake (default = 2 L/day for adults)
FI_i	=	Fish intake at trophic level (TL) I (I = 2, 3, and 4) (defaults for total intake = 0.0175 kg/day for general adult population and sport anglers, and 0.1424 kg/day for subsistence fishers). Trophic level breakouts for the general adult population and sport anglers are: TL2 = 0.0038 kg/day; TL3 = 0.0080 kg/day; and TL4 = 0.0057 kg/day.
BAF_i	=	Bioaccumulation factor at trophic level I (I=2, 3 and 4), lipid normalized (L/kg)

For highly bioaccumulative chemicals where ingestion from water might be considered negligible, EPA is currently evaluating the feasibility of developing and implementing AWQCs that are expressed in terms of concentrations in tissues of aquatic organisms. Such tissue residue criteria might be used as an alternative to AWQCs which are expressed as concentrations in water, particularly in situations where AWQCs are at or below the practical limits for quantifying a chemical in water. Even though tissue residue criteria would not require the use of a BAF in their derivation, implementing such criteria would still require a mechanism for relating chemical loads and concentrations in water and sediment to concentrations in tissues of appropriate fish and shellfish (e.g., a BAF or bioaccumulation model). At this time, no revisions are planned to the Methodology to provide specific guidance on developing fish tissue-based water quality criteria. However, guidance may be provided in the future either as a separate document or integrated in a specific 304(a) water quality criteria document for a chemical that warrants such an approach.

AWQC for the protection of human health are designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and consumption of fish obtained from surface waters. The Agency is not recommending the development of additional water quality criteria similar to the "drinking water health advisories" that focus on acute or short-term effects; these are not seen as routinely having a meaningful role in the water quality criteria and standards program. However, as discussed below, there may be some instances where the consideration of acute or short-term toxicity and exposure in the derivation of AWQC is warranted.

Although the AWQC are based on chronic health effects data (both cancer and noncancer effects), the criteria are intended to also be protective against adverse effects that may reasonably be expected to occur as a result of elevated acute or short-term exposures. That is, through the use of conservative assumptions with respect to both toxicity and exposure parameters, the resulting AWQC should provide adequate protection not only for the general population over a lifetime of exposure, but also for special subpopulations who, because of high water- or fish-intake rates, or because of biological sensitivities, have an increased risk of receiving a dose that would elicit adverse effects. The Agency recognizes that there may be some cases where the AWQC based on chronic toxicity may not provide adequate protection for a subpopulation at special risk from shorter-term exposures. The Agency encourages States, Tribes, and others employing the 2000 Human Health Methodology to give consideration to such circumstances in deriving criteria to ensure that adequate protection is afforded to all identifiable subpopulations. (See Section 4.3, Factors Used in the AWQC Computation, for additional discussion of these subpopulations.)

The EPA is in the process of revising its cancer guidelines, including its descriptions of human carcinogenic potential. Once final guidelines are published, they will be the basis for assessment under this methodology. In the meanwhile, the 1986 guidelines are used and extended with principles discussed in EPA's 1999 *Guidelines for Carcinogen Risk Assessment - Review Draft* (hereafter "1999 draft revised cancer guidelines"). These principles arise from new science about cancer discovered in the last 15 years and from EPA policy of recent years supporting full characterization of hazard and risk both for the general population and potentially sensitive groups such as children. These principles are incorporated in recent and ongoing assessments such as the reassessment of dioxin, consistent with the 1986 guidelines. Until final guidelines are published, information is presented to describe risk under both the old guidelines and draft revisions. Dose-response assessment under the 1986 guidelines employs a linearized multistage model to extrapolate tumor dose-response observed in animal or human studies down to zero dose, zero extra risk. The dose-response assessment under EPA's 1999 draft revised cancer guidelines is a two-step process. In the first step, the response data are modeled in the range of empirical observation. Modeling in the observed range is done with biologically based or appropriate curve-fitting modeling. In the second step, extrapolation below the range of observation is accomplished by biologically based modeling if there are sufficient data or by a default procedure (linear, nonlinear, or both). A point of departure (POD) for extrapolation is estimated from modeling observed data. The lower 95 percent confidence limit on a dose associated with 10 percent extra risk (LED_{10}) is the standard POD for low-dose extrapolation. The linear default procedure is a straight line extrapolation to the origin (i.e., zero dose, zero extra risk) from the POD, which is the LED_{10} identified in the observable response range. The result of this procedure is generally comparable (within 2-fold) to that of using a linearized multistage model under existing, 1986 guidelines. The linear low-dose extrapolation applies to agents that are best characterized by the assumption of linearity (e.g., direct DNA reactive mutagens) for their MOA. A linear approach would also be applied when inadequate or no information is available to explain the carcinogenic MOA; this is a science policy choice in the interest of public health. If it is determined that the MOA understanding fully supports a nonlinear extrapolation, the AWQC is derived using the nonlinear default which is based on a margin of exposure (MOE) analysis using the LED_{10} as the POD and applying uncertainty factors (UFs) to arrive at an acceptable MOE. There may be situations where it is appropriate to apply both the linear and nonlinear default procedures (e.g., for an agent that is both DNA reactive and active as a promoter at higher doses).

For substances that are carcinogenic, particularly those for which the MOA suggests nonlinearity at low doses, the Agency recommends that an integrated approach be taken in looking at cancer and noncancer effects. If one effect does not predominate, AWQC values should be determined for both carcinogenic and noncarcinogenic endpoints. The lower of the resulting values should be used for the AWQC.

When deriving AWQC for noncarcinogens and carcinogens based on a nonlinear low-dose extrapolation, a factor is included to account for other non-water exposure sources [both ingestion exposures (e.g., food) and exposures other than the oral route (e.g., inhalation)] so that the entire RfD, or POD/UF, is not apportioned to drinking water and fish consumption alone. Guidance is provided in the 2000 Human Health Methodology for determining the factor (i.e., the RSC) to be used for a particular chemical. The Agency is recommending the use of an Exposure Decision Tree procedure to support the determination of the appropriate RSC value for a given water contaminant. In the absence of data, the Agency intends to use 20 percent of the RfD (or POD/UF) as the default RSC in calculating 304(a) criteria or promulgating State or Tribal water quality standards under Section 303(c).

With AWQC derived for carcinogens based on a linear low-dose extrapolation, the Agency will publish recommended criteria values at a 10^{-6} risk level. States and authorized Tribes can always choose a more stringent risk level, such as 10^{-7}. EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10^{-4} level. Clarification on this risk management decision is provided in Section 2 of this document.

The default fish consumption value for the general adult population in the 2000 Human Health Methodology is 17.5 grams/day, which represents an estimate of the 90^{th} percentile consumption rate for the U.S. adult population based on the U.S. Department of Agriculture's (USDA's) Continuing Survey of Food Intake by Individuals (CSFII) 1994-96 data (USDA, 1998). EPA will use this default intake rate with future national 304(a) criteria derivations or revisions. This default value is chosen to be protective of the majority of the general population. However, States and authorized Tribes are urged to use a fish intake level derived from local data on fish consumption in place of this default value when deriving AWQC, ensuring that the fish intake level chosen is protective of highly exposed individuals in the population. EPA has provided default values for States and authorized Tribes that do not have adequate information on local or regional consumption patterns, based on numerous studies that EPA has reviewed on sport anglers and subsistence fishers. EPA's defaults for these population groups are estimates of their average consumption. EPA recommends a default of 17.5 grams/day for sport anglers as an approximation of their average consumption and 142.4 grams/day for subsistence fishers, which falls within the range of averages for this group. Consumption rates for women of childbearing age and children younger than 14 are also provided to maximize protection in those cases where these subpopulations may be at greatest risk.

In the 2000 Human Health Methodology, criteria are derived using a BAF rather than a BCF. To derive the BAF, States and authorized Tribes may use EPA's Methodology or any method consistent with this Methodology. EPA's highest preference in developing BAFs are BAFs based on field-measured data from local/regional fish.

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2. Clarifications on The Methodology, Risk Characterization, And Other Issues For Developing Criteria

2.1 IDENTIFYING THE POPULATION SUBGROUP THAT THE AWQC SHOULD PROTECT

Water quality criteria are derived to establish ambient concentrations of pollutants which, if not exceeded, will protect the general population from adverse health impacts from those pollutants due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities. For each pollutant, chronic criteria are derived to reflect long-term consumption of food and water. An important decision to make when setting AWQC is the choice of the particular population to protect. For instance, criteria could be set to protect those individuals who have average or "typical" exposures, or the criteria could be set so that they offer greater protection to those individuals who are more highly exposed. EPA has selected default parameter values that are representative of several defined populations: adults in the general population; sport (recreational) fishers; subsistence fishers; women of childbearing age (defined as ages 15-44); and children (up to the age of 14). In deciding on default parameter values, EPA is aware that multiple parameters are used in combination when calculating AWQC (e.g., intake rates and body weight). EPA describes the estimated population percentiles that are represented by each of the default exposure parameter values in Section 4.

EPA's national 304(a) criteria are usually derived to protect the majority of the general population from chronic adverse health effects. EPA has used a combination of median values, mean values, and percentile estimates for the parameter value defaults to calculate its national 304(a) criteria. EPA believes that its assumptions afford an overall level of protection targeted at the high end of the general population (i.e., the target population or the criteria-basis population). EPA also believes that this is reasonably conservative and appropriate to meet the goals of the CWA and the 304(a) criteria program. EPA considers that its target protection goal is satisfied if the population as a whole will be adequately protected by the human health criteria when the criteria are met in ambient water. However, associating the derived criteria with a specific population percentile is far more difficult, and such a quantitative descriptor typically requires detailed distributional exposure and dose information. EPA's *Guidelines For Exposure Assessment* (USEPA, 1992) describes the extreme difficulty in making accurate estimates of exposures and indicates that uncertainties at the more extreme ends of the distribution increase greatly. On quantifying population exposures/risks, the guidelines specifically state:

> *In practice, it is difficult even to establish an accurate mean health effect risk for a population. This is due to many complications, including uncertainties in using animal data for human dose-response relationships, nonlinearities in the dose-response curve, projecting incidence data from one group to another dissimilar group, etc. Although it has been common practice to estimate the number of cases of disease, especially cancer, for populations exposed to chemicals, it should be understood that these estimates are not meant to be accurate estimates of real (or actuarial) cases of disease. The estimate's value lies in framing*

hypothetical risk in an understandable way rather than in any literal interpretation of the term "cases."

Although it is not possible to subject the estimates to such a rigorous analysis (say, for example, to determine what criterion value provides protection of exactly the 90^{th} percentile of the population), EPA believes that the combination of parameter value assumptions achieves its target goal, without being inordinately conservative. The standard assumptions made for the national 304(a) criteria are as follows. The assumed body weight value used is an arithmetic mean, as are the RSC intake estimates of other exposures (e.g., non-fish dietary), when data are available. The BAF component data (e.g., for lipid values, for particulate and dissolved organic carbon) are based on median (i.e., 50^{th} percentile) values. The drinking water intake values are approximately 90^{th} percentile estimates and fish intake values are 90^{th} percentile estimates. EPA believes the use of these values will result in 304(a) criteria that are protective of a majority of the population; this is EPA's goal.

However, EPA also strongly believes that States and authorized Tribes should have the flexibility to develop criteria, on a site-specific basis, that provide additional protection appropriate for highly exposed populations. EPA is aware that exposure patterns in general, and fish consumption in particular, vary substantially. EPA understands that highly exposed populations may be widely distributed geographically throughout a given State or Tribal area. EPA recommends that priority be given to identifying and adequately protecting the most highly exposed population. Thus, if the State or Tribe determines that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, and by the national 304(a) criteria in particular, EPA recommends that the State or Tribe adopt more stringent criteria using alternative exposure assumptions.

EPA has provided recommended default intake rates for various population groups for State and Tribal consideration. EPA does not intend for these alternative default values to be prescriptive. EPA strongly emphasizes its preference that States and Tribes use local or regional data over EPA's defaults, if they so choose, as being more representative of their population groups of concern.

In the course of updating the 2000 Human Health Methodology, EPA received some questions regarding the population groups for which the criteria would be developed. EPA does not intend to derive multiple 304(a) criteria for all subpopulation groups for every chemical. As stated above, criteria that address chronic adverse health effects are most applicable to the CWA Section 304(a) criteria program and the chemicals evaluated for this program. If EPA determined that pregnant women/fetuses or young children were the target population (or criteria basis population) of a chemical's RfD or POD/UF, then the 304(a) criteria would be developed using exposure parameters for that subgroup. This would only be relevant for acute or subchronic toxicity situations. This does not conflict with the fact that chronic health effects potentially reflect a person's exposure during both childhood and adult years.

For RfD-based and POD/UF-based chemicals, EPA's policy is that, in general, the RfD (or POD/UF) should not be exceeded and the exposure assumptions used should reflect the population of concern. It is recommended that when a State or authorized Tribe sets a waterbody-specific AWQC, they consider the populations most exposed via water and fish. EPA's policy on cancer risk management goals is discussed in Section 2.4.

Health Risks to Children

In recognition that children have a special vulnerability to many toxic substances, EPA's Administrator directed the Agency in 1995 to explicitly and consistently take into account environmental health risks to infants and children in all risk assessments, risk characterizations, and public health standards set for the United States. In April 1997, President Clinton signed Executive Order 13045 on the protection of children from environmental health risks, which assigned a high priority to addressing risks to children. In May 1997, EPA established the Office of Children's Health Protection to ensure the implementation of the President's Executive Order. EPA has increased efforts to ensure its guidance and regulations take into account risks to children. Circumstances where risks to children should be considered in the context of the 2000 Human Health Methodology are discussed in the Section 3.2, Noncancer Effects (in terms of developmental and reproductive toxicity) and in Section 4, Exposure (for appropriate exposure intake parameters).

Details on risk characterization and the guiding principles stated above are included in EPA's March 21, 1995 policy statement and the discussion of risk characterization (USEPA, 1995) and the 1999 *Guidelines for Carcinogen Risk Assessment. Review Draft* (USEPA, 1999a) and the *Reproductive and Toxicity Risk Assessment Guidelines* of 1996 (USEPA, 1996b).

2.2 SCIENCE, SCIENCE POLICY, AND RISK MANAGEMENT

An important part of risk characterization, as described later in Section 2.7, is to make risk assessments transparent. This means that conclusions drawn from the science are identified separately from policy judgments and risk management decisions, and that the use of default values or methods, as well as the use of assumptions in risk assessments, are clearly articulated. In this Methodology, EPA has attempted to separate scientific analysis from science policy and risk management decisions for clarity. This should allow States and Tribes (who are also prospective users of this Methodology) to understand the elements of the Methodology accurately and clearly, and to easily separate out the scientific decisions from the science policy and risk management decisions. This is important so that when questions are asked regarding the scientific merit, validity, or apparent stringency or leniency of AWQC, the implementer of the criteria can clearly explain what judgments were made to develop the criterion in question and to what degree these judgments were based on science, science policy, or risk management. To some extent this process will also be displayed in future AWQC documents.

When EPA speaks of science or scientific analysis, it is referring to the extraction of data from toxicological or exposure studies and surveys with a minimum of judgment being used to make inferences from the available evidence. For example, if EPA is describing a POD from an animal study (e.g., a LOAEL), this is usually determined as a lowest dose that produces an observable adverse effect. This would constitute a scientific determination. Judgments applying science policy, however, may enter this determination. For example, several scientists may differ in their opinion of what is adverse, and this in turn can influence the selection of a LOAEL in a given study. The use of an animal study to predict effects in a human in the absence of human data is an inherent science policy decision. The selection of specific UFs when developing an RfD is another example of science policy. In any risk assessment, a number of decision points occur where risk to humans can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among several possible inferences when conducting a risk assessment.

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

Many of the components in the 2000 Human Health Methodology are an amalgam of science, science policy, and/or risk management. For example, most of the default values chosen by EPA are based on examination of scientific data and application of either science policy or risk management. This includes the default assumption of 2 liters a day of drinking water; the assumption of 70 kilograms for an adult body weight; the use of default percent lipid and particulate organic carbon/dissolved organic carbon (POC/DOC) for developing national BAFs; the default fish consumption rates for the general population and sport and subsistence anglers; and the choice of a default cancer risk level. Some decisions are more grounded in science and science policy (such as the choice of default BAFs) and others are more obviously risk management decisions (such as the determination of default fish consumption rates and cancer risk levels). Throughout the 2000 Human Health Methodology, EPA has identified the kind of decision necessary to develop defaults and what the basis for the decision was. More details on the concepts of science analysis, science policy, risk management, and how they are introduced into risk assessments are included in *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983).

2.3 SETTING CRITERIA TO PROTECT AGAINST MULTIPLE EXPOSURES FROM MULTIPLE CHEMICALS (CUMULATIVE RISK)

EPA is very much aware of the complex issues and implications of cumulative risk and has endeavored to begin developing an overall approach at the Agency-wide level. Assuming that multiple exposures to multiple chemicals are additive is scientifically sound if they exhibit the same toxic endpoints and modes of action. There are numerous publications relevant to cumulative risk that can assist States and Tribes in understanding the complex issues associated with cumulative risk. These include the following:

- Durkin, P.R., R.C. Hertzberg, W. Stiteler, and M. Mumtaz. 1995. The identification and testing of interaction patterns. *Toxicol. Letters* 79:251-264.

- Hertzberg, R.C., G. Rice, and L.K. Teuschler. 1999. Methods for health risk assessment of combustion mixtures. In: *Hazardous Waste Incineration: Evaluating the Human*

Health and Environmental Risks. S. Roberts, C. Teaf and J. Bean, (eds). CRC Press LLC, Boca Raton, FL. Pp. 105-148.

- Rice, G., J. Swartout, E. Brady-Roberts, D. Reisman, K. Mahaffey, and B. Lyon. 1999. Characterization of risks posed by combustor emissions. *Drug and Chem. Tox.* 22:221-240.

- USEPA. 1999. *Guidance for Conducting Health Risk Assessment of Chemical Mixtures*. *Final Draft.* Risk Assessment Forum Technical Panel. Washington, DC. NCEA-C-0148. September. Web site: http://www.epa.gov/ncea/raf/rafpub.htm

- USEPA. 1998. *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions*. (Update to EPA/600/6-90/003 *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions*). National Center for Environmental Assessment. Washington, DC. EPA-600-R-98-137. Website http://www.epa.gov/ncea/combust.htm

- USEPA. 1996. PCBs: *Cancer Dose-Response Assessment and Application to Environmental Mixtures*. National Center for Environmental Assessment. Washington, DC. EPA/600/P-96/001F.

- USEPA. 1993. *Review Draft Addendum to the Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions*. Office of Health and Environmental Assessment, Office of Research and Development. Washington, DC. EPA/600/AP-93/003. November.

- USEPA. 1993. *Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons*. Office of Research and Development. Washington, DC. EPA/600/R-93/089. July.

- USEPA. 1990. *Technical Support Document on Health Risk Assessment of Chemical Mixtures*. Office of Research and Development. Washington, DC. EPA/600/8/90/064. August.

- USEPA. 1989a. *Risk Assessment Guidance for Superfund. Vol. 1. Human Health Evaluation Manual (Part A)*. Office of Emergency and Remedial Response. Washington, DC. EPA/540/1-89/002.

- USEPA. 1989b. *Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans (CDDs and CDFs) and 1989 Update*. Risk Assessment Forum. Washington, DC. EPA/625/3-89/016. March.

The Agency's program offices are also engaged in on-going discussions of the great complexities, methodological challenges, data adequacy needs and other information gaps, as well as the science policy and risk management decisions that will need to be made, as they pursue developing a sound strategy and, eventually, specific guidance for addressing cumulative risks. As a matter of internal policy, EPA is committed to refining the Methodology as advances in relevant aspects of the science improve, as part of the water quality criteria program.

2.4 CANCER RISK RANGE

For deriving 304(a) criteria or promulgating water quality criteria for States and Tribes under Section 303(c) based on the 2000 Human Health Methodology, EPA intends to use the 10^{-6} risk level, which the Agency believes reflects an appropriate risk for the general population. EPA's program office guidance and regulatory actions have evolved in recent years to target a 10^{-6} risk level as an appropriate risk for the general population. EPA has recently reviewed the policies and regulatory language of other Agency mandates (e.g., the Clean Air Act Amendments of 1990, the Food Quality Protection Act) and believes the target of a 10^{-6} risk level is consistent with Agency-wide practice.

EPA believes that both 10^{-6} and 10^{-5} may be acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level. States or Tribes that have adopted standards based on criteria at the 10^{-5} risk level can continue to do so, if the highly exposed groups would at least be protected at the 10^{-4} risk level. However, EPA is not automatically assuming that 10^{-5} will protect "the highest consumers" at the 10^{-4} risk level. Nor is EPA advocating that States and Tribes automatically set criteria based on assumptions for highly exposed population groups at the 10^{-4} risk level. The Agency is simply endeavoring to add that a specific determination should be made to ensure that highly exposed groups do not exceed a 10^{-4} risk level. EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen. Such determinations should be made by the State or Tribal authorities and are subject to EPA's review and approval or disapproval under Section 303(c) of the CWA.

Adoption of a 10^{-6} or 10^{-5} risk level, both of which States and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes. EPA believes that such State or Tribal decisions are consistent with Section 303(c) if the State or authorized Tribe has identified the most highly exposed subpopulation, has demonstrated that the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation. States and authorized Tribes also have flexibility in how they demonstrate this protectiveness and obtain such information. A State or authorized Tribe may use existing information as well as collect new information in making this determination. In addition, if a State or authorized Tribe does not believe that the 10^{-6} risk level adequately protects the exposed subpopulations, water quality criteria based on a more stringent risk level may be adopted. This discretion includes combining the 10^{-6} risk level with fish consumption rates for highly exposed population groups.

It is important to understand that criteria for carcinogens are based on chosen risk levels that inherently reflect, in part, the exposure parameters used to derive those values. Therefore, changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are *relative*, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6}, those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level). (Note: Fish consumers of up to 1,750 gm/day would not exceed the 10^{-4} risk level.) If a criterion were based on high-end intake rates and the relative risk of 10^{-6}, then an average fish consumer would be protected at a cancer risk level of approximately 10^{-8}. The point is that the risks for different population groups are not the same.

2.5 MICROBIOLOGICAL AMBIENT WATER QUALITY CRITERIA

Guidance for deriving microbiological AWQC is not a part of this Methodology. In 1986, EPA published *Ambient Water Quality Criteria for Bacteria - 1986* (USEPA, 1986a), which updated and revised bacteriological criteria previously published in 1976 in *Quality Criteria for Water* (USEPA, 1976). The inclusion of guidance for deriving microbiological AWQC was considered in the 1992 national workshop that initiated the effort to revise the 1980 Methodology and was recommended by the SAB in 1993. Since that time, however, efforts separate from these Methodology revisions have addressed microbiological AWQC concerns. The purpose of this section is to briefly describe EPA's current recommendations and activities.

EPA's *Ambient Water Quality Criteria for Bacteria - 1986* recommends the use of *Escherichia coli* and enterococci rather than fecal coliforms (USEPA, 1986a). EPA's criteria recommendations are:

- Fresh water: *E. coli* not to exceed 126/100 ml or enterococci not to exceed 33/100 ml; and

- Marine water: enterococci not to exceed 35/100 ml.

These criteria should be calculated as the geometric mean based on five equally spaced samples taken over a 30-day period.

In addition, EPA recommends that States adopt a single sample maximum, based on the expected frequency of use. No sample taken should exceed this value. EPA specifies appropriate single sample maximum values in the 1986 criteria document.

<u>Current Activities and Plans for Future Work</u>

EPA has identified development of microbial water quality criteria as part of its strategy to control waterborne microbial disease, by controlling pathogens in waterbodies and by protecting designated uses, such as recreation and public water supplies. The program fosters an integrated approach to protect both ground-water and surface water sources. EPA plans to conduct additional monitoring for *Cryptosporidium parvum* and *E. coli*, and determine action plans in accordance with the results of this monitoring.

EPA recommends no change at this time in the stringency of its bacterial criteria for recreational waters; existing criteria and methodologies from 1986 will still apply. The recommended methods for *E. coli* and enterococci have been improved. As outlined in the *Action Plan for Beaches and Recreational Waters* (Beach Action Plan, see below), the Agency plans to conduct national studies on improving indicators together with epidemiology studies for new criteria development (USEPA, 1999b). The Agency is also planning to establish improved temporal and spatial monitoring protocols.

In the Beach Action Plan, EPA identifies a multi-year strategy for monitoring recreational water quality and communicating public health risks associated with potentially pathogen-contaminated recreational rivers, lakes, and ocean beaches. It articulates the Agency's rationale and goals in addressing specific problems and integrates all associated program, policy, and research needs and directions. The Beach Action Plan also provides information on timing, products and lead organization for each activity. These include activities and products in the areas of program development, risk communication, water quality indicator research, modeling and monitoring research, and exposure and health effects research.

Recently, EPA approved new 24-hour *E. coli* and enterococcus tests for recreational waters that may be used as an alternative to the 48-hour test (USEPA, 1997). EPA anticipates proposing these methods for inclusion in the 40 CRF 136 in the Fall of 2000. EPA has also published a video with accompanying manual on the original and newer methods for enterococci and *E. coli* (USEPA, 2000).

As part of the Beach Action Plan, EPA made the following recommendations for further Agency study:

- Future criteria development should consider the risk of diseases other than gastroenteritis. EPA intends to consider and evaluate such water-related exposure routes as inhalation and dermal absorption when addressing microbial health effects. The nature and significance of other than the classical waterborne pathogens are to some degree tied to the particular type of waste sources.

- A new set of indicator organisms may need to be developed for tropical water if it is proven that the current fecal indicators can maintain viable cell populations in the soil and water for significant periods of time in uniform tropical conditions. Some potential alternative indicators to be fully explored are coliphage, other bacteriophage, and *Clostridium perfringens*.

- Because animal sources of pathogens of concern for human infection such as *Giardia lamblia*, *Cryptosporidium parvum*, and *Escherichia coli* 0157:H7 may be waterborne or washed into water and thus become a potential source for infection, they should not be ignored in risk assessment. A likely approach would be phylogenetic differentiation; that is, indicators that are specific to, or can discriminate among, animal sources.

- EPA intends to develop additional data on secondary infection routes and infection rates from prospective epidemiology studies and outbreaks from various types of exposure (e.g., shellfish consumption, drinking water, recreational exposure).

- EPA needs to improve sampling strategies for recreational water monitoring including consideration of rainfall and pollution events to trigger sampling.

2.6 RISK CHARACTERIZATION CONSIDERATIONS

On March 21, 1995, EPA's Administrator issued the *EPA Risk Characterization Policy and Guidance* (USEPA, 1995). This policy and guidance is intended to ensure that characterization information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to risk managers, and from EPA to the public. The policy also provides the basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across EPA programs. The fundamental principles which form the basis for a risk characterization are as follows:

- Risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgments, and the use of default values or methods and the use of assumptions in the risk assessment are clearly articulated.

- Risk characterizations should include a summary of the key issues and conclusions of each of the other components of the risk assessments, as well as describe the likelihood of harm. The summary should include a description of the overall strengths and limitations (including uncertainties) of the assessment and conclusions.

- Risk characterizations should be consistent in general format, but recognize the unique characteristics of each specific situation.

- Risk characterizations should include, at least in a qualitative sense, a discussion of how a specific risk and its context compares with similar risks. This may be accomplished by comparisons with other pollutants or situations on which the Agency has decided to act, or other situations with which the public may be familiar. The discussion should highlight the limitations of such comparisons.

- Risk characterization is a key component of risk communication, which is an interactive process involving exchange of information and expert opinion among individuals, groups, and institutions.

Additional guiding principles include:

- The risk characterization integrates the information from the hazard identification, dose-response, and exposure assessments, using a combination of qualitative information, quantitative information, and information regarding uncertainties.

- The risk characterization includes a discussion of uncertainty and variability in the risk assessment.

- Well-balanced risk characterizations present conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, EPA decision-makers, and the public.

In developing the methodology presented here, EPA has closely followed the risk characterization guiding principles listed above. As States and Tribes adopt criteria using the 2000 Human Health Methodology, they are strongly encouraged to follow EPA's risk characterization guidance. There are a number of areas within the Methodology and criteria development process where risk characterization principles apply:

- Integration of cancer and noncancer assessments with exposure assessments, including bioaccumulation potential determinations, in essence, weighing the strengths and weaknesses of the risk assessment as a whole when developing a criterion.

- Selecting a fish consumption rate, either locally derived or the national default value, within the context of a target population (e.g., sensitive subpopulations) as compared to the general population.

- Presenting cancer and/or noncancer risk assessment options.

- Describing the uncertainty and variability in the hazard identification, the dose-response, and the exposure assessment.

2.7 DISCUSSION OF UNCERTAINTY

2.7.1 Observed Range of Toxicity Versus Range of Environmental Exposure

When characterizing a risk assessment, an important distinction to make is between the observed range of adverse effects (from an epidemiology or animal study) and the environmentally observed range of exposure (or anticipated human exposure) to the contaminant. In many cases, EPA intends to apply default factors to account for uncertainties or incomplete knowledge in developing RfDs or cancer risk assessments using nonlinear low-dose extrapolation to provide a margin of protection. In reality, the actual effect level and the environmental exposure levels may be separated by several orders of magnitude. The difference between the dose causing some observed response and the anticipated human exposure should be described by risk assessors and managers, especially when comparing criteria to environmental levels of a contaminant.

2.7.2 Continuum of Preferred Data/Use of Defaults

In both toxicological and exposure assessments, EPA has defined a continuum of preferred data for toxicological assessments ranging from a highest preference for chronic human data (e.g., studies that examine a long-term exposure of humans to a chemical, usually from occupational and/or residential exposure) and actual field data for many of the exposure parameter values (e.g., locally derived fish consumption rates, waterbody-specific bioaccumulation rates), to default values which are at the lower end of the preference continuum. EPA has supplied default values for all of the risk assessment parameters in the 2000 Human Health Methodology; however, it is important to note that when default values are used, the uncertainty in the final risk assessment may be higher, and the final resulting criterion may not be as applicable to local conditions, than is a risk assessment derived from human/field data. Using defaults assumes generalized conditions and may not capture the actual variability in the population (e.g., sensitive subpopulations/high-end consumers). If defaults are chosen as the basis for criteria, these inherent uncertainties should be communicated to the risk manager and the public. While this continuum is an expression of preference on the part of EPA, it does not imply in any way that any of the choices are unacceptable or scientifically indefensible.

2.7.3 Significant Figures

The number of significant figures in a numeric value is the number of certain digits plus one estimated digit. Digits should not be confused with decimal places. For example, 15.1, 0.0151, and 0.0150 all have 3 significant figures. Decimal places may have been used to maintain the correct number of significant figures, but in themselves they do not indicate significant figures (Brinker, 1984). Since the number of significant figures must include only one estimated digit, the sources of input parameters (e.g., fish consumption and water consumption rates) should be checked to determine the number of significant figures associated with data they provide. However, the original measured values may not be available to determine the number of significant figures in the input parameters. In these situations, EPA recommends utilizing the data as presented.

When developing criteria, EPA recommends rounding the number of significant figures at the end of the criterion calculation to the same number of significant figures in the least precise parameter. This is a generally accepted practice which can be found described in greater detail in APHA (1992) and Brinker (1984). The general rule is that for multiplication or division, the resulting value should not possess any more significant figures than is associated with the factor in the calculation with the least precision. When numbers are added or subtracted, the number that has the fewest decimal places, not necessarily the fewest significant figures, puts the limit on the number of places that justifiably may be carried in the sum or difference. Rounding off a number is the process of dropping one or more digits so that the value contains only those digits that are significant or necessary in subsequent computations (Brinker, 1984). The following rounding procedures are recommended: (1) if the digit 6, 7, 8, or 9 is dropped, increase the preceding digit by one unit; (2) if the digit 0, 1, 2, 3, or 4 is dropped, do not alter the preceding digit; and (3) if the digit 5 is dropped, round off the preceding digit to the nearest even number (e.g., 2.25 becomes 2.2 and 2.35 becomes 2.4) (APHA, 1992; Brinker, 1984).

EPA recommends that calculations of water quality criteria be performed without rounding of intermediate step values. The resulting criterion may be rounded to a manageable number of decimal places. However, in no case should the number of digits presented exceed the number of significant figures implied in the data and calculations performed on them. The term “intermediate step values” refers to values of the parameters in Equations 1-1 through 1-3. The final step is considered the resulting AWQC. Although AWQC are, in turn, used for purposes of establishing water quality-based effluent limits (WQBELs) in National Pollutant Discharge Elimination System (NPDES) permits, calculating total maximum daily loads (TMDLs), and applicable or relevant and appropriate requirements (ARARs) for Superfund, they are considered the final step of this Methodology and, for the purpose of this discussion, where the rounding should occur.

The determination of appropriate significant figures inevitably involves some judgment given that some of the equation parameters are adopted default exposure values. Specifically, the default drinking water intake rate of 2 L/day is a value adopted to represent a majority of the population over the course of a lifetime. Although supported by drinking water consumption survey data, this value was adopted as a policy decision and, as such, does not have to be considered in determining the parameter with the least precision. That is, the resulting AWQC need not always be reduced to one significant digit. Similarly, the 70-kg adult body weight has been adopted Agency-wide and represents a default policy decision.

The following example with a simplified AWQC equation illustrates the rule described above. The example is for hexachlorobutadiene (HCBD), which EPA used to demonstrate the 1998 draft Methodology revisions (USEPA, 1998b). The parameters that were calculated (i.e., not policy adopted values) include values with significant figures of two (the POD and RSC), three (the UF), and four (the FI and BAF). Based on the 2000 Human Health Methodology, the final criterion should be rounded to two significant figures. The bold numbers in parentheses indicate the number of significant figures and those with asterisks also indicate Agency adopted policy values.

$$\mathrm{AWQC} = \frac{\mathrm{POD}}{\mathrm{UF}} \cdot \mathrm{RSC} \cdot \left(\frac{\mathrm{BW}}{\mathrm{DI} + (\mathrm{FI} \cdot \mathrm{BAF})} \right) \qquad \text{(Equation 2-1)}$$

Example [Refer to draft HCBD document for details on the POD/UF, RSC and BAF data (EPA 822-R-98-004). Also note that the fish intake rate in this example is the revised value.]:

$$\mathrm{AWQC} = \left(\frac{0.054\mathbf{(2)}}{300\mathbf{(3)}} - 1.2 \times 10^{-4}\mathbf{(2)} \right) \times \left(\frac{70\mathbf{(2^{*})}}{2\mathbf{(1^{*})} + (0.01750\mathbf{(4)} \times 3{,}180\mathbf{(4)})} \right)$$

AWQC = 7.3×10^{-5} mg/L (0.073 µg/L, rounded from 7.285×10^{-2} µg/L)
* represents Agency adopted policy value

A number of the values used in the equation may result in intermediate step values that have more than four figures past the decimal place and may be carried throughout the calculation. However, carrying more than four figures past the decimal place (equivalent to the most precise parameter) is unnecessary as it has no effect on the resulting criterion value.

2.8 OTHER CONSIDERATIONS

2.8.1 Minimum Data Considerations

For many of the preceding technical areas, considerations have been presented for data quality in developing toxicological and exposure assessments. For greater detail and discussion of minimum data recommendations, the reader is referred to the specific sections in the Methodology on cancer and noncancer risk assessments (and especially to the referenced EPA risk assessment guidelines documents), exposure assessment, and bioaccumulation assessment, in addition to the TSD volumes for each.

2.8.2 Site-Specific Criterion Calculation

The 2000 Human Health Methodology allows for site-specific modifications by States and Tribes to reflect local environmental conditions and human exposure patterns. “Local” may refer to any appropriate geographic area where common aquatic environmental or exposure patterns exist. Thus “local” may signify Statewide, regional, a river reach, or an entire river.

Such site-specific criteria may be developed as long as the site-specific data, either toxicological or exposure-related, is justifiable. For example, when using a site-specific fish consumption rate, a State should use a value that represents at least the central tendency of the population surveyed (either sport or subsistence, or both). If a site-specific fish consumption rate for sport anglers or subsistence anglers is lower than an EPA default value, it may be used in calculating AWQC. However, to justify such a level (either higher or lower than EPA defaults), the State should assemble appropriate survey data to arrive at a defensible site-specific fish consumption rate.

Such data must also be submitted to EPA for its review when approving or disapproving State or Tribal water quality standards under Section 303(c). The same conditions apply to site-specific calculations of BAF, percent fish lipid, or the RSC. In the case of deviations from toxicological values (i.e., IRIS values: verified noncancer and cancer assessments), EPA strongly recommends that the data upon which the deviation is based be presented to and approved by the Agency before a criterion is developed.

Additional guidance on site-specific modifications to the 2000 Human Health Methodology is provided in each of the three TSD volumes.

2.8.3 Organoleptic Criteria

Organoleptic criteria define concentrations of chemicals or materials which impart undesirable taste and/or odor to water. Organoleptic effects, while significant from an aesthetic standpoint, are not a significant health concern. In developing and utilizing such criteria, two factors must be appreciated: (1) the limitations of most organoleptic data; and (2) the human health significance of organoleptic properties. In the past, EPA has developed organoleptic criteria if organoleptic data were available for a specific contaminant. The 1980 AWQC National Guidelines made a clear distinction that organoleptic criteria and toxicity-based criteria are derived from completely different endpoints, and that organoleptic criteria have no demonstrated relationship to potential adverse human health effects because there is no toxicological basis. EPA acknowledges that if organoleptic effects (i.e., objectionable taste and odor) cause people to reject the water and its designated uses, then the public is effectively deprived of the natural resource. It is also possible that intense organoleptic characteristics could result in depressed fluid intake which, in turn, might lead to an indirect human health effect via decreased fluid consumption. Although EPA has developed organoleptic criteria in the past and may potentially do so in the future, this will not be a significant part of the water quality criteria program. EPA encourages the development of organoleptic criteria when States and Tribes believe they are needed. However, EPA cautions States and Tribes that the quality of organoleptic data is often significantly less than that of toxicologic data used in establishing health-based criteria. Therefore, a comprehensive evaluation of available organoleptic data should be made, and the selection of the most appropriate database for the criterion should be based on sound scientific judgment.

In 1980, EPA provided recommended criteria summary language when both types of data are available. The following format was used and is repeated here:

> *For comparison purposes, two approaches were used to derive criterion levels for ____. Based on available toxicity data, for the protection of public health the derived level is ____. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water the estimated level is ____. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have no demonstrated relationship to potential adverse human health effects.*

Similarly, the 1980 Methodology recommended that in those instances where a level to limit toxicity cannot be derived, the following statement should be provided:

> *Sufficient data are not available for ____ to derive a level which would protect against the potential toxicity of this compound.*

2.8.4 Criteria for Chemical Classes

The 2000 Human Health Methodology also allows for the development of a criterion for classes of chemicals, as long as a justification is provided through the analysis of mechanistic data, toxicokinetic data, structure-activity relationship data, and limited acute and chronic toxicity data. When potency differences between members of a class is great (such as in the case of chlorinated dioxins and furans), toxicity equivalency factors (TEFs) may be more appropriately developed than one class criterion.

A chemical class is defined as any group of chemical compounds which are similar in chemical structure and biological activity, and which frequently occur together in the environment usually because they are generated by the same commercial process. In criterion development, isomers should be regarded as part of a chemical class rather than as a single compound. A class criterion, therefore, is an estimate of risk/safety which applies to more than one member of a class. It involves the use of available data on one or more chemicals of a class to derive criteria for other compounds of the same class in the event that there are insufficient data available to derive compound-specific criteria. The health-based criterion may apply to the water concentration of each member of the class, or may apply to the sum of the water concentrations of the compounds within the class. Because relatively minor structural changes within the class of compounds can have pronounced effects on their biological activities, reliance on class criteria should be minimized depending on the data available.

The following guidance should also be followed when considering the development of a class criterion.

- A detailed review of the chemical and physical properties of the chemicals within the group should be made. A close relationship within the class with respect to chemical activity would suggest a similar potential to reach common biological sites within tissues. Likewise, similar lipid solubilities would suggest the possibility of comparable absorption and distribution.

- Qualitative and quantitative toxicological data for chemicals within the group should be examined. Adequate toxicological data on a number of compounds within a group provides a more reasonable basis for extrapolation to other chemicals of the same class than minimal data on one chemical or a few chemicals within the group.

- Similarities in the nature of the toxicological response to chemicals in the class provides additional support for the prediction that the response to other members of the class may be similar. In contrast, where the biological response has been shown to differ markedly on a qualitative and quantitative basis for chemicals within a class, the extrapolation of a criterion to other members is not appropriate.

- Additional support for the validity of extrapolation of a criterion to other members of a class could be provided by evidence of similar metabolic and toxicokinetic data for some members of the class.

Additional guidance is described in the *Technical Support Document on Health Risk Assessment of Chemical Mixtures* (USEPA, 1990).

2.9.5 Criteria for Essential Elements

Developing criteria for essential elements, particularly metals, must be a balancing act between toxicity and the requirement for good health. The AWQC must consider essentiality and cannot be established at levels that would result in deficiency of the element in the human population. The difference between the recommended daily allowance (RDA) and the daily doses causing a specified risk level for carcinogens or the RfDs for noncarcinogens defines the spread of daily doses within which the criterion may be derived. Because errors are inherent in defining both essential and adverse-effect levels, the criterion is derived from a dose level near the center of such dose ranges.

The process for developing criteria for essential elements should be similar to that used for any other chemical with minor modifications. The RfD represents concern for one end of the exposure spectrum (toxicity), whereas the RDA represents the other end (minimum essentiality). While the RDA and RfD values might occasionally appear to be similar in magnitude to one another, it does not imply incompatibility of the two methodological approaches, nor does it imply inaccuracy or error in either calculation.

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3. RISK ASSESSMENT

This section describes the methods used to estimate ambient water quality criteria (AWQC) for the protection of human health for carcinogenic chemicals (Section 3.1) and for noncarcinogenic chemicals (Section 3.2).

3.1 CANCER EFFECTS

3.1.1 Background on EPA Cancer Risk Assessment Guidelines

The current EPA *Guidelines for Carcinogen Risk Assessment* were published in 1986 (USEPA, 1986a, hereafter the "1986 cancer guidelines"). The 1986 cancer guidelines categorize chemicals into alpha-numerical Groups: A, known human carcinogen (sufficient evidence from epidemiological studies or other human studies); B, probable human carcinogen (sufficient evidence in animals and limited or inadequate evidence in humans); C, possible human carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); D, not classifiable (inadequate or no animal evidence of carcinogenicity); and E, evidence of noncarcinogenicity for humans (no evidence of carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiological and animal studies). Within Group B there are two subgroups, Groups B1 and B2. Group B1 is reserved for agents for which there is limited evidence of carcinogenicity from epidemiological studies. Group B2 is generally for agents for which there is sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiological studies (USEPA, 1986). The system was similar to that used by the International Agency for Research on Cancer (IARC).

The 1986 cancer guidelines include guidance on what constitutes sufficient, limited, or inadequate evidence. In epidemiological studies, sufficient evidence indicates a causal relationship between the agent and human cancer; limited evidence indicates that a causal relationship is credible, but that alternative explanations, such as chance, bias, or confounding, could not adequately be excluded; inadequate evidence indicates either lack of pertinent data, or a causal interpretation is not credible. In general, although a single study may be indicative of a cause-effect relationship, confidence in inferring a causal association is increased when several independent studies are concordant in showing the association. In animal studies, sufficient evidence includes an increased incidence of malignant tumors or combined malignant and benign tumors:

- In multiple species or strains;
- In multiple experiments (e.g., with different routes of administration or using different dose levels);
- To an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset;
- Additional data on dose-response, short-term tests, or structural activity relationships.

In the 1986 cancer guidelines, hazard identification and the weight-of-evidence process focus on tumor findings. The weight-of-evidence approach for making judgments about cancer hazard analyzes human and animal tumor data separately, then combines them to make the overall conclusion about potential human carcinogenicity. The next step of the hazard analysis is an evaluation of supporting evidence (e.g., mutagenicity, cell transformation) to determine whether the overall weight-of-evidence conclusion should be modified.

For cancer risk quantification, the 1986 cancer guidelines recommend the use of linearized multistage model (LMS) as the only default approach. The 1986 cancer guidelines also mention that a low-dose extrapolation model other than the LMS might be considered more appropriate based on biological grounds. However, no guidance is given in choosing other approaches. The 1986 cancer guidelines recommended the use of body weight raised to the 2/3 power ($BW^{2/3}$) as a dose scaling factor between species.

3.1.2 EPA's Proposed Guidelines for Carcinogen Risk Assessment and the Subsequent July, 1999 Draft Revised Cancer Guidelines

In 1996, EPA published *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA, 1996a, hereafter the "1996 proposed cancer guidelines"). After the publication of the 1996 proposed cancer guidelines and a February, 1997 and January, 1999 Science Advisory Board (SAB) review, a revision was made in July, 1999 *Guidelines for Carcinogen Risk Assessment - Review Draft* (hereafter the "1999 draft revised cancer guidelines"; USEPA, 1999a), and an SAB meeting was convened to review this revised document. When final guidelines are published, they will replace the 1986 cancer guidelines. These revisions are designed to ensure that the Agency's cancer risk assessment methods reflect the most current scientific information and advances in risk assessment methodology.

In the meanwhile, the 1986 guidelines are used and extended with principles discussed in the 1999 draft revised cancer guidelines. These principles arise from scientific discoveries concerning cancer made in the last 15 years and from EPA policy of recent years supporting full characterization of hazard and risk both for the general population and potentially sensitive groups such as children. These principles are incorporated in recent and ongoing assessments such as the reassessment of dioxin, consistent with the 1986 guidelines. Until final guidelines are published, information is presented to describe risk under both the 1986 guidelines and 1999 draft revisions.

The 1999 draft revised cancer guidelines call for the full use of all relevant information to convey the circumstances or conditions under which a particular hazard is expressed (e.g., route, duration, pattern, or magnitude of exposure). They emphasize understanding the mode of action (MOA) whereby the agent induces tumors. The MOA underlies the hazard assessment and provides the rationale for dose-response assessments.

The key principles in the 1999 draft revised cancer guidelines include:

a) Hazard assessment is based on the analysis of all biological information rather than just tumor findings.

b) An agent's MOA in causing tumors is emphasized to reduce the uncertainty in describing the likelihood of harm and in determining the dose-response approach(es).

c) The 1999 draft revised cancer guidelines emphasize the conditions under which the hazard may be expressed (e.g., route, pattern, duration and magnitude of exposure). Further, the guidelines call for a *hazard characterization* to integrate the data analysis of all relevant studies into a weight-of-evidence conclusion of hazard and to develop a working conclusion regarding the agent's mode of action in leading to tumor development.

d) A weight-of-evidence narrative with accompanying descriptors (listed in Section 3.1.3.1 below) would replace the current alphanumeric classification system. The narrative summarizes the key evidence for carcinogenicity, describes the agent's MOA, characterizes the conditions of hazard expression, including route of exposure, describes any disproportionate effects on subgroups of the human population (e.g., children), and recommends appropriate dose-response approach(es). Significant strengths, weaknesses, and uncertainties of contributing evidence are also highlighted.

e) Biologically based extrapolation models are the preferred approach for quantifying risk. These models integrate data and conclusions about events in the carcinogenic process throughout the dose-response range from high to low doses. It is anticipated, however, that the necessary data for the parameters used in such models will not be available for most chemicals. The 1999 draft revised cancer guidelines allow for alternative quantitative methods, including several default approaches.

f) Dose-response assessment is a two-step process. In the first step, response data are modeled in the observable range of data and a determination is made of the point of departure (POD) from the observed range to extrapolate to low doses. The second step is extrapolation from the POD to estimate dose-response at lower doses. In addition to modeling tumor data, the 1999 draft revised cancer guidelines call for the use and modeling of other kinds of responses if they are considered to be more informed measures of carcinogenic risk. Nominally, these responses reflect key events in the carcinogenic process integral to the MOA of the agent.

g) Three default approaches are provided–linear, nonlinear, or both when adequate data are unavailable to generate a biologically based model. As the first step for all approaches, curve fitting in the observed range is used to determine a POD. A standard POD is the effective dose corresponding to the lower 95 percent limit on a dose associated with 10 percent extra risk (LED_{10}).[3] *Linear*: The linear default is a straight line extrapolation from the response at LED_{10} to the origin (zero dose, zero extra risk). *Nonlinear*: The nonlinear default begins with the identified POD and provides a margin of exposure (MOE) analysis rather than estimating the probability of effects at low doses. The MOE analysis is used to determine the appropriate margin between the POD and the exposure level of interest, in this Methodology, the AWQC. The key objective of the MOE analysis is to describe for the risk manager how rapidly responses may decline with dose. Other factors are also considered in the MOE analysis (i.e., nature of the response, slope of the dose-response curve, human sensitivity compared with experimental animals, nature and extent of human variability in sensitivity and human exposure). *Linear and nonlinear*: Section 3.1.3.4E describes the situations when both linear and nonlinear defaults are used.

h) The approach used to calculate an oral human equivalent dose when assessments are based on animal bioassays has been refined and includes a change in the default assumption for interspecies dose scaling. The 1999 draft revised cancer guidelines use body weight raised to the 3/4 power.

EPA health risk assessment practices for both cancer and noncancer endpoints are beginning to come together with recent proposals to emphasize MOA understanding in risk assessment and to model response data in the observable range to derive PODs for data sets and benchmark doses (BMDs) for individual studies. The modeling of observed response data to identify PODs in a standard way will help to harmonize cancer and noncancer dose-response approaches and permit comparisons of cancer and noncancer risk estimates.

3.1.3 Methodology for Deriving AWQC[4] by the 1999 Draft Revised Cancer Guidelines

Following the publication of the *Draft Water Quality Criteria Methodology: Human Health* (USEPA, 1998a) and the accompanying TSD (USEPA, 1998b), EPA received comments from the public. EPA also held an external peer review of the draft Methodology. Both the peer reviewers and the public recommended that EPA incorporate the new approaches into the AWQC Methodology.

Until new guidelines are published, the 1986 cancer guidelines will be used along with principles of the 1999 draft revised cancer guidelines. The 1986 guidelines are the basis for IRIS risk numbers which were used to derive the current AWQC. Each new assessment applying the principles of the 1999 draft revised cancer guidelines will be subject to peer review before being used as the basis of AWQC.

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[3] Use of the LED_{10} as the point of departure is recommended with this Methodology, as it is with the 1999 draft revised cancer guidelines.

[4] Additional information regarding the revised method for assessing carcinogens may be found in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Technical Support Document, Volume 1: Risk Assessment* (USEPA, 2000).

The remainder of Section 3 illustrates the methodology for deriving numerical AWQC for carcinogens applying the 1999 draft revised cancer guidelines (USEPA, 1999a). This discussion of the revised methodology for carcinogens focuses primarily on the quantitative aspects of deriving numerical AWQC values. It is important to note that the cancer risk assessment process outlined in the 1999 draft revised cancer guidelines is not limited to the quantitative aspects. A numerical AWQC value derived for a carcinogen is to be based on appropriate hazard characterization and accompanied by risk characterization information.

This section contains a discussion of the weight-of-evidence narrative, that describes all information relevant to a cancer risk evaluation, followed by a discussion of the quantitative aspects of deriving numerical AWQC values for carcinogens. It is assumed that data from an appropriately conducted animal bioassay or human epidemiological study provide the underlying basis for deriving the AWQC value. The discussion focuses on the following: (1) the weight-of-evidence narrative; (2) general considerations and framework for analysis of the MOA; (3) dose estimation; (4) characterizing dose-response relationships in the range of observation and at low, environmentally relevant doses; (5) calculating the AWQC value; (6) risk characterization; and (7) use of Toxicity Equivalent Factors (TEF) and Relative Potency Estimates. The first three topics encompass the quantitative aspects of deriving AWQC for carcinogens.

3.1.3.1 Weight-of-Evidence Narrative[5]

The 1999 draft revised cancer guidelines include a weight-of-evidence narrative that is based on an overall judgment of biological and chemical/physical considerations. Hazard assessment information accompanying an AWQC value for a carcinogen in the form of a weight-of-evidence narrative is described in the footnote. Of particular importance is that the weight-of-evidence narrative explicitly provides adequate support based on human studies, animal bioassays, and other key evidence for the conclusion whether the substance is or is likely to be carcinogenic to humans from exposures through drinking water and/or fish ingestion. The Agency emphasizes the importance of providing an explicit discussion of the MOA for the substance in the weight-of-evidence narrative if data are available, including a discussion that relates the MOA to the quantitative procedures used in the derivation of the AWQC.

3.1.3.2 Mode of Action - General Considerations and Framework for Analysis

[5] The weight-of-evidence narrative is intended for the risk manager, and thus explains in nontechnical language the key data and conclusions, as well as the conditions for hazard expression. Conclusions about potential human carcinogenicity are presented by route of exposure. Contained within this narrative are simple likelihood descriptors that essentially distinguish whether there is enough evidence to make a projection about human hazard (i.e., Carcinogenic to humans; Likely to be carcinogenic to humans; Suggestive evidence of carcinogenicity but not sufficient to assess human carcinogenic potential; Data are inadequate for an assessment of human carcinogenic potential; and Not likely to be carcinogenic to humans). Because one encounters a variety of data sets on agents, these descriptors are not meant to stand alone; rather, the context of the weight-of-evidence narrative is intended to provide a transparent explanation of the biological evidence and how the conclusions were derived. Moreover, these descriptors should not be viewed as classification categories (like the alphameric system), which often obscure key scientific differences among chemicals. The new weight-of-evidence narrative also presents conclusions about how the agent induces tumors and the relevance of the mode of action to humans, and recommends a dose-response approach based on the MOA understanding (USEPA, 1996a, 1999a).

An MOA is composed of key events and processes starting with the interaction of an agent with a cell, through operational and anatomical changes, resulting in cancer formation. "Mode" of action is contrasted with "mechanism" of action, which implies a more detailed, molecular description of events than is meant by MOA.

Mode of action analysis is based on physical, chemical, and biological information that helps to explain key events[6] in an agent's influence on development of tumors. Inputs to MOA analysis include tumor data in humans, animals, and among structural analogues as well as the other key data.

There are many examples of possible modes of carcinogenic action, such as mutagenicity, mitogenesis, inhibition of cell death, cytotoxicity with reparative cell proliferation, and immune suppression. All pertinent studies are reviewed in analyzing an MOA, and an overall weighing of evidence is performed, laying out the strengths, weaknesses, and uncertainties of the case as well as potential alternative positions and rationales. Identifying data gaps and research needs is also part of the assessment.

Mode of action conclusions are used to address the question of human relevance of animal tumor responses, to address differences in anticipated response among humans such as between children and adults or men and women, and as the basis of decisions about the anticipated shape of the dose-response relationship.

In reaching conclusions, the question of "general acceptance" of an MOA will be tested as part of the independent peer review that EPA obtains for its assessment and conclusions.

Framework for Evaluating a Postulated Carcinogenic Mode(s) of Action

The framework is intended to be an analytic tool for judging whether available data support a mode of carcinogenic action postulated for an agent and includes nine elements:

1. Summary description of postulated MOA
2. Identification of key events
3. Strength, consistency, specificity of association
4. Dose-response relationship
5. Temporal relationship
6. Biological plausibility and coherence
7. Other modes of action
8. Conclusion
9. Human relevance, including subpopulations

3.1.3.3 Dose Estimation

[6]A "key event" is an empirically observable, precursor step that is itself a necessary element of the mode of action, or is a marker for such an element.

A. Determining the Human Equivalent Dose by the Oral Route

An important objective in the dose-response assessment is to use a measure of internal or delivered dose at the target site where possible. This is particularly important in those cases where the carcinogenic response information is being extrapolated to humans from animal studies. Generally, by the oral exposure route, the measure of a dose provided in the underlying human studies or animal bioassays is the applied dose, typically given in terms of unit mass per unit body weight per unit time, (e.g., mg/kg-day). When animal bioassay data are used, it is necessary to make adjustments to the applied dose values to account for differences in toxicokinetics between animals and humans that affect the relationship between applied dose and delivered dose at the target organ.

In the estimation of a human equivalent dose, the 1999 draft revised cancer guidelines recommend that when adequate data are available, the doses used in animal studies can be adjusted to equivalent human doses using toxicokinetic information on the particular agent. However, in most cases, there are insufficient data available to compare dose between species. In these cases, the estimate of a human equivalent dose is based on science policy default assumptions. To derive an equivalent human oral dose from animal data, the default procedure in the 1999 draft revised cancer guidelines is to scale daily applied oral doses experienced for a lifetime in proportion to body weight raised to the 3/4 power ($BW^{3/4}$). The adjustment factor is used because metabolic rates, as well as most rates of physiological processes that determine the disposition of dose, scale this way. Thus, the rationale for this factor rests on the empirical observation that rates of physiological processes consistently tend to maintain proportionality with body weight raised to 3/4 power (USEPA, 1992a, 1999a).

The use of $BW^{3/4}$ is a departure from the scaling factor of $BW^{2/3}$ that was based on surface area adjustment and was included in the 1980 AWQC National Guidelines as well as the 1986 cancer guidelines.

B. Dose-Response Analysis

If data on the agent are sufficient to support the parameters of a biologically based model and the purpose of the assessment is such as to justify investing resources supporting its use, this is the preferred approach for both the observed tumor and related response data and for extrapolation below the range of observed data in either animal or human studies.

3.1.3.4 Characterizing Dose-Response Relationships in the Range of Observation and at Low Environmentally Relevant Doses

The first quantitative component in the derivation of AWQC for carcinogens is the dose-response assessment in the range of observation. For most agents, in the absence of adequate data to generate a biologically based model, dose-response relationships in the observed range can be addressed through curve-fitting procedures for response data. It should be noted that the 1999 draft revised cancer guidelines call for modeling of not only tumor data in the observable range, but also other responses thought to be important events preceding tumor development (e.g., DNA adducts, cellular proliferation, receptor binding, hormonal changes). The modeling of these data is intended to better inform the dose-response assessment by providing insights into the relationships of exposure (or dose) below the observable range for tumor response. These non-tumor response data can only play a role in the dose-response assessment if the agent's carcinogenic mode of action is reasonably understood, as well as the role of that precursor event.

The 1999 draft revised cancer guidelines recommend calculating the lower 95 percent confidence limit on a dose associated with an estimated 10 percent increased tumor or relevant non-tumor response (LED_{10}) for quantitative modeling of dose-response relationships in the observed range. The estimate of the LED_{10} is used as the POD for low-dose extrapolations discussed below. This standard point of departure (LED_{10}) is adopted as a matter of science policy to remain as consistent and comparable from case to case as possible. It is also a convenient comparison point for noncancer endpoints. The rationale supporting use of the LED_{10} is that a 10 percent response is at or just below the limit of sensitivity for discerning a statistically significant tumor response in most long-term rodent studies and is within the observed range for other toxicity studies. Use of lower limit takes experimental variability and sample size into account. The ED_{10} (central estimate) is also presented as a reference for comparison uses, especially for use in relative hazard/potency ranking among agents for priority setting.

For some data sets, a choice of the POD other than the LED_{10} may be appropriate. The objective is to determine the lowest reliable part of the dose-response curve for the beginning of the second step of the dose-response assessment—determine the extrapolation range. Therefore, if the observed response is below the LED_{10}, then a lower point may be a better choice (e.g., LED_5). Human studies more often support a lower POD than animal studies because of greater sample size.

The POD may be a NOAEL when a margin of exposure analysis is the nonlinear dose-response approach. The kinds of data available and the circumstances of the assessment both contribute to deciding to use a NOAEL or LOAEL which is not as rigorous or as ideal as curve fitting, but can be appropriate. If several data sets for key events and tumor response are available for an agent, and they are a mixture of continuous and incidence data, the most practicable way to assess them together is often through a NOAEL/LOAEL approach.

When an LED value estimated from animal data is used as the POD, it is adjusted to the human equivalent dose using an interspecies dose adjustment or a toxicokinetic analysis as described in Section 3.1.3.3.

Analysis of human studies in the observed range is designed on a case-by-case basis depending on the type of study and how dose and response are measured in the study.

A. Extrapolation to Low, Environmentally Relevant Doses

In most cases, the derivation of an AWQC will require an evaluation of carcinogenic risk at environmental exposure levels substantially lower than those used in the underlying study. Various approaches are used to extrapolate risk outside the range of observed experimental data. In the 1999 draft revised cancer guidelines, the choice of extrapolation method is largely dependent on the mode of action. It should be noted that the term “mode of action” (MOA) is deliberately chosen in the 1999 draft revised cancer guidelines in lieu of the term “mechanism” to indicate using knowledge that is sufficient to draw a reasonable working conclusion without having to know the processes in detail as the term mechanism might imply. The 1999 draft revised cancer guidelines favor the choice of a biologically based model, if the parameters of such models can be calculated from data sources independent of tumor data. It is anticipated that the necessary data for such parameters will not be available for most chemicals. Thus, the 1999 draft revised cancer guidelines allow for several default extrapolation approaches (low-dose linear, nonlinear, or both).

B. Biologically Based Modeling Approaches

If a biologically based approach has been used to characterize the dose-response relationships in the observed range, and the confidence in the model is high, it may be used to extrapolate the dose-response relationship to environmentally relevant doses. For the purposes of deriving AWQC, the environmentally relevant dose would be the risk-specific dose (RSD) associated with incremental lifetime cancer risks in the 10^{-6} to 10^{-4} range for carcinogens for which a linear extrapolation approach is applied.[7] The use of the RSD and the POD/UF to compute the AWQC is presented in Section 3.1.3.5, below. Although biologically-based approaches are appropriate both for characterizing observed dose-response relationships and extrapolating to environmentally relevant doses, it is not expected that adequate data will be available to support the use of such approaches for most substances. In the absence of such data, the default linear approach, the nonlinear (MOE) approach, or both linear and nonlinear approaches will be used.

[7] For discussion of the cancer risk range, see Section 2.4.

C. Default Linear Extrapolation Approach

The default linear approach replaces the LMS approach that has served as the default for EPA cancer risk assessments. Any of the following conclusions leads to selection of a linear dose-response assessment approach:

- There is an absence of sufficient tumor MOA information.
- The chemical has direct DNA mutagenic reactivity or other indications of DNA effects that are consistent with linearity.
- Human exposure or body burden is high and near doses associated with key events in the carcinogenic process (e.g., 2,3,7,8-tetrachlorodibenzo-p-dioxin).
- Mode of action analysis does not support direct DNA effects, but the dose-response relationship is expected to be linear (e.g., certain receptor-mediated effects).

The procedures for implementing the default linear approach begin with the estimation of a POD as described above. The point of departure, LED_{10}, reflects the interspecies conversion to the human equivalent dose and the other adjustments for less-than-lifetime experimental duration. In most cases, the extrapolation for estimating response rates at low, environmentally relevant exposures is accomplished by drawing a straight line between the POD and the origin (i.e., zero dose, zero extra risk). This is mathematically represented as:

$$y = mx + b \qquad \text{(Equation 3-1)}$$
$$b = 0$$

where:

y	=	Response or incidence
m	=	Slope of the line (cancer potency factor) = $\Delta y/\Delta x$
x	=	Dose
b	=	Slope intercept

The slope of the line, “m” (the estimated cancer potency factor at low doses), is computed as:

$$m = \frac{0.10}{LED_{10}} \qquad \text{(Equation 3-2)}$$

The RSD is then calculated for a specific incremental targeted lifetime cancer risk (in the range of 10^{-6} to 10^{-4}) as:

$$RSD = \frac{\text{Target Incremental Cancer Risk}}{m} \qquad \text{(Equation 3-3)}$$

where:

RSD	=	Risk-specific dose (mg/kg-day)
Target Incremental Cancer Risk[8]	=	Value in the range of 10^{-6} to 10^{-4}
m	=	Cancer potency factor $(mg/kg\text{-}day)^{-1}$

The use of the RSD to compute the AWQC is described in Section 3.1.3.5 below.

D. Default Nonlinear Approach

As discussed in the 1999 draft revised cancer guidelines, any of the following conclusions leads to a selection of a nonlinear (MOE) approach to dose-response assessment:

- A tumor MOA supporting nonlinearity applies (e.g., some cytotoxic and hormonal agents such as disruptors of hormonal homeostasis), and the chemical does not demonstrate mutagenic effects consistent with linearity.

- An MOA supporting nonlinearity has been demonstrated, and the chemical has some indication of mutagenic activity, but it is judged not to play a significant role in tumor causation.

Thus, a default assumption of nonlinearity is appropriate when there is no evidence for linearity and sufficient evidence to support an assumption of nonlinearity. The MOA may lead to a dose-response relationship that is nonlinear, with response falling much more quickly than linearly with dose, or being most influenced by individual differences in sensitivity. Alternatively, the MOA may theoretically have a threshold (e.g., the carcinogenicity may be a secondary effect of toxicity or of an induced physiological change that is itself a threshold phenomenon).

The nonlinear approach may be used, for instance, in the case of a bladder tumor inducer, where the chemical is not mutagenic and causes only stone formation in male rat bladders at high doses. This dynamic leads to tumor formation only at the high doses. Stone and subsequent tumor formation are not expected to occur at doses lower than those that induce the physiological changes that lead to stone formation. (More detail on this chemical is provided in the cancer section of the Risk Assessment TSD; USEPA, 2000). EPA does not generally try to distinguish between modes of action that might imply a "true threshold" from others with a

[8] In 1980, the target lifetime cancer risk range was set at 10-7 to 10-5. However, both the expert panel for the AWQC workshop (USEPA, 1993) and the peer review workshop experts (USEPA,1999c) recommended that EPA change the risk range to 10-6 to 10-4, to be consistent with SDWA program decisions. See Section 2.4 for more details.

nonlinear dose-response relationship, because there is usually not sufficient information to distinguish between those possibilities empirically.

The nonlinear MOE approach in the 1986 proposed cancer guidelines compares an observed response rate such as the LED_{10}, NOAEL, or LOAEL with actual or nominal environmental exposures of interest by computing the ratio between the two. In the context of deriving AWQC, the environmentally relevant exposures are nominal targets rather than actual exposures.

If the evidence for an agent indicates nonlinearity (e.g., when carcinogenicity is secondary to another toxicity for which there is a threshold), the MOE analysis for the toxicity is similar to what is done for a noncancer endpoint, and an RfD or RfC for that toxicity may also be estimated and considered in the cancer assessment. However, a threshold of carcinogenic response is not necessarily assumed. It should be noted that for cancer assessment, the MOE analysis begins from a POD that is adjusted for toxicokinetic differences between species to give a human equivalent dose.

To support the use of the MOE approach, risk assessment information provides evaluation of the current understanding of the phenomena that may be occurring as dose (exposure) decreases substantially below the observed data. This gives information about the risk reduction that is expected to accompany a lowering of exposure. The various factors that influence the selection of the UF in an MOE approach are also discussed below.

There are two main steps in the MOE approach. The first step is the selection of a POD. The POD may be the LED_{10} for tumor incidence or a precursor, or in some cases, it may also be appropriate to use a NOAEL or LOAEL value. When animal data are used, the POD is a human equivalent dose or concentration arrived at by interspecies dose adjustment (as discussed in Section 3.1.3.3) or toxicokinetic analysis.

The second step in using MOE analysis to establish AWQC is the selection of an appropriate margin or UF to apply to the POD. This is supported by analyses in the MOE discussion in the risk assessment. The following issues should be considered when establishing the overall UF for the derivation of AWQC using the MOE approach (others may be found appropriate in specific cases):

- The nature of the response used for the dose-response assessment, for instance, whether it is a precursor effect or a tumor response. The latter may support a greater MOE.

- The slope of the observed dose-response relationship at the POD and its uncertainties and implications for risk reduction associated with exposure reduction. (A steeper slope implies a greater reduction in risk as exposure decreases. This may support a smaller MOE).

- Human sensitivity compared with that of experimental animals.

- Nature and extent of human variability and sensitivity.

- Human exposure. The MOE evaluation also takes into account the magnitude, frequency, and duration of exposure. If the population exposed in a particular scenario is wholly or largely composed of a subpopulation of special concern (e.g., children) for whom evidence indicates a special sensitivity to the agent's MOA, an adequate MOE would be larger than for general population exposure.

E. Both Linear and Nonlinear Approaches

Any of the following conclusions leads to selection of both a linear and nonlinear approach to dose-response assessment. Relative support for each dose-response method and advice on the use of that information needs to be documented for the AWQC. In some cases, evidence for one MOA is stronger than for the other, allowing emphasis to be placed on that dose-response approach. In other cases, both modes of action are equally possible, and both dose-response approaches should be emphasized.

- Modes of action for a single tumor type support both linear and nonlinear dose response in different parts of the dose-response curve (e.g., 4,4' methylene chloride).

- A tumor mode of action supports different approaches at high and low doses; e.g., at high dose, nonlinearity, but, at low dose, linearity (e.g., formaldehyde).

- The agent is not DNA-reactive and all plausible modes of action are consistent with nonlinearity, but not fully established.

- Modes of action for different tumor types support differing approaches, e.g., nonlinear for one tumor type and linear for another due to lack of MOA information (e.g., trichloroethylene).

3.1.3.5 AWQC Calculation

A. Linear Approach

The following equation is used for the calculation of the AWQC for carcinogens where an RSD is obtained from the linear approach:

$$AWQC = RSD \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 3-4)}$$

AWQC	=	Ambient water quality criterion (mg/L)
RSD	=	Risk-specific dose (mg/kg-day)
BW	=	Human body weight (kg)
DI	=	Drinking water intake (L/day)

FI_i	=	Fish intake at trophic level I (I = 2, 3, and 4) (kg/day)
BAF_i	=	Bioaccumulation factor for trophic level I (I = 2, 3, and 4), lipid normalized (L/kg)

B. Nonlinear Approach

In those cases where the nonlinear, MOE approach is used, a similar equation is used to calculate the AWQC [9]

$$AWQC = \frac{POD}{UF} \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right) \qquad \text{(Equation 3-5)}$$

where variables are defined as for Equation 3-4 and:

POD	=	Point of departure (mg/kg-day)
UF	=	Uncertainty factor (unitless)
RSC	=	Relative source contribution (percentage or subtraction)

Differences between the AWQC values obtained using the linear and nonlinear approaches should be noted. First, the AWQC value obtained using the default linear approach corresponds to a specific estimated incremental lifetime cancer risk level in the range of 10^{-4} to 10^{-6}. In contrast, the AWQC obtained using the nonlinear approach does not describe a specific cancer risk. The AWQC calculations shown above are appropriate for waterbodies that are used as sources of drinking water.

The actual AWQC chosen for the protection of human health is based on a review of all relevant information, including cancer and noncancer data. The AWQC may, or may not, utilize the value obtained from the cancer analysis in the final AWQC value. The endpoint selected for the AWQC will be based on consideration of the weight of evidence and a complete analysis of all toxicity endpoints.

3.1.3.6 Risk Characterization

Risk assessment is an integrative process that is documented in a risk characterization summary. Risk characterization is the final step of the risk assessment process in which all preceding analyses (i.e., hazard, dose-response, and exposure assessments) are tied together to convey the overall conclusions about potential human risk. This component of the risk assessment process characterizes the data in nontechnical terms, explaining the extent and weight of evidence, major points of interpretation and rationale, and strengths and weaknesses of

[9] Although appearing in this equation as a factor to be multiplied, the RSC can also be an amount subtracted.

the evidence, and discussing alternative approaches, conclusions, uncertainties, and variability that deserve serious consideration.

Risk characterization information accompanies the numerical AWQC value and addresses the major strengths and weaknesses of the assessment arising from the availability of data and the current limits of understanding the process of cancer causation. Key issues relating to the confidence in the hazard assessment and the dose-response analysis (including the low-dose extrapolation procedure used) are discussed. Whenever more than one interpretation of the weight of evidence for carcinogenicity or the dose-response characterization can be supported, and when choosing among them is difficult, the alternative views are provided along with the rationale for the interpretation chosen in the derivation of the AWQC value. Where possible, quantitative uncertainty analyses of the data are provided; at a minimum, a qualitative discussion of the important uncertainties is presented.

3.1.3.7 Use of Toxicity Equivalence Factors and Relative Potency Estimates

The 1999 draft revised cancer guidelines state:

> *A toxicity equivalence factor (TEF) procedure is one used to derive quantitative dose-response estimates for agents that are members of a category or class of agents. TEFs are based on shared characteristics that can be used to order the class members by carcinogenic potency when cancer bioassay data are inadequate for this purpose. The ordering is by reference to the characteristics and potency of a well-studied member or members of the class. Other class members are indexed to the reference agent(s) by one or more shared characteristics to generate their TEFs.*

In addition, the 1999 draft revised cancer guidelines state that TEFs are generated and used for the limited purpose of assessment of agents or mixtures of agents in environmental media when better data are not available. When better data become available for an agent, the TEF should be replaced or revised. To date, adequate data to support use of TEFs have been found only for dibenzofurans (dioxins) and coplanar polychlorinated biphenyls (PCBs) (USEPA, 1989, 1999b).

The uncertainties associated with TEFs must be described when this approach is used. This is a default approach to be used when tumor data are not available for individual components in a mixture. Relative potency factors (RPFs) can be similarly derived and used for agents with carcinogenicity or other supporting data. The RPF is conceptually similar to TEFs, but does not have the same level of data to support it and thus has a less rigorous definition compared with the TEF. TEFs and RPFs are used only when there is no better alternative. When they are used, assumptions and uncertainties associated with them are discussed. As of today, there are only three classes of compounds for which relative potency approaches have been examined by EPA: dibenzofurans (dioxins), polychlorinated biphenyls (PCBs), and polycyclic aromatic hydrocarbons (PAHs). There are limitations to the use of TEF and RFP approaches, and caution should be exercised when using them. More guidance can be found in the draft document for conducting health risk assessment of chemical mixtures, published by the EPA Risk Assessment Forum (USEPA,1999b).

3.1.4 References for Cancer Section

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3.2 NONCANCER EFFECTS

3.2.1 1980 AWQC National Guidelines for Noncancer Effects

In the 1980 AWQC National Guidelines, the Agency evaluated noncancer human health effects from exposure to chemical contaminants using Acceptable Daily Intake (ADI) levels. ADIs were calculated by dividing NOAELs by safety factors (SFs) to obtain estimates of doses of chemicals that would not be expected to cause adverse effects over a lifetime of exposure. In accordance with the National Research Council report of 1977 (NRC, 1977), EPA used SFs of 10, 100, or 1,000, depending on the quality and quantity of the overall database. In general, a factor of 10 was suggested when good-quality data identifying a NOAEL from human studies were available. A factor of 100 was suggested if no human data were available, but the database contained valid chronic animal data. For chemicals with no human data and scant animal data, a factor of 1,000 was recommended. Intermediate SFs could also be used for databases that fell between these categories.

AWQC were calculated using the ADI levels together with standard exposure assumptions about the rates of human ingestion of water and fish, and also accounting for intake from other sources (see Equation 1-1 in the Introduction). Surface water concentrations at or below the calculated criteria concentrations would be expected to result in human exposure levels at or below the ADI. Inherent in these calculations is the assumption that, generally, adverse effects from noncarcinogens exhibit a threshold.

3.2.2 Noncancer Risk Assessment Developments Since 1980

Since 1980, the risk assessment of noncarcinogenic chemicals has changed. To remove the value judgments implied by the words “acceptable” and “safety,” the ADI and SF terms have been replaced with the terms RfD and UF/modifying factor (MF), respectively.

For the risk assessment of general systemic toxicity, the Agency currently uses the guidelines contained in the IRIS background document entitled *Reference Dose (RfD): Description and Use in Health Risk Assessments* (hereafter the “IRIS background document”. That document defines an RfD as “an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime” (USEPA, 1993a). The most common approach for deriving the RfD does not involve dose-response modeling. Instead, an RfD for a given chemical is usually derived by first identifying the NOAEL for the most sensitive known toxicity endpoint, that is, the toxic effect that occurs at the lowest dose. This effect is called the critical effect. Factors such as the study protocol, the species of experimental animal, the nature of the toxicity endpoint assessed and its relevance to human effects, the route of exposure, and exposure duration are critically evaluated in order to select the most appropriate NOAEL from among all available studies in the chemical's database. If no appropriate NOAEL can be identified from any study, then the LOAEL for the critical effect endpoint is used and an uncertainly factor for LOAEL-to-NOAEL extrapolation is applied. Using this approach, the RfD is equal to the NOAEL (or LOAEL) divided by the product of UFs and, occasionally, an MF:

$$\text{RfD (mg/kg/day)} = \frac{\text{NOAEL (or LOAEL)}}{\text{UF} \cdot \text{MF}} \qquad \text{(Equation 3-6)}$$

The definitions and guidance for use of the UFs and the MFs are provided in the IRIS background document and are repeated in Table 3-1.

The IRIS background document on the RfD (USEPA, 1993a) provides guidance for critically assessing noncarcinogenic effects of chemicals and for deriving the RfD. Another reference on this topic is Dourson (1994). Furthermore, the Agency has also published separate guidelines for assessing specific toxic endpoints, such as developmental toxicity (USEPA, 1991a), reproductive toxicity (USEPA, 1996a), and neurotoxicity risk assessment (USEPA, 1995). These endpoint-specific guidelines will be used for their respective areas in the hazard assessment step and will complement the overall toxicological assessment. It should be noted, however, that an RfD, derived using the most sensitive known endpoint, is considered protective against all noncarcinogenic effects.

TABLE 3-1. UNCERTAINTY FACTORS AND THE MODIFYING FACTOR

Uncertainty Factor	Definition
UF_H	Use a 1, 3, or 10-fold factor when extrapolating from valid data in studies using long-term exposure to average healthy humans. This factor is intended to account for the variation in sensitivity (intraspecies variation) among the members of the human population.
UF_A	Use an additional factor of 1, 3, or 10 when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty involved in extrapolating from animal data to humans (interspecies variation).
UF_S	Use an additional factor of 1, 3, or 10 when extrapolating from less-than-chronic results on experimental animals when there are no useful long-term human data. This factor is intended to account for the uncertainty involved in extrapolating from less-than-chronic NOAELs to chronic NOAELs.
UF_L	Use an additional factor of 1, 3, or 10 when deriving an RfD from a LOAEL, instead of a NOAEL. This factor is intended to account for the uncertainty involved in extrapolating from LOAELs to NOAELs.
UF_D	Use an additional 3- or 10-fold factor when deriving an RfD from an "incomplete" database. This factor is meant to account for the inability of any single type of study to consider all toxic endpoints. The intermediate factor of 3 (approximately ½ $\log_{10}$ unit, i.e., the square root of 10) is often used when there is a single data gap exclusive of chronic data. It is often designated as UF_D.

Modifying Factor

Use professional judgment to determine the MF, which is an additional uncertainty factor that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and database not explicitly treated above (e.g., the number of species tested). The default value for the MF is 1.

Note: With each UF or MF assignment, it is recognized that professional scientific judgment must be used. The total product of the uncertainty factors and modifying factor should not exceed 3,000.

Similar to the procedure used in the 1980 AWQC National Guidelines, the revised method of deriving AWQC for noncarcinogens uses the RfD together with various assumptions concerning intake of the contaminant from both water and non-water sources of exposure. The objective of an AWQC for noncarcinogens is to ensure that human exposure to a substance related to its presence in surface water, combined with exposure from other sources, does not exceed the RfD. The algorithm for deriving AWQC for noncarcinogens using the RfD is presented as Equation 1-1 in the Introduction.

3.2.3 Issues and Recommendations Concerning the Derivation of AWQC for Noncarcinogens

During a review of the 1980 AWQC National Guidelines (USEPA, 1993b), the Agency identified several issues that must be resolved in order to develop a final revised methodology for deriving AWQC based on noncancer effects. These issues, as discussed below, mainly concern the derivation of the RfD as the basis for such an AWQC. Foremost among these issues is whether the Agency should revise the present method or adopt entirely new procedures that use quantitative dose-response modeling for the derivation of the RfD. Other issues include the following:

- Presenting the RfD as a single point value or as a range to reflect the inherent imprecision of the RfD;
- Selecting specific guidance documents for derivation of noncancer health effect levels;
- Considering severity of effect in the development of the RfD;
- Using less-than-90-day studies as the basis for RfDs;
- Integrating reproductive/developmental, immunotoxicity, and neurotoxicity data into the RfD calculation;
- Applying toxicokinetic data in risk assessments; and
- Considering the possibility that some noncarcinogenic effects do not exhibit a threshold.

3.2.3.1 Using the Current NOAEL/UF-Based RfD Approach or Adopting More Quantitative Approaches for Noncancer Risk Assessment

The current NOAEL/UF-based RfD methodology, or its predecessor ADI/SF methodology, have been used since 1980. This approach assumes that there is a threshold exposure below which adverse noncancer health effects are not expected to occur. Exposures above this threshold are believed to pose some risk to exposed individuals; however, the current approach does not address the nature and magnitude of the risk above the threshold level (i.e., the shape of the dose-response curve above the threshold). The NOAEL/UF-based RfD approach is intended primarily to ensure that the RfD value derived from the available data falls below the population effects threshold. However, the NOAEL/UF-based RfD procedure has limitations. In particular, this method requires that one of the actual experimental doses used by the researchers in the critical study be selected as the NOAEL or LOAEL value. The determination that a dose is a NOAEL or LOAEL will depend on the biological endpoints used and the statistical significance of the data. Statistical significance will depend on the number and spacing of dose groups and the numbers of animals used in each dose group. Studies using a small number of animals can limit the ability to distinguish statistically significant differences among measurable responses seen in dose groups and control groups. Furthermore, the determination of the NOAEL or LOAEL also depends on the dose spacing of the study. Doses are often widely spaced, typically differing by factors of three to ten. A study can identify a NOAEL and a LOAEL from among the doses studied, but the "true" effects threshold cannot be determined from those results. The study size and dose spacing limitations also limit the ability to characterize the nature of the expected response to exposures between the observed NOAEL and LOAEL values.

The limitations of the NOAEL/UF approach have prompted development of alternative approaches that incorporate more quantitative dose-response information. The traditional NOAEL approach for noncancer risk assessment has often been a source of controversy and has been criticized in several ways. For example, experiments involving fewer animals tend to produce higher NOAELs and, as a consequence, may produce higher RfDs. Larger sample sizes, on the other hand, should provide greater experimental sensitivity and lower NOAELs. The focus of the NOAEL approach is only on the dose that is the NOAEL, and the NOAEL must be one of the experimental doses. It also ignores the shape of the dose-response curve. Thus, the slope of the dose-response plays little role in determining acceptable exposures for human beings. Therefore, in addition to the NOAEL/UF-based RfD approach described above, EPA will accept other approaches that incorporate more quantitative dose-response information in appropriate situations for the evaluation of noncancer effects and the derivation of RfDs. However, the Agency wishes to emphasize that it still believes the NOAEL/UF RfD methodology is valid and can continue to be used to develop RfDs.

Two alternative approaches that may have relevance in assisting in the derivation of the RfD for a chemical are the BMD and the categorical regression approaches. These alternative approaches may overcome some of the inherent limitations in the NOAEL/UF approach. For example, the BMD analyses for developmental effects show that NOAELs from studies correlate well with a 5 percent response level (Allen et al., 1994). The BMD and the categorical regression approaches usually have greater data requirements than the RfD approach. Thus, it is unlikely that any one approach will apply to every circumstance; in some cases, different approaches may be needed to accommodate the varying databases for the range of chemicals for which water quality criteria must be developed. Acceptable approaches will satisfy the following criteria: (1) meet the appropriate risk assessment goal; (2) adequately describe the toxicity database and its quality; (3) characterize the endpoints properly; (4) provide a measure of the quality of the "fit" of the model when a model is used for dose-response analysis; and (5) describe the key assumptions and uncertainties.

A. The Benchmark Dose

The BMD is defined as the dose estimated to produce a predetermined level of change in response (the Benchmark Response level, or BMR) relative to control. The BMDL is defined as the statistical lower confidence limit on the BMD. In the derivation of an RfD, the BMDL is used as the dose to which uncertainty factors are applied instead of the NOAEL. The BMD approach first models a dose-response curve for the critical effect(s) using available experimental data. Several mathematical algorithms can be used to model the dose-response curve, such as polynomial or Weibull functions. To define a BMD from the modeled curve for quantal data, the assessor first selects the BMR. The choice of the BMR is critical. For quantal endpoints, a particular level of response is chosen (e.g., 1 percent, 5 percent, or 10 percent). For continuous endpoints, the BMR is the degree of change from controls and is based on what is considered a biologically significant change. The BMD is derived from the BMR dose by applying the desired confidence limit calculation. The RfD is obtained by dividing the BMD by one or more uncertainty factors, similar to the NOAEL approach. Because the BMD is used like the NOAEL to obtain the RfD, the BMR should be selected at or near the low end of the range of increased risks that can be detected in a study of typical size. Generally, this falls in the range between the ED_{01} and the ED_{10}.

The Agency will accept use of a BMD approach to derive RfDs for those agents for which there is an adequate database. There are a number of technical decisions associated with the application of the BMD technique. These include the following:

- The definition of an adverse response;
- Selection of response data to model;
- The form of the data used (continuous versus quantal);
- The choice of the measures of increased risk (extra risk versus additional risk);
- The choice of mathematical model (including use of nonstandard models for unusual data sets);
- The selection of the BMR;
- Methods for calculating the confidence interval;
- Selection of the appropriate BMD as the basis for the RfD (when multiple endpoints are modeled from a single study, when multiple models are applied to a single response, and when multiple BMDs are calculated from different studies); and
- The use of uncertainty factors with the BMD approach.

These topics are discussed in detail in Crump et al. (1995) and in the Risk Assessment TSD Volume (USEPA, 2000). The use of the BMD approach has been discussed in general terms by several authors (Gaylor, 1983; Crump, 1984; Dourson et al., 1985; Kimmel and Gaylor, 1988; Brown and Erdreich, 1989; Kimmel, 1990). The International Life Sciences Institute

(ILSI) also held a major workshop on the BMD in September 1993; the workshop proceedings are summarized in ILSI (1993) and in Barnes et al. (1995). For further information on these technical issues, the reader is referred to the publications referenced above.

The BMD approach addresses several of the quantitative or statistical criticisms of the NOAEL approach. These are discussed at greater length in Crump et al. (1995) and are summarized here. First, the BMD approach uses all the dose-response information in the selected study rather than just a single data point, such as the NOAEL or LOAEL. By using response data from all of the dose groups to model a dose-response curve, the BMD approach allows for consideration of the steepness of the slope of the curve when estimating the ED_{10}. The use of the full data set also makes the BMD approach less sensitive to small changes in data than the NOAEL approach, which relies on the statistical comparison of individual dose groups. The BMD approach also allows consistency in the consideration of the level of effect (e.g., a 10 percent response rate) across endpoints.

The BMD approach accounts more appropriately for the size of each dose group than the NOAEL approach. Laboratory tests with fewer animals per dose group tend to yield higher NOAELs, and thus higher RfDs, because statistically significant differences in response rates are harder to detect. Therefore, in the NOAEL approach, dose groups with fewer animals lead to a higher (less conservative) RfD. In contrast, with the BMD approach, smaller dose groups will tend to have the effect of extending the confidence interval around the ED_{10}; therefore, the lower confidence limit on the ED_{10} (the BMD) will be lower. With the BMD approach, greater uncertainty (smaller test groups) leads to a lower (more conservative) RfD.

There are some issues to be resolved before the BMD approach is used routinely. These were identified in a 1996 Peer Consultation Workshop (USEPA, 1996b). Methods for routine use of the BMD are currently under development by EPA. Several RfCs and RfDs based on the BMD approach are included in EPA's IRIS database. These include reference values for methylmercury based on delayed postnatal development in humans; carbon disulfide based on neurotoxicity; 1,1,1,2-tetrafluoroethane based on testicular effects in rats; and antimony trioxide based on chronic pulmonary interstitial inflammation in female rats.

Various mathematical approaches have been proposed for modeling developmental toxicity data (e.g., Crump, 1984; Kimmel and Gaylor, 1988; Rai and Van Ryzin, 1985; Faustman et al., 1989), which could be used to calculate a BMD. Similar methods can be used to model other types of toxicity data, such as neurotoxicity data (Gaylor and Slikker, 1990, 1992; Glowa and MacPhail, 1995). The choice of the mathematical model may not be critical, as long as estimation is within the observed dose range. Since the model fits a mathematical equation to the observed data, the assumptions in a particular model regarding the existence or absence of a threshold for the effect may not be pertinent (USEPA, 1997). Thus, any model that suitably fits the empirical data is likely to provide a reasonable estimate of a BMD. However, research has shown that flexible models that are nonsymmetric (e.g., the Weibull) are superior to symmetric models (e.g., the probit) in estimating the BMD because the data points at the higher doses have less influence on the shape of the curve than at low doses. In addition, models should incorporate fundamental biological factors where such factors are known (e.g., intralitter correlation for developmental toxicity data) in order to account for as much variability in the data as possible. The Agency is currently using the BMD approach in risk assessments where the data support its use. Draft guidelines for application of the BMD approach also are being developed by the Agency.

Use of BMD methods involves fitting mathematical models to dose-response data obtained primarily from toxicology studies. When considering available models to use for a BMD analysis, it is important to select the model that fits the data the best and is the most biologically appropriate. EPA has developed software following several years of research and development, expert peer review, public comment, subsequent revision, and quality assurance testing. The software (BMDS, Version 1.2) can be downloaded from http://www.epa.gov/ncea/bmds.htm. BMDS facilitates these operations by providing simple data-management tools, a comprehensive help manual, an online help system, and an easy-to-use interface to run multiple models on the same dose-response data.

As part of this software package, EPA has included sixteen (16) different models that are appropriate for the analysis of dichotomous (quantal) data (Gamma, Logistic, Log-Logistic, Multistage, Probit, Log-Probit, Quantal-Linear, Quantal-Quadratic, Weibull), continuous data (Linear, Polynomial, Power, Hill), and nested developmental toxicology data (NLogistic, NCTR, Rai & Van Ryzin). Results from all models include a reiteration of the model formula and model run options chosen by the user, goodness-of-fit information, the BMD, and the estimate of the lower-bound confidence limit on the benchmark dose (BMDL). Model results are presented in textual and graphical output files which can be printed or saved and incorporated into other documents.

B. Categorical Regression

Categorical regression is an emerging technique that may have relevance for the derivation of RfDs or for estimating risk above the RfD (Dourson et al., 1997; Guth et al., 1997). The categorical regression approach, like the BMD approach, can be used to estimate a dose that corresponds to a given probability of adverse effects. This dose would then be divided by UFs to establish an RfD. However, unlike the BMD approach, the Categorical regression approach can incorporate information on different health endpoints in a single dose-response analysis. For those health effects for which studies exist, responses to the substance in question are grouped into severity categories; for example (1) no effect, (2) no adverse effect, (3) mild-to-moderate adverse effect, and (4) frank effect. These categories correspond to the dose categories currently used in setting the RfD, namely, the no-observed-effect level (NOEL), NOAEL, LOAEL, and frank-effect level (FEL), respectively. Logistic transformation or other applicable mathematical operations are used to model the probability of experiencing effects in a certain category as a function of dose (Harrell, 1986; Hertzberg, 1989). The "acceptability" of the fit of the model to the data can be judged using several statistical measures, including the χ^2 statistic, correlation coefficients, and the statistical significance of its model parameter estimates.

The resulting mathematical equation can be used to find a dose (or the lower confidence bound on the dose) at which the probability of experiencing adverse effects does not exceed a selected level, e.g., 10 percent. This dose (like the NOAEL or BMD) would then be divided by relevant UFs to calculate an RfD. For more detail on how to employ the categorical regression approach, see the discussion in the Risk Assessment TSD (USEPA, 2000).

As with the BMD approach, the categorical regression approach has the advantage of using more of the available dose-response data to account for response variability as well as accounting for uncertainty due to sample size through the use of confidence intervals. Additional advantages of categorical regression include the combining of data sets prior to modeling, thus allowing the calculation of the slope of a dose-response curve for multiple adverse effects rather than only one effect at a time. Another advantage is the ability to estimate risks for different levels of severity from exposures above the RfD.

On the other hand, as with BMD, opinions differ over the amount and adequacy of data necessary to implement the method. The categorical regression approach also requires judgments regarding combining data sets, judging goodness-of-fit, and assigning severity to a particular effect. Furthermore, this approach is still in the developmental stage. It is not recommended for routine use, but may be used when data are available and justify the extensive analyses required.

C. Summary

Whether a NOAEL/UF-based methodology, a BMD, a categorical regression model, or other approach is used to develop the RfD, the dose-response-evaluation step of a risk assessment process should include additional discussion about the nature of the toxicity data and its applicability to human exposure and toxicity. The discussion should present the range of doses that are effective in producing toxicity for a given agent; the route, timing, and duration of exposure; species specificity of effects; and any toxicokinetic or other considerations relevant to extrapolation from the toxicity data to human-health-based AWQC. This information should always accompany the characterization of the adequacy of the data.

3.2.3.2 Presenting the RfD as a Single Point or as a Range for Deriving AWQC

Although the RfD has traditionally been presented and used as a single point, its definition contains the phrase ". . . an estimate (with uncertainty spanning perhaps an order of magnitude) . . ." (USEPA, 1993a). Underlying this concept is the reasoning that the selection of the critical effect and the total uncertainty factor used in the derivation of the RfD is based on the "best" scientific judgment, and that competent scientists examining the same database could derive RfDs which varied within an order of magnitude.

In one instance, IRIS presented the RfD as a point value within an accompanying range. EPA derived a single number as the RfD for arsenic (0.3 µg/kg-day), but added that "strong scientific arguments can be made for various values within a factor of 2 or 3 of the currently recommended RfD value, i.e., 0.1 to 0.8 µg/kg/day" (USEPA, 1993c). EPA noted that regulatory managers should be aware of the flexibility afforded them through this action.

There are situations in which the risk manager can select an alternative value to use in place of the RfD in the AWQC calculations. The domain from which this alternative value can be selected is restricted to a defined range around the point estimate. As explained further below, the Agency is recommending that sometimes the use of a value other than the calculated RfD point estimate is appropriate in characterizing risk. The selection of an alternative value within an appropriate range must be determined for each individual situation, since several factors affect the selection of the alternative value. Observing similar effects in several animal species, including humans, can increase confidence in the selection of the critical effect and thereby narrow the range of uncertainty. There are other factors that can affect the precision. These include the slope of the dose-response curve, seriousness of the observed effect, dose spacing, and possibly the route for the experimental doses. Dose spacing and the number of animals in the study groups used in the experiment can also affect the confidence in the RfD.

To derive the AWQC, the calculated point estimate of the RfD is the default. Based on consideration of the available data, the use of another number within the range defined by the product of the UF(s) (and MF, if used) could be justified in some specific situations. This means that there are risk considerations which indicate that some value in the range other than the point estimate may be more appropriate, based on human health or environmental fate considerations. For example, the bioavailability of the contaminant in fish tissues is one factor to consider. If bioavailability from fish tissues is much lower than that from water and the RfD was derived from a study in which the contaminant exposure was from drinking water, the alternative to the calculated RfD could be selected from the high end of the range and justified using the quantitative difference in bioavailability.

Most inorganic contaminants, particularly divalent cations, have bioavailability values of 20 percent or less from a food matrix, but are much more available (about 80 percent or higher) from drinking water. Accordingly, the external dose necessary to produce a toxic internal dose would likely be higher for a study where the exposure occurred through the diet rather than the drinking water. As a result, the RfD from a dietary study would likely be higher than that for the drinking water study if equivalent external doses had been used. Conversely, in cases where the NOAEL that was the basis for the RfD came from a dietary study, the alternative value could be slightly lower than the calculated RfD.

Because the uncertainty around the dose-response relationship increases as extrapolation below the observed data increases, the use of an alternative point within the range may be more appropriate in characterizing the risk than the use of the calculated RfD, especially in situations when the uncertainty is high. Therefore, as a matter of policy, the 2000 Human Health Methodology permits the selection of a single point within a range about the calculated RfD to be used as the basis of the AWQC if an adequate justification of the alternative point is provided. More complete discussion of this option, including limitations on the span of the range, is provided in the Risk Assessment TSD (USEPA, 2000).

3.2.3.3 Guidelines to be Adopted for Derivation of Noncancer Health Effects Values

The Agency currently is using the IRIS background document as the general basis for the risk assessment of noncarcinogenic effects of chemicals (USEPA, 1993a). EPA recommends continued use of this document for this purpose. However, it should be noted that the process for evaluating chemicals for inclusion in IRIS is undergoing revision (USEPA, 1996c). The revised assessments for many chemicals are now available on IRIS and can be consulted as examples of the RfD development process and required supporting documentation.

3.2.3.4 Treatment of Uncertainty Factors/Severity of Effects During the RfD Derivation and Verification Process

During the RfD derivation and toxicology review process, EPA considers the uncertainty in extrapolating between animal species and within individuals of a species, as well as specific uncertainties associated with the completeness of the database. The Agency's RfD Work Group has always considered the severity of the observed effects induced by the chemical under review when choosing the value of the UF with a LOAEL. For example, during the derivation and verification of the RfD for zinc (USEPA, 1992), an uncertainty factor less than the standard factor of 10 (UF of 3) was assigned to the relatively mild decrease in erythrocyte superoxide dismutase activity in human subjects. EPA recommends that the severity of the critical effect be assessed when deriving an RfD and that risk managers be made aware of the severity of the effect and the weight placed on this attribute of the effect when the RfD was derived.

3.2.3.5 Use of Less-Than-90-Day Studies to Derive RfDs

Generally, less-than-90-day experimental studies are not used to derive an RfD. This is based on the rationale that studies lasting for less than 90 days may be too short to detect various toxic effects. However, EPA, has in certain circumstances, derived an RfD based on a less-than-90-day study. For example, the RfD for nonradioactive effects of uranium is based on a 30-day rabbit study (USEPA, 1989). The short-term exposure period was used, because it was adequate for determining doses that cause chronic toxicity. In other cases, it may be appropriate to use a less-than-90-day study because the critical effect is expressed in less than 90 days. For example, the RfD for nitrate was derived and verified using studies that were less than 3-months in duration (USEPA, 1991b). For nitrate, the critical effect of methemoglobinemia in infants occurs in less than 90 days. When it can be demonstrated from other data in the toxicological database that the critical adverse effect is expressed within the study period and that a longer exposure duration would not exacerbate the observed effect or cause the appearance of some other adverse effect, the Agency may choose to use less-than-90-day studies as the basis of the RfD. Such values would have to be used with care because of the uncertainty in determining if other effects might be expressed if exposure was of greater duration than 90 days.

3.2.3.6 Use of Reproductive/Developmental, Immunotoxicity, and Neurotoxicity Data as the Basis for Deriving RfDs

All relevant toxicity data have some bearing on the RfD derivation and verification and are considered by EPA. The "critical" effect is the adverse effect most relevant to humans or, in the absence of an effect known to be relevant to humans, the adverse effect that occurs at the lowest dose in animal studies. If the critical effect is neurotoxicity, EPA will use that endpoint as the basis for the derivation and verification of an RfD, as it did for the RfD for acrylamide. Moreover, the Agency is continually revising its procedures for noncancer risk assessment. For example, EPA has released guidelines for deriving developmental RfDs (RfD_{DT}, USEPA, 1991a), for using reproductive toxicity (USEPA, 1996a), and neurotoxicity (USEPA, 1995) data in risk assessments. The Agency is currently working on guidelines for using immunotoxicity data to derive RfDs. In addition, the Agency is proceeding with the process of generating acceptable emergency health levels for hazardous substances in acute exposure situations based on established guidelines (NRC, 1993).

3.2.3.7 Applicability of Toxicokinetic Data in Risk Assessment

All pertinent toxicity data should be used in the risk assessment process, including toxicokinetic and mechanistic data. The Agency has used toxicokinetic data in deriving the RfD for cadmium and other compounds and currently is using toxicokinetic data to better characterize human inhalation exposures from animal inhalation experiments during derivation/verification of RfCs. In analogy to the RfD, the RfC is considered to be an estimate of a concentration in the air that is not anticipated to cause adverse noncancer effects over a lifetime of inhalation exposure (USEPA, 1994; Jarabek, 1995a). For RfCs, different dosimetry adjustments are made to account for the differences between laboratory animals and humans in gas uptake and disposition or in particle clearance and retention. This procedure results in calculation of a "human equivalent concentration." Based on the use of these procedures, an interspecies UF of 3 (i.e., approximately $10^{0.5}$), instead of the standard factor of 10, is used in the RfC derivation (Jarabek, 1995b).

Toxicokinetics and toxicodynamics of a chemical each contribute to a chemical's observed toxicity, and specifically, to observed differences among species in sensitivity. Toxicokinetics describes the disposition (i.e., deposition, absorption, distribution, metabolism, and elimination of chemicals in the body) and can be approximated using toxicokinetic models. Toxicodynamics describes the toxic interaction of the agent with the target cell. In the absence of specific data on their relative contributions to the toxic effects observed in species, each is considered to account for approximately one-half of the difference in observed effects for humans compared with laboratory animals. The implication of this assumption is that an interspecies uncertainty factor of 3 rather than 10 could be used for deriving an RfD when valid toxicokinetic data and models can be applied to obtain an oral "human equivalent applied dose" (Jarabek, 1995b). If specific data exist on the relative contribution of either element to observed effects, that proportion will be used. The role exposure duration may play, and whether or not the chemical or its damage may accumulate over time in a particular scenario, also requires careful consideration (Jarabek, 1995c).

3.2.3.8 Consideration of Linearity (or Lack of a Threshold) for Noncarcinogenic Chemicals

It is quite possible that there are chemicals with noncarcinogenic endpoints that have no threshold for effects. For example, in the case of lead, it has not been possible to identify a threshold for effects on neurological development. Other examples could include genotoxic teratogens and germline mutagens. Genotoxic teratogens act by causing mutational events during organogenesis, histogenesis, or other stages of development. Germline mutagens interact with germ cells to produce mutations which may be transmitted to the zygote and expressed during one or more stages of development. However, there are few chemicals which currently have sufficient mechanistic information about these possible modes of action. It should be recognized that although an MOA consistent with linearity is possible (especially for agents known to be mutagenic), this has yet to be reasonably demonstrated for most toxic endpoints other than cancer.

EPA has recognized the potential for nonthreshold noncarcinogenic endpoints and discussed this issue in the *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991a) and in the 1986 *Guidelines for Mutagenicity Risk Assessment* (USEPA, 1986). An awareness of the potential for such teratogenic/mutagenic effects should be established in order to deal with such data. However, without adequate data to support a genetic or mutational basis for developmental or reproductive effects, the default becomes a UF or MOA approach, which are procedures utilized for noncarcinogens assumed to have a threshold. Therefore, genotoxic teratogens and germline mutagens should be considered an exception while the traditional uncertainty factor approach is the general rule for calculating criteria or values for chemicals demonstrating developmental/reproductive effects. For the exceptional cases, since there is no well-established mechanism for calculating criteria protective of human health from the effects of these agents, criteria will be established on a case-by-case basis. Other types of nonthreshold noncarcinogens must also be handled on a case-by-case basis.

3.2.3.9 Minimum Data Guidance

For details on minimum data guidance for RfD development, see the Risk Assessment TSD (USEPA, 2000).

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4. EXPOSURE

The derivation of AWQC for the protection of human health requires information about both the toxicological endpoints of concern for water pollutants and the pathways of human exposure to those pollutants. The two primary pathways of human exposure to pollutants present in a particular ambient waterbody that have been considered in deriving AWQC are direct ingestion of drinking water obtained from that waterbody and the consumption of fish/shellfish obtained from that waterbody. The water pathway also includes other exposures from household uses (e.g., showering). The derivation of an AWQC involves the calculation of the maximum water concentration for a pollutant (i.e., the water quality criteria level) that ensures drinking water and/or fish ingestion exposures will not result in human intake of that pollutant in amounts that exceed a specified level based upon the toxicological endpoint of concern.

The equation for noncancer effects is presented again here, in simplified form, to emphasize the exposure-related parameters (in bold). [Note: the RSC parameter also applies to nonlinear low-dose extrapolation for cancer effects and the other exposure parameters apply to all three of the equations (see Section 1.6).]

$$AWQC = RfD \bullet \boldsymbol{RSC} \bullet \frac{(\boldsymbol{BW})}{[\boldsymbol{DI} + (\boldsymbol{FI} \bullet BAF)]} \qquad \text{(Equation 4-1)}$$

where:

AWQC	=	Ambient Water Quality Criterion (mg/L)
RfD	=	Reference dose for noncancer effects (mg/kg-day)
RSC	=	Relative source contribution factor to account for non-water sources of exposure
BW	=	Human body weight (kg)
DI	=	Drinking water intake (L/day)
FI	=	Fish intake (kg/day)
BAF	=	Bioaccumulation factor (L/kg)

The following subsections discuss exposure issues relevant to the 2000 Human Health Methodology: exposure policy issues; consideration of non-water sources of exposure (the Relative Source Contribution approach); and the factors used in AWQC computation. In relevant sections, science policy and risk management decisions made by EPA are discussed.

4.1 EXPOSURE POLICY ISSUES

This section discusses broad policy issues related to exposure concerning the major objectives that the Agency believes should be met in setting AWQC.

An Exposure Assessment TSD provides greater detail on numerous topics discussed in this guidance: suggested sources of contaminant concentration and exposure intake information; suggestions of survey methods for obtaining and analyzing exposure data necessary for deriving AWQC; summaries of studies on fish consumption among sport fishers and subsistence fishers; more detailed presentation of parameter values (e.g., fish consumption rates, body weights); and additional guidance on the application of the RSC approach.

4.1.1 Sources of Exposure Associated With Ambient Water

4.1.1.1 Appropriateness of Including the Drinking Water Pathway in AWQC

EPA intends to continue including the drinking water exposure pathway in the derivation of its national default human health criteria (AWQC), as has been done since the 1980 AWQC National Guidelines were first published.

EPA recommends inclusion of the drinking water exposure pathway where drinking water is a designated use for the following reasons: (1) Drinking water is a designated use for surface waters under the CWA and, therefore, criteria are needed to assure that this designated use can be protected and maintained. (2) Although rare, there are some public water supplies that provide drinking water from surface water sources without treatment. (3) Even among the majority of water supplies that do treat surface waters, existing treatments may not necessarily be effective for reducing levels of particular contaminants. (4) In consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users to bear the costs of upgraded or supplemental water treatment.

This policy decision has been supported by the States, most of the public stakeholders, and by external peer reviewers. As with the other exposure parameters, States and authorized Tribes have the flexibility to use alternative intake rates if they believe that drinking water consumption is substantively different than EPA's recommended default assumptions of 2 L/day for adults and 1 L/day for children. EPA recommends that States and authorized Tribes use an intake rate that would be protective of a majority of consumers and will consider whether an alternative assumption is adequately protective of a State's or Tribe's population based on the information or rationale provided at the time EPA reviews State and Tribal water quality standards submissions.

4.1.1.2 Setting Separate AWQC for Drinking Water and Fish Consumption

In conjunction with the issue of the appropriateness of including the drinking water pathway explicitly in the derivation of AWQC for the protection of human health, EPA intends to continue its practice of setting a single AWQC for both drinking water and fish/shellfish consumption, and a separate AWQC based on ingestion of fish/shellfish alone. This latter criterion applies in those cases where the designated uses of a waterbody include supporting fishable uses under Section 101(a) of the CWA and, thus, fish or shellfish for human consumption, but not as a drinking water supply source (e.g., non-potable estuarine waters).

EPA does not believe that national water quality criteria for protection of drinking water uses only are particularly useful for two reasons. First, State and Tribal standards for human health are set to protect Section 101(a) uses (e.g., "fishable, swimmable uses") under the CWA. Second, most waters have multiple designated uses. Additionally, the water quality standards program protects aquatic life. The 2000 Human Health Methodology revisions do not change EPA's policy to apply aquatic life criteria to protect aquatic species where they are more sensitive (i.e., when human health criteria would not be protective enough) or where human health via fish or water ingestion is not an issue.

4.1.1.3 Incidental Ingestion from Ambient Surface Waters

The 2000 Human Health Methodology does not routinely include criteria to address incidental ingestion of water from recreational uses. EPA has considered whether there are cases where water quality criteria for the protection of human health based only on fish ingestion (or only criteria for the protection of aquatic life) may not adequately protect recreational users from health effects resulting from incidental water ingestion.

EPA reviewed information that provided estimates of incidental water ingestion rates averaged over time. EPA generally believes that the averaged amount is negligible and will not have any impact on the chemical criteria values representative of both drinking water and fish ingestion. A lack of impact on the criteria values would likely also be true for chemical criteria based on fish consumption only, unless the chemical exhibits no bioaccumulation potential. However, EPA also believes that incidental/accidental water ingestion could be important for the development of microbial contaminant water quality criteria, and for either chemical or microbial criteria for States where recreational uses such as swimming and boating are substantially higher than the national average. EPA also notes that some States have indicated they already have established incidental ingestion rates for use in developing criteria. Therefore, although EPA will not use this intake parameter when deriving its national 304(a) chemical criteria, limited guidance is provided in the Exposure Assessment TSD volume in order to assist States and authorized Tribes that face situations where this intake parameter could be of significance.

4.2 CONSIDERATION OF NON-WATER SOURCES OF EXPOSURE WHEN SETTING AWQC

4.2.1 Policy Background

The 2000 Human Health Methodology uses different approaches for addressing non-water exposure pathways in setting AWQC for the protection of human health depending upon the toxicological endpoint of concern. With those substances for which the appropriate toxic endpoint is carcinogenicity based on a linear low-dose extrapolation, only the two water sources (i.e., drinking water and fish ingestion) are considered in the derivation of the AWQC. Non-water sources are not considered explicitly. In the case of carcinogens based on linear low-dose extrapolation, the AWQC is being determined with respect to the *incremental* lifetime risk posed by a substance's presence in water, and is not being set with regard to an individual's total risk from all sources of exposure. Thus, the AWQC represents the water concentration that would be expected to increase an individual's lifetime risk of carcinogenicity from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

Furthermore, health-based criteria values for one medium based on linear low-dose extrapolation typically vary from values for other media in terms of the concentration value, and often the associated risk level. Therefore, the RSC concept could not even theoretically apply unless all risk assessments for a particular carcinogen based on linear low-dose extrapolation resulted in the same concentration value and same risk level; that is, an apportionment would need to be based on a single risk value and level.

In the case of substances for which the AWQC is set on the basis of a carcinogen based on a nonlinear low-dose extrapolation or for a noncancer endpoint where a threshold is assumed to exist, non-water exposures are considered when deriving the AWQC using the RSC approach. The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure does not exceed that threshold level.

There has been some discussion of whether it is, in fact, necessary in most cases to explicitly account for other sources of exposure when computing the AWQC for pollutants exhibiting threshold effects. It has been argued that because of the conservative assumptions generally incorporated in the calculation of RfDs (or POD/UF values) used as the basis for the AWQC derivation, total exposures slightly exceeding the RfD are unlikely to produce adverse effects.

EPA emphasizes that the purpose of the RSC is to ensure that the level of a chemical allowed by a criterion or multiple criteria, when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD or the POD/UF. The policy of considering multiple sources of exposure when deriving health-based criteria has become common in EPA's program office risk characterizations and criteria and standard-setting actions. Numerous EPA workgroups have evaluated the appropriateness of factoring in such exposures, and the Agency concludes that it is important for adequately protecting human health. Consequently, EPA risk management policy has evolved significantly over the last six years. Various EPA program initiatives and policy documents regarding aggregate exposure and cumulative risk have been developed, including the consideration of inhalation and dermal exposures. Additionally, accounting for other exposures has been included in recent mandates (e.g., the Food Quality Protection Act) and, thus, is becoming a requirement for the Agency. The Exposure Decision Tree approach has been shared with other EPA offices, and efforts to coordinate policies on aggregate exposure, where appropriate, have begun. EPA intends to continue developing policy guidance on the RSC issue and guidance to address the concern that human health may not be adequately protected if criteria allow for higher levels of exposure that, combined, may exceed the RfD or POD/UF. EPA also intends to refine the 2000 Human Health Methodology in the future to incorporate additional guidance on inhalation and dermal exposures. As stated previously, EPA is required to derive national water quality criteria under Section 304(a) of the CWA and does not intend to derive site-specific criteria. However, States and authorized Tribes have the flexibility to make alternative exposure and RSC estimates based on local data, and EPA strongly encourages this.

Uncertainty factors used in the derivation of the RfD (or POD/UF) to account for intra- and interspecies variability and the incompleteness of the toxicity data set(s)/animal studies are specifically relevant to the chemical's internal toxicological action, irrespective of the sources of exposure that humans may be experiencing. The Agency's policy is to consider and account for other sources of exposure in order to set protective health criteria. EPA believes that multiple route exposures may be particularly important when uncertainty factors associated with the RfD are small. Although EPA is well aware that RfDs are not all equivalent in their derivation, EPA does not believe that uncertainty in the toxicological data should result in less stringent criteria by ignoring exposure sources. However, the RSC policy approach does allow less stringent assumptions when multiple sources of exposure are not anticipated.

The AWQC are designed to be protective criteria, generally applicable to the waters of the United States. While EPA cannot quantitatively predict the actual human health risk associated with combined exposures above the RfD or POD/UF, a combination of health criteria for multiple media exceeding the RfD or POD/UF may not be sufficiently protective. Therefore, EPA's policy is to routinely account for all sources and routes of non-occupational exposure when setting AWQC for noncarcinogens and for carcinogens based on nonlinear low-dose extrapolations. EPA believes that maintaining total exposure below the RfD (or POD/UF) is a reasonable health goal and that there are circumstances where health-based criteria for a chemical should not exceed the RfD (or POD/UF), either alone (if only one criterion is relevant, along with other intake sources considered as background exposures) or in combination. EPA believes its RSC policy ensures this goal.

Also, given the inability to reasonably predict future changes in exposure patterns, the uncertainties in the exposure estimates due to typical data inadequacy, possible unknown sources of exposure, and the potential for some populations to experience greater exposures than indicated by the available data, EPA believes that utilizing the entire RfD (or POD/UF) does not ensure adequate protection.

4.2.2 The Exposure Decision Tree Approach

As indicated in Section 1, EPA has, in the past, used a "subtraction" method to account for multiple sources of exposure to pollutants. In the subtraction method, other sources of exposure (i.e., those other than the drinking water and fish exposures) are subtracted from the RfD (or POD/UF). However, EPA also previously used a "percentage" method for the same purpose. In this approach, the percentage of total exposure typically accounted for by the exposure source for which the criterion is being determined, referred to as the relative source contribution (RSC), is applied to the RfD to determine the maximum amount of the RfD "apportioned" to that source. With both procedures, a "ceiling" level of 80 percent of the RfD and a "floor level" of 20 percent of the RfD are applied.

The subtraction method is considered acceptable when only one criterion is relevant for a particular chemical. The percentage method is recommended in the context of the above goals when multiple media criteria are at issue. The percentage method does not simply depend on the amount of a contaminant in the prospective criterion source only. It is intended to reflect health considerations, the relative portions of other sources, and the likelihood for ever-changing levels in each of those multiple sources (due to ever-changing sources of emissions and discharges). Rather than simply defaulting in every instance, the Agency attempts to compare multiple source exposures with one another to estimate their relative contribution to the total–given that understanding the degree to which their concentrations vary, or making any distributional analysis, is often not possible. The criteria levels, when multiple criteria are at issue, are based on the actual levels, with an assumption that there may be enough relative variability such that an apportionment (relating that percentage to the RfD) is a reasonable way of accounting for the uncertainty regarding that variability.

The specific RSC approach recommended by EPA, which we will use for the derivation of AWQC for noncarcinogens and carcinogens assessed using nonlinear low-dose extrapolation, is called the Exposure Decision Tree and is described below. To account for exposures from other media when setting an AWQC (i.e., non-drinking water/non-fish ingestion exposures, and inhalation or dermal exposures), the Exposure Decision Tree for determining proposed RfD or POD/UF apportionments represents a method of comprehensively assessing a chemical for water quality criteria development. This method considers the adequacy of available exposure data, levels of exposure, relevant sources/media of exposure, and regulatory agendas (i.e., whether there are multiple health-based criteria or regulatory standards for the same chemical). The Decision Tree addresses most of the disadvantages associated with the exclusive use of either the percentage or subtraction approaches, because they are not arbitrarily chosen prior to determining the following: specific population(s) of concern, whether these populations are relevant to multiple-source exposures for the chemical in question (i.e., whether the population is actually or potentially experiencing exposure from multiple sources), and whether levels of exposure, regulatory agendas, or other circumstances make apportionment of the RfD or POD/UF desirable. Both subtraction and percentage methods are potentially utilized under different circumstances with the Exposure Decision Tree approach, and the Decision Tree is recommended with the idea that there is enough flexibility to use other procedures if information on the contaminant in question suggests it is not appropriate to follow the Decision Tree. EPA recognizes that there may be other valid approaches in addition to the Exposure Decision Tree.

The Exposure Decision Tree approach allows flexibility in the RfD (or POD/UF) apportionment among sources of exposure. When adequate data are available, they are used to make protective exposure estimates for the population(s) of concern. When other sources or routes of exposure are anticipated but data are not adequate, there is an even greater need to make sure that public health protection is achieved. For these circumstances, a series of qualitative alternatives is used (with the less adequate data or default assumptions) that allow for the inadequacies of the data while protecting human health. Specifically, the Decision Tree makes use of chemical information when actual monitoring data are inadequate. It considers information on the chemical/physical properties, uses of the chemical, and environmental fate and transformation, as well as the likelihood of occurrence in various media. Review of such information, when available, and determination of a reasonable exposure characterization for the chemical will result in a water quality criterion that more accurately reflects exposures than automatically using a default value. Although the 20 percent default will still generally be used when information is not adequate, the need for using it should be reduced. There may also be some situations where EPA would consider the use of an 80 percent default (see Section 4.2.3).

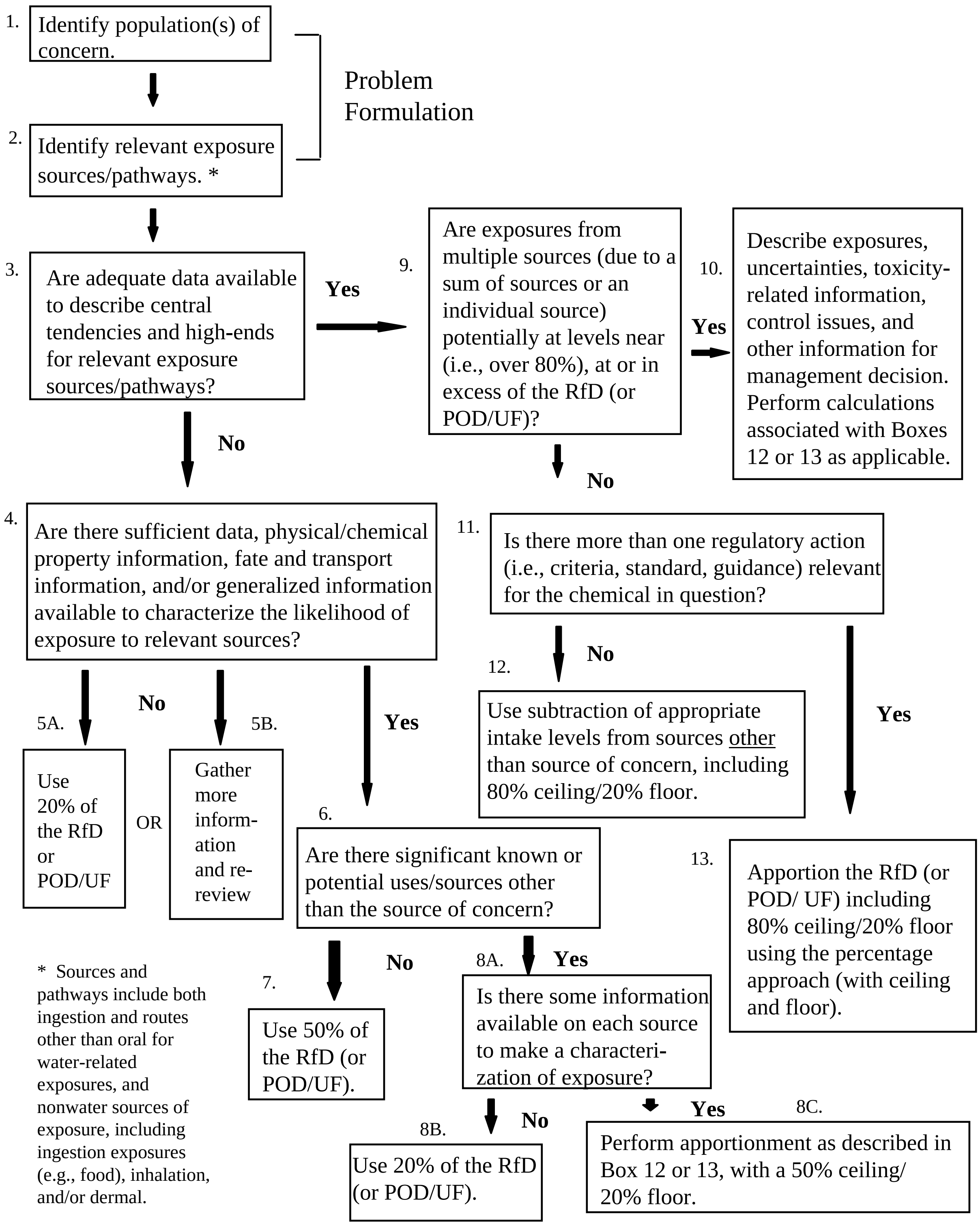
The Decision Tree also allows for use of either the subtraction or percentage method to account for other exposures, depending on whether one or more health-based criterion is relevant for the chemical in question. The subtraction method is considered acceptable when only one criterion is relevant for a particular chemical. In these cases, other sources of exposure can be considered "background" and can be subtracted from the RfD (or POD/UF).

EPA cautions States and Tribes when using the subtraction method in these circumstances. The subtraction method results in a criterion allowing the maximum possible chemical concentration in water after subtracting other sources. As such, it removes any cushion between pre-criteria levels (i.e., actual "current" levels) and the RfD, thereby setting criteria at the highest levels short of exceeding the RfD. It is somewhat counter to the goals of the CWA for maintaining and restoring the nation's waters. It is also directly counter to Agency policies, explicitly stated in numerous programs, regarding pollution prevention. EPA has advocated that it is good health policy to set criteria such that exposures are kept low when current levels are already low. The subtraction method generally results in criteria levels of a contaminant in a particular medium at significantly higher levels than the percentage method and, in this respect, is contradictory to such goals. In fact, many chemicals have pre-criteria levels in environmental media substantially lower (compared to the RfD) than the resulting criteria allow.

When more than one criterion is relevant to a particular chemical, apportioning the RfD (or POD/UF) via the percentage method is considered appropriate to ensure that the combination of criteria and, thus, the potential for resulting exposures do not exceed the RfD (or POD/UF). The Exposure Decision Tree (with numbered boxes) is shown in Figure 4-1. The explanation in the text on the following pages must be read in tandem with the Decision Tree figure; the text in each box of the figure only nominally identifies the process and conditions for determining the outcome for that step of the Decision Tree. The underlying objective is to maintain total exposure below the RfD (or POD/UF) while generally avoiding an extremely low limit in a single medium that represents just a nominal fraction of the total exposure. To meet this objective, all proposed numeric limits lie between 80 percent and 20 percent of the RfD (or POD/UF). Again, EPA will use the Exposure Decision Tree approach when deriving its AWQC but also recognizes that departures from the approach may be appropriate in certain cases. EPA understands that there may be situations where the Decision Tree procedure is not practicable or

Figure 4-1

Exposure Decision Tree for Defining Proposed RfD (or POD/UF) Apportionment



may be simply irrelevant after considering the properties, uses, and sources of the chemical in question. EPA endorses such flexibility by States and authorized Tribes when developing alternative water quality criteria in order to choose other procedures that are more appropriate for setting health-based criteria and, perhaps, apportioning the RfD or POD/UF, as long as reasons are given as to why it is not appropriate to follow the Exposure Decision Tree approach and as long as the steps taken to evaluate the potential sources and levels of exposure are clearly described. Often, however, the common situation of multiple exposure sources for a chemical is likely to merit a Decision Tree evaluation for the purpose of developing human health water quality criteria for a given chemical.

It is clear that this will be an interactive process; input by exposure assessors will be provided to, and received from, risk managers throughout the process, given that there may be significant implications regarding control issues (i.e., cost/feasibility), environmental justice issues, etc. In cases where the Decision Tree is not chosen, communication and concurrence about the decision rationale and the alternative water quality criteria are of great importance.

Descriptions of the boxes within the Decision Tree are separated by the following process headings to facilitate an understanding of the major considerations involved. The decision to perform, or not to perform, an apportionment could actually be made at several points during the Decision Tree process. Working through the process is most helpful for identifying possible exposure sources and the potential for exposure, determining the relevancy of the Decision Tree to developing an AWQC for a particular chemical and, possibly, determining the appropriateness of using an alternative approach to account for overall exposure. "Relevancy" here means determining whether more than one criterion, standard, or other guidance is being planned or is in existence for the chemical in question. Additional guidance for States and Tribes that wish to use the Exposure Decision Tree is provided in the Exposure Assessment TSD.

4.2.2.1 Problem Formulation

Initial Decision Tree discussion centers around the first two boxes: identification of population(s) of concern (Box 1) and identification of relevant exposure sources and pathways (Box 2). The term "problem formulation" refers to evaluating the population(s) and sources of exposure in a manner that allows determination of the potential for the population of concern to experience exposures from multiple sources for the chemical in question. Also, the data for the chemical in question must be representative of each source/medium of exposure and be relevant to the identified population(s). Evaluation includes determining whether the levels, multiple criteria or regulatory standards, or other circumstances make apportionment of the RfD or POD/UF reasonable. The initial problem formulation also determines the exposure parameters chosen, the intake assumptions chosen for each route, and any environmental justice or other social issues that aid in determining the population of concern. The term "data," as used here and discussed throughout this section, refers to ambient sampling data (whether from Federal, regional, State, or area-specific studies) and not internal human exposure measurements.

4.2.2.2 Data Adequacy

In Box 3, it is necessary that adequate data exist for the relevant sources/pathways of exposure if one is to avoid using default procedures. The adequacy of data is a professional judgment for each individual chemical of concern, but EPA recommends that the minimum acceptable data for Box 3 are exposure distributions that can be used to determine, with an acceptable 95 percent confidence interval, the central tendency and high-end exposure levels for each source. In fact, distributional data may exist for some or most of the sources of exposure.

There are numerous factors to consider in order to determine whether a dataset is adequate. These include: (1) sample size (i.e., the number of data points); (2) whether the data set is a random sample representative of the target population (if not, estimates drawn from it may be biased no matter how large the sample); (3) the magnitude of the error that can be tolerated in the estimate (estimator precision); (4) the sample size needed to achieve a given precision for a given parameter (e.g., a larger sample is needed to precisely estimate an upper percentile than a mean or median value); (5) an acceptable analytical method detection limit; and (6) the functional form and variability of the underlying distribution, which determines the estimator precision (e.g., whether the distribution is normal or lognormal and whether the standard deviation is 1 or 10). Lack of information may prevent assessment of each of these factors; monitoring study reports often fail to include background information or sufficient summary statistics (and rarely the raw data) to completely characterize data adequacy. Thus, a case-by-case determination of data adequacy may be necessary.

That being stated, there are some guidelines, as presented below, that lead to a rough rule-of-thumb on what constitutes an "adequate" sample size for exposure assessment. Again, first and foremost, the representativeness of the data for the population evaluated and the analytical quality of the data must be acceptable. If so, the primary objective then becomes estimating an upper percentile (e.g., say the 90^{th}) and a central tendency value of some exposure distribution based on a random sample from the distribution. Assuming that the distribution of exposures is unknown, a nonparametric estimate of the 90^{th} percentile is required. The required estimate, based on a random sample of n observations from a target population, is obtained by ranking the data from smallest to largest and selecting the observation whose rank is 1 greater than the largest integer in the product of 0.9 times n. For example, in a data set of 25 points, the nonparametric estimate of the 90^{th} percentile is the 23rd largest observation.

In addition to this point estimate, it is useful to have an upper confidence bound on the 90^{th} percentile. To find the rank of the order statistic that gives an upper 95 percent confidence limit on the 90^{th} percentile, the smallest value of r that satisfies the following formula is determined:

$$0.95 \approx \sum_{i=0}^{r-1} \binom{n}{i} \; 0.9^{i} \; 0.1^{n-i} \qquad \text{(Equation 4-2)}$$

where:

r	=	the rank order of the observation
n	=	the number of observations
I	=	integer from 0 to r - 1

For relatively small data sets, the above formula will lead to selecting the largest observation as the upper confidence limit on the 90th percentile. However, the problem with using the maximum is that, in many environmental datasets, the largest observation is an outlier and would provide an unrealistic upper bound on the 90th percentile. It would, therefore, be preferable if the sample size *n* were large enough so that the formula yielded the second largest observation as the confidence limit (see for example Gibbons, 1971).

This motivates establishing the following criterion for setting an "adequate" sample size: pick the smallest *n* such that the nonparametric upper 95 percent confidence limit on the 90th percentile is the second largest value. Application of the above formula with *r* set to *n*-1 yields *n* = 45 for this minimum sample size.

For the upper 95 percent confidence limit to be a useful indicator of a high-end exposure, it must not be overly conservative (too large relative to the 90th percentile). It is, therefore, of interest to estimate the expected magnitude of the ratio of the upper 95 percent confidence limit to the 90th percentile. This quantity generally cannot be computed, since it is a function of the unknown distribution. However, to get a rough idea of its value, consider the particular case of a normal distribution. If the coefficient of variation (i.e., the standard deviation divided by the mean) is between 0.5 and 2.0, the expected value of the ratio in samples of 45 will be approximately 1.17 to 1.31; i.e., the upper 95 percent confidence limit will be only about 17 to 31 percent greater than the 90th percentile on the average.

It should be noted that the nonparametric estimate of the 95 percent upper confidence limit based on the second largest value can be obtained even if the data set has only two detects (it is assumed that the two detects are greater than the detection limit associated with all non-detects). This is an argument for using nonparametric rather than parametric estimation, since use of parametric methods would require more detected values. On the other hand, if non-detects were not a problem and the underlying distribution were known, a parametric estimate of the 90th percentile would generally be more precise.

As stated above, adequacy also depends on whether the samples are relevant to and representative of the population at risk. Data may, therefore, be adequate for some decisions and inadequate for others; this determination requires some professional judgment.

If the answer to Box 3 is no, based on the above determination of adequacy, then the decision tree moves to Box 4. As suggested by the separate boxes, the available data that will be reviewed as part of Box 4 do not meet the requirements necessary for Box 3. In Box 4, any limited data that are available (in addition to information about the chemical/physical properties, uses, and environmental fate and transformation, as well as any other information that would characterize the likelihood of exposure from various media for the chemical) are evaluated to make a qualitative determination of the relation of one exposure source to another. Although this information should always be reviewed at the outset, it is recommended that this information also be used to estimate the health-based water quality criteria. The estimate should be rather conservative (as indicated in the Decision Tree), given that it is either not based on actual monitoring data or is based on data that has been considered to be inadequate for a more accurate quantitative estimate. Therefore, greater uncertainties exist and accounting for variability is not really possible. Whether the available data are adequate and sufficiently representative will likely vary from chemical to chemical and may depend on the population of concern. If there are some data and/or other information to make a characterization of exposure, a determination can be made as to whether there are significant known or potential uses for the chemical/sources of exposure other than the source of concern (i.e., in this case, the drinking water and fish intakes relevant to developing an AWQC) that would allow one to anticipate/quantify those exposures (Box 6). If there are not, then it is recommended that 50 percent of the RfD or POD/UF can be safely apportioned to the source of concern (Box 7). While this leaves half of the RfD or POD/UF unapportioned, it is recommended as the maximum apportionment due to the lack of data needed to more accurately quantify actual or potential exposures. If the answer to the question in Box 6 is yes (there is multiple source information available for the exposures of concern), and some information is available on each source of exposure (Box 8A), apply the procedure in either Box 12 or Box 13 (depending on whether one or more criterion is relevant to the chemical), using a 50 percent ceiling (Box 8C)–again due to the lack of adequate data. If the answer to the question in Box 8A is no (there is no available information to characterize exposure), then the 20 percent default of the RfD or POD/UF is used (Box 8B).

If the answer to the question in Box 4 is no; that is, there are not sufficient data/information to characterize exposure, EPA intends to generally use the "default" assumption of 20 percent of the RfD or POD/UF (Box 5A) when deriving or revising the AWQC. It may be better to gather more data or information and re-review when this information becomes available (Box 5B). EPA has done this on occasion when resources permit the acquisition of additional data to enable better estimates of exposure instead of the default. If this is not possible, then the assumption of 20 percent of the RfD or POD/UF (Box 5A) should be used. Box 5A is likely to be used infrequently with the Exposure Decision Tree approach, given that the information described in Box 4 should be available in most cases. However, EPA intends to use 20 percent of the RfD (or POD/UF), which has also been used in past water program regulations, as the default value.

4.2.2.3 Regulatory Actions

If there are adequate data available to describe the central tendencies and high ends from each exposure source/pathway, then the levels of exposure relative to the RfD or POD/UF are compared (Box 9). If the levels of exposure for the chemical in question are not near (currently defined as greater than 80 percent), at, or in excess of the RfD or POD/UF, then a subsequent determination is made (Box 11) as to whether there is more than one health-based criterion or regulatory action relevant for the given chemical (i.e., more than one medium-specific criterion, standard or other guidance being planned, performed or in existence for the chemical). The subtraction method is considered acceptable when only one criterion (standard, etc.) is relevant for a particular chemical. In these cases, other sources of exposure can be considered "background" and can be subtracted from the RfD (or POD/UF). When more than one criterion is relevant to a particular chemical, apportioning the RfD (or POD/UF) via the percentage method is considered appropriate to ensure that the combination of health criteria, and thus the potential for resulting exposures, do not exceed the RfD (or POD/UF).

As indicated in Section 2, for EPA's national 304(a) criteria, the RSC intake estimates of non-water exposures (e.g., non-fish dietary exposures) will be based on arithmetic mean values when data are available. The assumed body weight used in calculating the national criteria will also be based on average values. The drinking water and fish intake values are 90^{th} percentile estimates. EPA believes that these assumptions will be protective of a majority of the population and recommends them for State and Tribal use. However, States and authorized Tribes have the flexibility to choose alternative intake rate and exposure estimate assumptions to protect specific population groups that they have chosen.

4.2.2.4 Apportionment Decisions

If the answer to the question in Box 11 is no (there is not more than one relevant medium-specific criterion/regulatory action), then the recommended method for setting a health-based water quality criterion is to utilize a subtraction calculation (Box 12). Specifically, appropriate intake values for each exposure source other than the source of concern are subtracted out. EPA will rely on average values commonly used in the Agency for food ingestion and inhalation rates, combined with mean contaminant concentration values, for calculating RSC estimates to subtract. Alternatively, contaminant concentrations could be selected based on the variability associated with those concentrations for each source. This implies that a case-by-case determination of the variability and the resulting intake chosen would be made, as each chemical evaluated can be expected to have different variations in concentration associated with each source of intake. However, EPA anticipates that the available data for most contaminants will not allow this for determination (based on past experience). Guidance addressing this possibility is addressed in the Exposure Assessment TSD. EPA does not recommend that high-end intakes be subtracted for every exposure source, since the combination may not be representative of any actually exposed population or individual. The subtraction method would also include an 80 percent ceiling and a 20 percent floor.

If the answer to the question in Box 11 is yes (there is more than one medium-specific criterion/regulation relevant), then the recommended method for setting health-based water quality criteria is to apportion the RfD or POD/UF among those sources for which health-based criteria are being set (Box 13). This is done via a percentage approach (with a ceiling and floor). This simply refers to the percentage of overall exposure contributed by an individual exposure source. For example, if for a particular chemical, drinking water were to represent half of total exposure and diet were to represent the other half, then the drinking water contribution (or RSC) would be 50 percent. The health-based criteria would, in turn, be set at 50 percent of the RfD or POD/UF. This method also utilizes an appropriate combination of intake values for each exposure source based on values commonly used in the Agency for food ingestion and inhalation rates, combined with mean contaminant concentration values.

Finally, if the levels of exposure for the chemical in question are near (currently defined as greater than 80 percent), at, or in excess of the RfD or POD/UF (i.e., the answer in Box 9 is yes), then the estimates of exposures and related uncertainties, recommended apportionment (either box 12 or 13), toxicity-related information, control issues, and other information are to be presented to managers for a decision (Box 10). The high levels referred to in Box 9 may be due to one source contributing that high level (while other sources contribute relatively little) or due to more than one source contributing levels that, in combination, approach or exceed the RfD or POD/UF. Management input may be necessary due to the control issues (i.e., cost and feasibility concerns), especially when multiple criteria are at issue. In practice, risk managers are routinely a part of decisions regarding regulatory actions and will be involved with any recommended outcome of the Exposure Decision Tree or, for that matter, any alternative to the Exposure Decision Tree. However, because exposures approach or exceed the RfD or POD/UF and because the feasibility of controlling different sources of exposure are complicated issues, risk managers will especially need to be directly involved in final decisions in these circumstances.

It is emphasized here that the procedures in these circumstances are not different than the procedures when exposures are not at or above the RfD (or POD/UF). Therefore, in these cases, estimates should be performed as with Boxes 11, 12, and 13. The recommendation should be made based on health-based considerations only, just as when the chemical in question was not a Box 10 situation. If the chemical is relevant to one health criterion or regulatory action only, the other sources of exposure could be subtracted from the RfD or POD/UF to determine if there is any leftover amount for setting the criterion. If the chemical is a multiple media criteria issue, then an apportionment should be made, even though it is possible that all sources would need to be reduced. Regardless of the outcome of Box 9, all apportionments made (via the methods of Boxes 12 or 13) should include a presentation of the uncertainty in the estimate and in the RfD or POD/UF for a more complete characterization.

The process for a Box 10 situation (versus a situation that is not) differs in that the presentations for Boxes 12 and 13 are based on apportionments (following the review of available information and a determination of appropriate exposure parameters) that must address additional control issues and may result in more selective reductions. With Box 10, one or several criteria possibilities (“scenarios”) could be presented for comparison along with implications of the effects of various control options. It is appropriate to present information in this manner to risk managers given the complexity of these additional control issues.

4.2.3 Additional Points of Clarification on the Exposure Decision Tree Approach for Setting AWQC

As with Box 9, if a determination is made in Box 8A (i.e., information is available to characterize exposure) that exposures are near, at, or above the RfD (or POD/UF) based on the available information, the apportionments made need to be presented to risk managers for decision. If information is lacking on some of the multiple exposure sources, then EPA would use a default of 20 percent of the RfD or POD/UF (Box 8B).

Results of both Boxes 12 and 13 rely on the 80 percent ceiling and 20 percent floor. The 80 percent ceiling was implemented to ensure that the health-based goal will be low enough to provide adequate protection for individuals whose total exposure to a contaminant is, due to any of the exposure sources, higher than currently indicated by the available data. This also increases the margin of safety to account for possible unknown sources of exposure. The 20 percent floor has been traditionally rationalized to prevent a situation where small fractional exposures are being controlled. That is, below that point, it is more appropriate to reduce other sources of exposure, rather than promulgating standards for *de minimus* reductions in overall exposure.

If it can be demonstrated that other sources and routes of exposure are not anticipated for the pollutant in question (based on information about its known/anticipated uses and chemical/physical properties), then EPA would use the 80 percent ceiling. EPA qualifies this policy with the understanding that as its policy on cumulative risk assessment continues to develop, the 80 percent RSC may prove to be underprotective.

In the cases of pollutants for which substantial data sets describing exposures across all anticipated pathways of exposure exist, and probabilistic analyses have been conducted based on those data, consideration will be given to the results of those assessments as part of the Exposure Decision Tree approach for setting AWQC.

For many chemicals, the rate of absorption from ingestion can differ substantially from absorption by inhalation. There is also available information for some chemicals that demonstrates appreciable differences in gastrointestinal absorption depending on whether the chemical is ingested from water, soil, or food. For some contaminants, the absorption of the contaminant from food can differ appreciably for plant compared with animal food products. Regardless of the apportionment approach used, EPA recommends using existing data on differences in bioavailability between water, air, soils, and different foods when estimating total exposure for use in apportioning the RfD or POD/UF. The Agency has developed such exposure estimates for cadmium (USEPA, 1994). In the absence of data, EPA will assume equal rates of absorption from different routes and sources of exposure.

4.2.4 Quantification of Exposure

When selecting contaminant concentration values in environmental media and exposure intake values for the RSC analysis, it is important to realize that each value selected (including those recommended as default assumptions in the AWQC equation) may be associated with a distribution of values for that parameter. Determining how various subgroups fall within the distributions of overall exposure and how the combination of exposure variables defines what population is being protected is a complicated and, perhaps, unmanageable task, depending on the amount of information available on each exposure factor included. Many times, the default assumptions used in EPA risk assessments are derived from the evaluation of numerous studies and are considered to generally represent a particular population group or a national average. Therefore, describing with certainty the exact percentile of a particular population that is protected with a resulting criteria is often not possible.

By and large, the AWQC are derived to protect the majority of the general population from chronic adverse health effects. However, as stated above in Section 4.1.1.1, States and authorized Tribes are encouraged to consider protecting population groups that they determine are at greater risk and, thus, would be better protected using alternative exposure assumptions. The ultimate choice of the contaminant concentrations used in the RSC estimate and the exposure intake rates requires the use of professional judgment. This is discussed in greater detail in the Exposure Assessment TSD.

4.2.5 Inclusion of Inhalation and Dermal Exposures

EPA intends to develop policy guidelines to apply to this Methodology for explicitly incorporating inhalation and dermal exposures. When estimating overall exposure to pollutants for AWQC development, EPA believes that the sources of inhalation and dermal exposures considered should include, on a case-by-case basis, both non-oral exposures from water and other inhalation and dermal sources (e.g., ambient or indoor air, soil). When the policy guidelines are completed, this Methodology will be refined to include that guidance.

A number of drinking water contaminants are volatile and thus diffuse from water into the air where they may be inhaled. In addition, drinking water is used for bathing and, thus, there is at least the possibility that some contaminants in water may be dermally absorbed. Volatilization may increase exposure via inhalation and decrease exposure via ingestion and dermal absorption. The net effect of volatilization and dermal absorption upon total exposure to volatile drinking water contaminants is unclear in some cases and varies from chemical to chemical. Dermal exposures are also important to consider for certain population groups, such as children and other groups with high soil contact.

With regard to additional non-water related exposures, it is clear that the type and magnitude of toxicity produced via inhalation, ingestion, and dermal contact may differ; that is, the route of exposure can affect absorption of a chemical and can otherwise modify its toxicity. For example, an inhaled chemical such as hydrogen fluoride may produce localized effects on the lung that are not observed (or only observed at much higher doses) when the chemical is administered orally. Also, the active form of a chemical (and principal toxicity) can be the parent compound and/or one or more metabolites. With this Methodology, EPA recommends that differences in absorption and toxicity by different routes of exposure be determined and accounted for in dose estimates and applied to the exposure assessment. EPA acknowledges that the issue of whether the doses received from inhalation and ingestion exposures are cumulative (i.e., toward the same threshold of toxicity) is complicated. Such a determination involves evaluating the chemical’s physical characteristics, speciation, and reactivity. A chemical may also exhibit different metabolism by inhalation versus oral exposure and may not typically be metabolized by all tissues. In addition, a metabolite may be much more or much less toxic than the parent compound. Certainly with a systemic effect, if the chemical absorbed via different routes enters the bloodstream, then there is some likelihood that it will contact the same target organ. Attention also needs to be given to the fact that both the RfD and RfC are derived based on the administered level. Toxicologists generally believe that the effective concentration of the active form of a chemical(s) at the site(s) of action determines the toxicity. If specific differences between routes of exposure are not known, it may be reasonable to assume that the internal concentration at the site from any route contributes as much to the same effect as any other route. A default of assuming equal absorption has often been used. However, for many of the chemicals that the Agency has reviewed, there is a substantial amount of information already known to determine differences in rates of absorption. For example, absorption is, in part, a function of blood solubility (i.e., Henry's Constant) and better estimations than the default can be made.

The RSC analyses that accompany the 2000 Human Health Methodology accommodate inclusion of inhalation exposures. Even if different target organs are involved between different routes of exposure, a conservative policy may be appropriate to keep all exposures below a certain level. A possible alternative is to set allowable levels (via an equation) such that the total of ingestion exposures over the ingestion RfD added to the total of inhalation exposures over the inhalation RfC is not greater than 1 (Note: the RfD is typically presented in mg/kg-day and the RfC is in mg/m^3). Again, EPA intends to develop guidance for this Methodology to explicitly incorporate inhalation and dermal exposures, and will refine the Methodology when that guidance is completed.

4.3 EXPOSURE FACTORS USED IN THE AWQC COMPUTATION

This section presents values for the specific exposure factors that EPA will use in the derivation of AWQC. These include human body weight, drinking water consumption rates, and fish ingestion rates.

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 population(s) that is (are) most susceptible to that pollutant. In addition, highly exposed populations should be considered when setting criteria. In general, exposure factor values specific to adults and relevant to lifetime exposures are the most appropriate values to consider when determining criteria to protect against effects from long-term exposure which, by and large, the human health criteria are derived to protect. However, infants and children may have higher rates of water and food consumption per unit body weight compared with adults and also may be more susceptible to some pollutants than adults (USEPA, 1997a). There may be instances where acute or subchronic developmental toxicity makes children the population group of concern. In addition, exposure of pregnant women to certain toxic chemicals may cause developmental effects in the fetus (USEPA, 1997b). Exposures resulting in developmental effects may be of concern for some contaminants and should be considered along with information applicable to long-term health effects when setting AWQC. (See Section 3.2 for further discussion of this issue.) Short-term exposure may include multiple intermittent or continuous exposures occurring over a week or so. Exposure factor values relevant for considering chronic toxicity, as well as exposure factor values relevant for short-term exposure developmental concerns, that could result in adverse health effects are discussed in the sections below. In appropriate situations, EPA may consider developing criteria for developmental health effects based on exposure factor values specific to children or to women of childbearing age. EPA encourages States and Tribes to do the same when health risks are associated with short-term exposures.

EPA believes that the recommended exposure factor default intakes for adults in chronic exposure situations are adequately protective of the population over a lifetime. In providing additional exposure intake values for highly exposed subpopulations (e.g., sport anglers, subsistence fishers), EPA is providing flexibility for States and authorized Tribes to establish criteria specifically targeted to provide additional protection using adjusted values for exposure parameters for body weight, drinking water intake, and fish consumption. The exposure factor values provided for women of childbearing age and children would only be used in the circumstances indicated above.

Each of the following sections recommends exposure parameter values for use in developing AWQC. These are based on both science policy decisions that consider the best available data, as well as risk management judgments regarding the overall protection afforded by the choice in the derivation of AWQC. These will be used by EPA to derive new, or revise existing, 304(a) national criteria.

4.3.1 Human Body Weight Values for Dose Calculations

The source of data for default human body weights used in deriving the AWQC is the third *National Health and Nutrition Examination Survey* (NHANES III). NHANES III represents a very large interview and examination endeavor of the National Center for Health Statistics (NCHS) and included participation from the Centers for Disease Control (CDC). The NHANES III was conducted on a nationwide probability sample of over 30,000 persons from the civilian, non-institutionalized population of the United States. The survey began in October 1988 and was completed in October 1994 (WESTAT, 2000; McDowell, 2000). Body weight data were taken from the NHANES III Examination Data File. Sampling weights were applied to all persons examined in the Mobile Examination Centers (MECs) or at home, as was recommended by the NHANES data analysts (WESTAT, 2000).

The NHANES III survey has numerous strengths and very few weaknesses. Its primary strengths are the national representativeness, large sample size, and precise estimates due to this large sample size. Another strength is its high response rate; the examination rate was 73 percent overall, 89 percent for children under 1 year old, and approximately 85 percent for children 1 to 5 years old (McDowell, 2000). Interview response rates were even higher, but the body weight data come from the NHANES examinations; that is, all body weights were carefully measured by survey staff, rather than the use of self-reported body weights. The only significant potential weakness of the NHANES data is the fact that the data are now between 6 and 12 years old. Given that there were upward trends in body weight from NHANES II to NHANES III, and that NCHS has indicated the prevalence of overweight people increased in all age groups, the data could underestimate current body weights if that trend has continued (WESTAT, 2000).

The NHANES III collected standard body measurements of sample subjects, including height and weight, that were made at various times of the day and in different seasons of the year. This technique was used because one’s weight may vary between winter and summer and may fluctuate with recency of food and water intake and other daily activities (McDowell, 2000).

As with the other exposure assumptions, States and authorized Tribes are encouraged to use alternative body weight assumptions for population groups other than the general population and to use local or regional data over default values as more representative of their target population group(s).

4.3.1.1 <u>Rate Protective of Human Health from Chronic Exposure</u>

EPA recommends maintaining the default body weight of 70 kg for calculating AWQC as a representative average value for both male and female adults. As previously indicated, exposure factor values specific to adults are recommended to protect against effects from long-term exposure. The value of 70 kg is based on the following information. In the analysis of the NHANES III database, median and mean values for female adults 18-74 years old are 65.8 and 69.5 kg, respectively (WESTAT, 2000). For males in the same age range, the median and mean values are 79.9 and 82.1 kg, respectively. The mean body weight value for men and women ages 18 to 74 years old from this survey is 75.6 kg (WESTAT, 2000). This mean value is higher than the mean value for adults ages 20-64 years old of 70.5 kg from a study by the National Cancer Institute (NCI) which primarily measured drinking water intake (Ershow and Cantor, 1989). The NCI study is described in the subsection on Drinking Water Intake Rates that follows (Section 4.3.2). The value from the NHANES III database is also higher than the value given in the revised EPA *Exposure Factors Handbook* (USEPA, 1997b), which recommends 71.8 kg for adults, based on the older NHANES II data. The Handbook also acknowledges the commonly used 70 kg value and encourages risk assessors to use values which most accurately reflect the exposed population. However, the point is also made that the 70 kg value is used in the derivation of cancer slope factors and unit risks that appear in IRIS. Consistency is advocated between the dose-response relationship and exposure factors assumed. Therefore, if a value higher than 70 kg is used, the assessor needs to adjust the dose-response relationship as described in the Appendix to Chapter 1, Volume 1 of the Handbook (USEPA, 1997b).

4.3.1.2 <u>Rates Protective of Developmental Human Health Effects</u>

As noted above, pregnant women may represent a more appropriate population for which to assess risks from exposure to chemicals in ambient waters in some cases, because of the potential for developmental effects in fetuses. In these cases, body weights representative of women of childbearing age may be appropriate to adequately protect offspring from such health effects. To determine a mean body weight value appropriate to this population, separate body weight values for women in individual age groups within the range of 15 to 44 years old were analyzed from the NHANES III data (WESTAT, 2000). The resulting median and mean body weight values are 63.2 and 67.3 kg, respectively. Ershow and Cantor (1989) present body weight values specifically for pregnant women included in the survey; median and mean weights are 64.4 and 65.8 kilograms, respectively. Ershow and Cantor (1989), however, do not indicate the ages of these pregnant women. Based on this information for women of childbearing age and pregnant women, EPA recommends use of a body weight value of 67 kg in cases where pregnant women are the specific population of concern and the chemical of concern exhibits reproductive and/or developmental effects (i.e., the critical effect upon which the RfD or POD/UF is based). Using the 67 kg assumption would result in lower (more protective) criteria than criteria based on 70 kg.

As discussed earlier, because infants and children generally have a higher rate of water and food consumption per unit body weight compared with adults, a higher intake rate per unit body weight may be needed when comparing estimated exposure doses with critical doses when RfDs are based on health effects in children. To calculate intake rates relevant to such effects, the body weight of children should be used. As with the default body weight for pregnant women, EPA is not recommending the development of additional AWQC (i.e., similar to drinking water health advisories) that focus on acute or short-term effects, since these are not seen routinely as having a meaningful role in the water quality criteria program. However, there may be circumstances where the consideration of exposures for these groups is warranted. Although the AWQC generally are based on chronic health effects data, they are intended to also be protective with respect to adverse effects that may reasonably be expected to occur as a result of elevated shorter-term exposures. EPA acknowledges this as a potential course of action and is, therefore, recommending these default values which EPA would consider in an appropriate circumstance and for States and authorized Tribes to utilize in such situations.

EPA is recommending an assumption of 30 kg as a default child's body weight to calculate AWQC to provide additional protection for children when the chemical of concern indicates health effects in children are of predominant concern (i.e., test results show children are more susceptible due to less developed immune systems, neurological systems, and/or lower body weights). The value is based on the mean body weight value of 29.9 kg for children ages 1 to14 years old, which combines body weight values for individual age groups within this larger group. The mean value is based on body weight information from NHANES III for individual-year age groups between one and 14 years old (WESTAT, 2000). A mean body weight of 28 kg is obtained using body weight values from Ershow and Cantor (1989) for five age groups within this range of 0-14 years and applying a weighting method for different ages by population percentages from the U.S. Bureau of the Census. The 30 kg assumption is also consistent with the age range for children used with the estimated fish intake rates. Unfortunately, fish intake rates for finer age group divisions are not possible due to the limited sampling base from the fish intake survey; there is limited confidence in calculated values (e.g., the mean) for such fine age groups. Given this limitation, the broad age category of body weight for children is suitable for use with the default fish intake assumption.

Given the hierarchy of preferences regarding the use of fish intake information (see Section 4.3.3), States may have more comprehensive data and prefer to target a more narrow, younger age group. If States choose to specifically evaluate toddlers, EPA recommends using 13 kg as a default body weight assumption for children ages 1 to 3 years old. The median and mean values of body weight for children 1 to 3 years old are 13.2 and 13.1 kg, respectively, based on an analysis of the NHANES III database (WESTAT, 2000). The NHANES III median and mean values for females between 1 and 3 years old are 13.0 and 12.9 kg, respectively, and are 13.4 and 13.4 kg for males, respectively. Median and mean body weight values from the earlier Ershow and Cantor (1989) study for children ages 1 to 3 years old were 13.6 and 14.1 kg, respectively. Finally, if infants are specifically evaluated, EPA recommends a default body weight of 7 kg based on the NHANES III analysis. Median and mean body weights for both male and female infants (combined) 2 months old were 6.3 and 6.3 kg, respectively, and for infants 3 months old were 7.0 and 6.9 kg, respectively. With the broader age category of males and females 2 to 6 months old, median and mean body weights were 7.4 and 7.4 kg, respectively. The NHANES analysis did not include infants under 2 months of age. Although EPA is not recommending body weight values for newborns, the NCHS National Vital Statistics Report indicates that, for 1997, the median birth weight ranged from 3 to 3.5 kg, according to WESTAT (2000).

Body weight values for individual ages within the larger range of 0-14 years are listed in the Exposure Assessment TSD for those States and authorized Tribes who wish to use body weight values for these individual groups. States and Tribes may wish to consider certain general developmental ages (e.g., infants, pre-adolescents, etc.), or certain specific developmental landmarks (e.g., neurological development in the first four years), depending on the chemical of concern. EPA encourages States and authorized Tribes to choose a body weight intake from the tables presented in the TSD, if they believe a particular age subgroup is more appropriate.

4.3.2 Drinking Water Intake Rates

The basis for the drinking water intake rates (also for the fish intake rates presented in Section 4.3.3) is the 1994-96 Continuing Survey of Food Intake by Individuals *(*CSFII) conducted by the U.S. Department of Agriculture (USDA, 1998). The CSFII survey collects dietary intake information from nationally representative samples of non-institutionalized persons residing in United States households. Households in these national surveys are sampled from the 50 states and the District of Columbia. Each survey collects daily consumption records for approximately 10,000 food codes across nine food groups. These food groups are (1) milk and milk products; (2) meat, poultry, and fish; (3) eggs; (4) dry beans, peas, legumes, nuts, and seeds; (5) grain products; (6) fruit; (7) vegetables; (8) fats, oils, and salad dressings; and (9) sweets, sugars, and beverages. The survey also asks each respondent how many fluid ounces of plain drinking water he or she drank during each of the survey days. In addition, the CSFII collects household information, including the source of plain drinking water, water used to prepare beverages, and water used to prepare foods. Data provide "up-to-date information on food intakes by Americans for use in policy formation, regulation, program planning and evaluation, education, and research." The survey is "the cornerstone of the National Nutritional Monitoring and Related Research Program, a set of related federal activities intended to provide regular information on the nutritional status of the United States population" (USDA, 1998).

The 1994-96 CSFII was conducted according to a stratified, multi-area probability sample organized using estimates of the 1990 United States population. Stratification accounted for geographic location, degree of urbanization, and socioeconomics. Each year of the survey consisted of one sample with oversampling for low-income households.

Survey participants provided two non-consecutive, 24-hour days of dietary data. Both days' dietary recall information was collected by an in-home interviewer. Interviewers provided participants with an instructional booklet and standard measuring cups and spoons to assist them in adequately describing the type and amount of food ingested. If the respondent referred to a cup or bowl in their own home, a 2-cup measuring cup was provided to aid in the calculation of the amount consumed. The sample person could fill their own bowl or cup with water to represent the amount eaten or drunk, and the interviewer could then measure the amount consumed by pouring it into the 2-cup measure. The Day 2 interview occurred three to 10 days after the Day 1 interview, but not on the same day of the week. The interviews allowed participants "three passes" through the daily intake record to maximize recall (USDA, 1998). Proxy interviews were conducted for children aged six and younger and sampled individuals unable to report due to mental or physical limitations. The average questionnaire administration time for Day 1 intake was 30 minutes, while Day 2 averaged 27 minutes.

Two days of dietary recall data were provided by 15,303 individuals across the three survey years. This constitutes an overall two-day response rate of 75.9 percent. Survey weights were corrected by the USDA for nonresponse.

All three 1994-96 CSFII surveys are multistage, stratified-cluster samples. Sample weights, which project the data from a sampled individual to the population, are based on the probability of an individual being sampled at each stage of the sampling design. The sample weights associated with each individual reporting two days of consumption data were adjusted to correct for nonresponse bias.

The 1994-96 CSFII surveys have advantages and limitations for estimating per capita water (or fish) consumption. The primary advantage of the CSFII surveys is that they were designed and conducted by the USDA to support unbiased estimation of food consumption across the population in the United States and the District of Columbia. Second, the survey is designed to record daily intakes of foods and nutrients and support estimation of food consumption.

One limitation of the 1994-96 CSFII surveys is that individual food consumption data were collected for only two days–a brief period which does not necessarily depict "usual intake." Usual dietary intake is defined as "the long-run average of daily intakes by an individual." Upper percentile estimates may differ for short-term and longer-term data because short-term food consumption data tend to be inherently more variable. It is important to note, however, that variability due to duration of the survey does not result in bias of estimates of overall mean consumption levels. Also, the multistage survey design does not support interval estimates for many of the subpopulations of interest because of sparse representation in the sample. Subpopulations with sparse representation include Native Americans on reservations and certain ethnic groups. While these individuals are participants in the survey, they are not present in sufficient numbers to support consumption estimates.

Despite these limitations, the CSFII is considered one of the best sources of current information on consumption of water and fish-containing foods. The objective of estimating per capita water and fish consumption by the United States population is compatible with the statistical design and scope of the CSFII survey.

4.3.2.1 Rate Protective of Human Health from Chronic Exposure

EPA recommends maintaining the default drinking water intake rate of 2 L/day to protect most consumers from contaminants in drinking water. EPA believes that the 2 L/day assumption is representative of a majority of the population over the course of a lifetime. EPA also notes that there is comparatively little variability in water intake within the population compared with fish intake (i.e., drinking water intake varies, by and large, by about a three-fold range, whereas fish intake can vary by 100-fold). EPA believes that the 2 L/day assumption continues to represent an appropriate risk management decision. The results of the 1994-96 CSFII analysis indicate that the arithmetic mean, 75th, and 90th percentile values for adults 20 years and older are 1.1, 1.5, and 2.2 L/day, respectively (USEPA, 2000a). The 2 L/day value represents the 86th percentile for adults. These values can also be compared to data from an older National Cancer Institute (NCI) study, which estimated intakes of tapwater in the United States based on the USDA's 1977-78 Nationwide Food Consumption Survey (NFCS). The arithmetic mean, 75th, and 90th percentile values for adults 20 - 64 years old were 1.4, 1.7, and 2.3 L/day, respectively (Ershow and Cantor, 1989). The 2 L/day value represents the 88th percentile for adults from the NCI study.

The 2 L/day assumption was used with the original 1980 AWQC National Guidelines and has also been used in EPA's drinking water program. EPA believes that the newer studies continue to support the use of 2 L/day as a reasonable and protective consumption rate that represents the intake of most water consumers in the general population. However, individuals who work or exercise in hot climates could have water consumption rates significantly above 2 L/day, and EPA believes that States and Tribes should consider regional or occupational variations in water consumption.

4.3.2.2 Rates Protective of Developmental Human Health Effects

Based on the 1994-96 CSFII study data, EPA also recommends 2 L/day for women of childbearing age. The analysis for women of childbearing age (ages 15-44) indicate mean, 75th, and 90th percentile values of 0.9, 1.3, and 2.0 L/day, respectively. These rates compare well with those based on an analysis of tapwater intake by pregnant and lactating women by Ershow et al. (1991), based on the older USDA data, for women ages 15-49. Arithmetic mean, 75th and 90th percentile values were 1.2, 1.5, and 2.2 L/day, respectively, for pregnant women. For lactating women, the arithmetic mean, 75th and 90th percentile values were 1.3, 1.7, and 1.9 L/day, respectively.

As noted above, because infants and children have a higher daily water intake per unit body weight compared with adults, a water consumption rate measured for children is recommended for use when RfDs are based on health effects in children. Use of this water consumption rate should result in adequate protection for infants and children when setting criteria based on health effects for this target population. EPA recommends a drinking water intake of 1 L/day to, again, represent a majority of the population of children that consume drinking water. The results of the 1994-96 CSFII analysis indicate that for children from 1 to 10 years of age, the arithmetic mean, 75th, and 90th percentile values are 0.4, 0.6, and 0.9 L/day, respectively (USEPA, 2000a). The 1 L/day value represents the 93rd percentile for this group. The arithmetic mean, 75th, and 90th percentile values for smaller children, ages 1 to 3 years, are 0.3, 0.5, and 0.7 L/day, respectively. The 1 L/day value represents the 97th percentile of the group ages 1 to 3 years old. For the category of infants under 1 year of age, the arithmetic mean, 75th, and 90th percentile values are 0.3, 0.7, and 0.9 L/day, respectively. These data can similarly be compared to those of the older National Cancer Institute (NCI) study. The arithmetic mean, 75th, and 90th percentile values for children 1 to 10 years old were 0.74, 0.96, and 1.3 L/day, respectively. The mean, 75^{th}, and 90^{th} percentile values for children 1 to 3 years old in the NCI study were 0.6, 0.8, and 1.2 L/day, respectively. Finally, the mean, 75^{th}, and 90^{th} percentile values for infants less than 6 months old were 0.3, 0.3, and 0.6 L/day, respectively (Ershow and Cantor, 1989).

4.3.2.3 <u>Rates Based on Combining Drinking Water Intake and Body Weight</u>

As an alternative to considering body weight and drinking water intake rates separately, EPA is providing rates based on intake per unit body weight data (in units of ml/kg) in the Exposure Assessment TSD, with additional discussion on their use. These rates are based on self-reported body weights from the CSFII survey respondents for the 1994-96 data. While EPA intends to derive or revise national default criteria on the separate intake values and body weights, in part due to the strong input received from its State stakeholders, the ml/kg-BW/day values are provided in the TSD for States or authorized Tribes that prefer their use. It should be noted that in their 1993 review, EPA's Science Advisory Board (SAB) felt that using drinking water intake rate assumptions on a per unit body weight basis would be more accurate, but did not believe this change would appreciably affect the criteria values (USEPA, 1993).

4.3.3 Fish Intake Rates

The basis for the fish intake rates is the 1994-96 CSFII conducted by the USDA, and described above in Section 4.3.2.

4.3.3.1 <u>Rates Protective of Human Health from Chronic Exposure</u>

EPA recommends a default fish intake rate of 17.5 grams/day to adequately protect the general population of fish consumers, based on the 1994 to 1996 data from the USDA's CSFII Survey. EPA will use this value when deriving or revising its national 304(a) criteria. This value represents the 90^{th} percentile of the 1994-96 CSFII data. This value also represents the uncooked weight estimated from the CSFII data, and represents intake of freshwater and estuarine finfish and shellfish only. For deriving AWQC, EPA has also considered the States' and Tribes' needs to provide adequate protection from adverse health effects to highly exposed populations such as recreational and subsistence fishers, in addition to the general population. Based on available studies that characterize consumers of fish, recreational fishers and subsistence fishers are two distinct groups whose intake rates may be greater than the general population. It is, therefore, EPA's decision to discuss intakes for these two groups, in addition to the general population.

EPA recommends default fish intake rates for recreational and subsistence fishers of 17.5 grams/day and 142.4 grams/day, respectively. These rates are also based on uncooked weights for fresh/estuarine finfish and shellfish only. However, because the level of fish intake in highly exposed populations varies by geographical location, EPA suggests a four preference hierarchy for States and authorized Tribes to follow when deriving consumption rates that encourages use of the best local, State, or regional data available. A thorough discussion of the development of this policy method and relevant data sources is contained in the Exposure Assessment TSD. The hierarchy is also presented here because EPA strongly emphasizes that States and authorized

Tribes should consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s). The four preference hierarchy is: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates.

The recommended four preference hierarchy is intended for use in evaluating fish intake from fresh and estuarine species only. Therefore, to protect humans who additionally consume marine species of fish, the marine portion should be considered an *other source of exposure* when calculating an RSC for dietary intake. Refer to the Exposure Assessment TSD for further discussion. States and Tribes need to ensure that when evaluating overall exposure to a contaminant, marine fish intake is not double-counted with the other dietary intake estimate used. Coastal States and authorized Tribes that believe accounting for total fish consumption (i.e., fresh/estuarine <u>and</u> marine species) is more appropriate for protecting the population of concern may do so, provided that the marine intake component is not double-counted with the RSC estimate. Tables of fish consumption intakes based on the CSFII in the TSD provide rates for fresh/estuarine species, marine species, and total (combined) values to facilitate this option for States and Tribes. Throughout this section, the terms "fish intake" or "fish consumption" are used. These terms refer to the consumption of finfish <u>and</u> shellfish, and the CSFII survey includes both. States and Tribes should ensure that when selecting local or regionally-specific studies, both finfish and shellfish are included when the population exposed are consumers of both types.

EPA's first preference is that States and authorized Tribes use the results from fish intake surveys of local watersheds within the State or Tribal jurisdiction to establish fish intake rates that are representative of the defined populations being addressed for the particular waterbody. Again, EPA recommends that data indicative of fresh/estuarine species only be used which is, by and large, most appropriate for developing AWQC. EPA also recommends the use of uncooked weight intake values, which is discussed in greater detail with the fourth preference. States and authorized Tribes may use either high-end values (such as the 90^{th} or 95^{th} percentile values) or average values for an identified population that they plan to protect (e.g., subsistence fishers, sport fishers, or the general population). EPA generally recommends that arithmetic mean values should be the lowest value considered by States or Tribes when choosing intake rates for use in criteria derivation. When considering geometric mean (median) values from fish consumption studies, States and authorized Tribes need to ensure that the distribution is based on survey respondents who reported consuming fish because surveys based on both consumers and nonconsumers can often result in median values of zero. If a State or Tribe chooses values (whether the central tendency or high-end values) from studies that particularly target high-end consumers, these values should be compared to high-end fish intake rates for the general population to make sure that the high-end consumers within the general population would be protected by the chosen intake rates. EPA believes this is a reasonable procedure and is also consistent with the recent Great Lakes Water Quality Initiative (known as the "GLI") (USEPA, 1995). States and authorized Tribes may wish to conduct their own surveys of fish intake, and EPA guidance is available on methods to conduct such studies in *Guidance for Conducting Fish and Wildlife Consumption Surveys* (USEPA, 1998). Results from broader geographic regions in which the State or Tribe is located can also be used, but may not be as applicable as results from local watersheds. Since such studies would ultimately form the basis of a State or Tribe's AWQC, EPA would review any surveys of fish intake for consistency with the principles of EPA's guidance as part of the Agency's review of water quality standards under Section 303(c).

If surveys conducted in the geographic area of the State or Tribe are not available, EPA's second preference is that States and authorized Tribes consider results from existing fish intake surveys that reflect similar geography and population groups (e.g., from a neighboring State or Tribe or a similar watershed type), and follow the method described above regarding target values to derive a fish intake rate. Again, EPA recommends the use of uncooked weight intake values and the use of fresh/estuarine species data only. Results of existing local and regional surveys are discussed in greater detail in the TSD.

If applicable consumption rates are not available from local, State, or regional surveys, EPA's third preference is that States and authorized Tribes select intake rate assumptions for different population groups from national food consumption surveys. EPA has analyzed one such national survey, the 1994-96 CSFII. As described in Section 4.3.2, this survey, conducted annually by the USDA, collects food consumption information from a probability sample of the population of all 50 states. Respondents to the survey provide two days of dietary recall data. A detailed description of the combined 1994-96 CSFII survey, the statistical methodology, and the results and uncertainties of the EPA analyses are provided in a separate EPA report (USEPA, 2000b). The Exposure Assessment TSD for this Methodology presents selected results from this report including point and interval estimates of combined finfish and shellfish consumption for the mean, 50^{th} (median), 90^{th}, 95^{th}, and 99^{th} percentiles. The estimated fish consumption rates are by fish habitat (i.e., freshwater/estuarine, marine and all habitats) for the following population groups: (1) all individuals; (2) individuals age 18 and over; (3) women ages 15-44; and (4) children age 14 and under. Three kinds of estimated fish consumption rates are provided: (1) per capita rates (i.e., rates based on consumers and nonconsumers of fish from the survey period–refer to the TSD for further discussion); (2) consumers-only rates (i.e., rates based on respondents who reported consuming finfish or shellfish during the two-day reporting period); and (3) per capita consumption by body weight (i.e., per capita rates reported as milligrams of fish per kilogram of body weight per day).

EPA's fourth preference is that States and authorized Tribes use as fish intake assumptions the following default rates, based on the 1994-96 CSFII data, that EPA believes are representative of fish intake for different population groups: 17.5 grams/day for the general adult population and sport fishers, and 142.4 grams/day for subsistence fishers. These are risk management decisions that EPA has made after evaluating numerous fish intake surveys. These values represent the uncooked weight intake of freshwater/estuarine finfish and shellfish. As with the other preferences, EPA requests that States and authorized Tribes routinely consider whether there is a substantial population of sport fishers or subsistence fishers when developing site-specific estimates, rather than automatically basing them on the typical individual. Because the combined 1994-96 CSFII survey is national in scope, EPA will use the results from this survey to estimate fish intake for deriving national criteria. EPA has recognized the data gaps and uncertainties associated with the analysis of the 1994-96 CSFII survey in the process of making its default recommendations. The estimated mean of freshwater and estuarine fish ingestion for adults is 7.50 grams/day, and the median is 0 grams/day. The estimated 90^{th}

percentile is 17.53 grams/day; the estimated 95th percentile is 49.59 grams/day; and the estimated 99th percentile is 142.41 grams/day. The median value of 0 grams/day may reflect the portion of individuals in the population who never eat fish as well as the limited reporting period (2 days) over which intake was measured. By applying as a default 17.5 grams/day for the general adult population, EPA intends to select an intake rate that is protective of a majority of the population (again, the 90th percentile of consumers and nonconsumers according to the 1994-96 CSFII survey data). Trophic level breakouts are: TL2 = 3.8 grams/day; TL3 = 8.0 grams/day; and TL4 = 5.7 grams/day. EPA further considers 17.5 grams/day to be indicative of the average consumption among sport fishers based on averages in the studies reviewed, which are presented in the Exposure Assessment TSD. Similarly, EPA believes that the assumption of 142.4 grams/day is within the range of average consumption estimates for subsistence fishers based on the studies reviewed. Experts at the 1992 National Workshop that initiated the effort to revise this Methodology acknowledged that the national survey high-end values are representative of average rates for highly exposed groups such as subsistence fishermen, specific ethnic groups, or other highly exposed people. EPA is aware that some local and regional studies indicate greater consumption among Native American, Pacific Asian American, and other subsistence consumers, and recommends the use of those studies in appropriate cases, as indicated by the first and second preferences. Again, States and authorized Tribes have the flexibility to choose intake rates higher than an average value for these population groups. If a State or authorized Tribe has not identified a separate well-defined population of high-end consumers and believes that the national data from the 1994-96 CSFII are representative, they may choose these recommended rates.

As indicated above, the default intake values are based on the uncooked weights of the fish analyzed. There has been some question regarding whether to use cooked or uncooked weights of fish intake for deriving the AWQC. Studies show that, typically, with a filet or steak of fish, the weight loss in cooking is about 20 percent; that is, the uncooked weight is approximately 20 percent higher (Jacobs et al., 1998). This obviously means that using uncooked weights results in a slightly higher intake rate and slightly more stringent AWQC. In researching consumption surveys for this proposal, EPA has found that some surveys have reported rates for cooked fish, others have reported uncooked rates, and many more are unclear as to whether cooked or uncooked rates are used. The basis of the CSFII survey was prepared or *as consumed* intakes; that is, the survey respondents estimated the weight of fish that they consumed. This was also true with the GLI (which was specifically based on studies describing consumption rates of cooked fish) and, by and large, cooked fish is what people consume. However, EPA's *Guidance For Assessing Chemical Contaminant Data For Use In Fish Advisories* recommends analysis and advisories based on uncooked fish (USEPA, 1997a). EPA considered the potential confusion over the fact that the uncooked weights are used in the fish advisory program. Further, the measures of a contaminant in fish tissue samples that are applicable to compliance monitoring and the permitting program are related to the uncooked weights. The choice of intakes is also complicated by factors such as the effect of the cooking process, the different parts of a fish where a chemical may accumulate, and the method of preparation.

After considering all of the above (in addition to public input received), EPA will derive its national default criteria based on the uncooked weight fish intakes. The Exposure

Assessment TSD provides additional guidance on site-specific modifications. Specifically, an alternate approach is described for calculating AWQC with the *as consumed* weight–which is more directly associated with human exposure and risk–and then adjusting the value by the approximate 20 percent loss to an uncooked equivalent (thereby representing the same relative risk as the *as consumed* value). This approach results in a different AWQC value (than using the uncooked weights) and represents a more direct translation of the *as consumed* risk to the uncooked equivalent. However, EPA understands that it is more scientifically rigorous and may be too intensive of a process for States and Tribes to rely on. The option is presented in the TSD to offer States and authorized Tribes greater flexibility with their water quality standards program.

The default fish intake values also reflect specific designations of species classified in accordance with information regarding the life history of the species or based on landings information form the National Marine Fisheries Service. Most significantly, salmon has been reclassified from a freshwater/estuarine species to a marine species. As marine harvested salmon represents approximately 99 percent of salmon consumption in the 1994-96 CSFII Survey, removal reduces the overall fresh/estuarine fish consumption rate by 13 percent. Although they represent a very small percentage of freshwater/estuarine intake, land-locked and farm-raised salmon consumed by 1994-96 CSFII respondents are still included. The rationale for the default intake species designations is explained in the Exposure Assessment TSD. Once again, EPA emphasizes the flexibility for States and authorized Tribes to use alternative assumptions based on local or regional data to better represent their population groups of concern.

4.3.3.2 <u>Rates Protective of Developmental Human Health Effects</u>

Exposures resulting in health effects in children or developmental effects in fetuses may be of primary concern. As discussed at the beginning of this section on exposure factors used, in a situation where acute or sub-chronic toxicity and exposure are the basis of an RfD (or POD/UF), EPA will consider basing its national default criteria on children or women of childbearing age, depending on the target population at greatest risk. EPA recommends that States and authorized Tribes use exposure factors for children or women of childbearing age in these situations. As stated previously, EPA is not recommending the development of additional AWQC but is acknowledging that basing a criterion on these population groups is a potential course of action and is, therefore, recommending the following default intake rates for such situations.

EPA's preferences for States and authorized Tribes in selecting values for intake rates relevant for children is the same as that discussed above for establishing values for average daily consumption rates for chronic effects; i.e., in decreasing order of preference, results from fish intake surveys of local watersheds, results from existing fish intake surveys that reflect similar geography and population groups, the distribution of intake rates from nationally based surveys (e.g., the CSFII), or lastly, the EPA default rates. When an RfD is based on health effects in children, EPA recommends a default intake rate of 156.3 grams/day for assessing those contaminants that exhibit adverse effects. This represents the 90th percentile consumption rate for actual consumers of freshwater/estuarine finfish and shellfish for children ages 14 and under using the combined 1994 to 1996 results from the CSFII survey. The value was calculated based on data for only those children who ate fish during the 2-day survey period, and the intake was averaged over the number of days during which fish was actually consumed. EPA believes that by selecting the data for consumers only, the 90th percentile is a reasonable intake rate to approximate consumption of fresh/estuarine finfish and shellfish within a short period of time for use in assessments where adverse effects in children are of primary concern. As discussed previously, EPA will use a default body weight of 30 kg to address potential acute or subchronic effects from fish consumption by children. EPA is also providing these default intake values for States and authorized Tribes that choose to provide additional protection when developing criteria that they believe should be based on health effects in children. This is consistent with the rationale in the recent GLI (USEPA, 1995) and is an approach that EPA believes is reasonable. Distributional information on intake values relevant for assessing exposure when health effects to children are of concern is presented in the Exposure Assessment TSD.

There are also cases in which pregnant women may be the population of most concern, due to the possibility of developmental effects that may result from exposures of the mother to toxicants. In these cases, fish intake rates specific to females of childbearing age are most appropriate when assessing exposures to developmental toxicants. When an RfD is based on developmental toxicity, EPA proposes a default intake rate of 165.5 grams/day for assessing exposures for women of childbearing age from contaminants that cause developmental effects. This is equivalent to the 90th percentile consumption rate for actual consumers of freshwater/ estuarine finfish and shellfish for women ages 15 to 44 using the combined 1994 to1996 results from the CSFII survey. As with the rate for children, this value represents only those women who ate fish during the 2-day survey period. As discussed previously, EPA will use a default body weight of 67 kg for women of childbearing age.

4.3.3.3 <u>Rates Based on Combining Fish Intake and Body Weight</u>

As with the drinking water intake values, EPA is providing values for fish intake based on a per unit body weight basis (in units of mg/kg) in the Exposure Assessment TSD. These rates use the self-reported body weights of the 1994-96 CSFII survey. Again, while EPA intends to derive or revise national default criteria on the separate intake values and body weights, the mg/kg-BW/day values are provided in the TSD for States or authorized Tribes that prefer their use.

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5. BIOACCUMULATION

5.1 INTRODUCTION

Aquatic organisms can accumulate certain chemicals in their bodies when exposed to these chemicals through water, their diet, and other sources. This process is called bioaccumulation. The magnitude of bioaccumulation by aquatic organisms varies widely depending on the chemical but can be extremely high for some highly persistent and hydrophobic chemicals. For such highly bioaccumulative chemicals, concentrations in aquatic organisms may pose unacceptable human health risks from fish and shellfish consumption even when concentrations in water are too low to cause unacceptable health risks from drinking water consumption alone. These chemicals may also biomagnify in aquatic food webs, a process whereby chemical concentrations increase in aquatic organisms of each successive trophic level due to increasing dietary exposures (e.g., increasing concentrations from algae, to zooplankton, to forage fish, to predatory fish).

In order to prevent harmful exposures to waterborne chemicals through the consumption of contaminated fish and shellfish, national 304(a) water quality criteria for the protection of human health must address the process of chemical bioaccumulation in aquatic organisms. For deriving national 304(a) criteria to protect human health, EPA accounts for potential bioaccumulation of chemicals in fish and shellfish through the use of national bioaccumulation factors (BAFs). A national BAF is a ratio (in L/kg) that relates the concentration of a chemical in water to its expected concentration in commonly consumed aquatic organisms in a specified trophic level. An illustration of how national BAFs are used in the derivation of 304(a) criteria for carcinogens using linear low-dose extrapolation is shown in the following equation:

$$\mathrm{AWQC} = \mathrm{RSD} \bullet \left(\frac{\mathrm{BW}}{\mathrm{DI} + \sum_{i=2}^{4} (\mathrm{FI}_i \bullet \mathrm{BAF}_i)} \right) \qquad \text{(Equation 5-1)}$$

where:

RSD	=	Risk specific dose (mg/kg-day)
BW	=	Human body weight (kg)
DI	=	Drinking water intake (L/day)
FI_i	=	Fish intake at trophic level I, where I=2, 3, and 4;
BAF_i	=	National bioaccumulation factor at trophic level I, where I=2, 3, and 4

The purpose of this chapter is to present EPA's recommended methodology for deriving national bioaccumulation factors for setting national 304(a) water quality criteria to protect human health. A detailed scientific basis of the recommended national BAF methodology is provided in the Bioaccumulation TSD. While the methodology detailed in this chapter is intended to be used by EPA for deriving national BAFs, EPA encourages States and authorized Tribes to derive BAFs that are specific to certain regions or waterbodies, where appropriate. Guidance to States and authorized Tribes for deriving site-specific BAFs is provided in the Biaccumulation TSD.

5.1.1 Important Bioaccumulation and Bioconcentration Concepts

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in setting national 304(a) criteria. First, the term "bioaccumulation" refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media (e.g., water, food, sediment). The term "bioconcentration" refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone would underestimate the extent of accumulation in aquatic biota for these chemicals. Accordingly, EPA's guidelines presented in this chapter emphasize the measurement of chemical bioaccumulation by aquatic organisms, whereas EPA's 1980 Methodology emphasized the measurement of bioconcentration.

Another noteworthy aspect of bioaccumulation process is the issue of steady-state conditions. Specifically, both bioaccumulation and bioconcentration can be viewed simply as the result of competing rates of chemical uptake and depuration (chemical loss) by an aquatic organism. The rates of chemical uptake and depuration can be affected by various factors including the properties of the chemical, the physiology of the organism in question, water quality and other environmental conditions, ecological characteristics of the waterbody (e.g., food web structure), and the concentration and loadings history of the chemical. When the rates of chemical uptake and depuration are equal, tissue concentrations remain constant over time and the distribution of the chemical between the organism and its source(s) is said to be at steady-state. For constant chemical exposures and other conditions, the steady-state concentration in the organism represents the highest accumulation potential of the chemical in that organism under those conditions. The time required for a chemical to achieve steady state has been shown to vary according to the properties of the chemical and other factors. For example, some highly hydrophobic chemicals can require long periods of time to reach steady state between environmental compartments (e.g., many months), while highly hydrophilic chemicals usually reach steady-state relatively quickly (e.g., hours to days).

Since national 304(a) criteria for the protection of human health are typically designed to protect humans from harmful lifetime or long-term exposures to waterborne contaminants, the assessment of bioaccumulation that equals or approximates steady-state accumulation is one of the principles underlying the derivation of national BAFs. For some chemicals that require relatively long periods of time to reach steady-state in tissues of aquatic organisms, changes in water column concentrations may occur on a much more rapid time scale compared to the corresponding changes in tissue concentrations. Thus, if the system departs substantially from steady-state conditions and water concentrations are not averaged over a sufficient time period, the ratio of the tissue concentration to a water concentration may have little resemblance to the steady-state ratio and have little predictive value of long-term bioaccumulation potential.

Therefore, BAF measurements should be based on water column concentrations which are averaged over a sufficient period of time (e.g., a duration comparable to the time required for the chemical to reach steady-state). In addition, BAF measurements should be based on adequate spatial averaging of both tissue and water column concentrations for use in deriving 304(a) criteria for the protection of human health.

For this reason, a BAF is defined in this Methodology as representing the ratio (in L/kg-tissue) of a concentration of a chemical in tissue to its concentration in the surrounding water in situations where the organism and its food are exposed and the ratio does not change substantially over time (i.e., the ratio which reflects bioaccumulation at or near steady-state). A bioconcentration factor (BCF) is the ratio (in L/kg-tissue) of the concentration of a substance in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

5.1.2 Goal of the National BAF

The goal of EPA's national BAF is to represent the long-term, average bioaccumulation potential of a chemical in edible tissues of aquatic organisms that are commonly consumed by humans throughout the United States. National BAFs are not intended to reflect fluctuations in bioaccumulation over short time periods (e.g., a few days) because 304(a) human health criteria are generally designed to protect humans from long-term exposures to waterborne chemicals. National BAFs are also intended to account for some major chemical, biological, and ecological attributes that can affect bioaccumulation in bodies of water across the United States. For example, separate procedures are provided for deriving national BAFs depending on the type of chemical (i.e., nonionic organic, ionic organic, inorganic and organometallic). In addition, EPA's national BAFs are derived separately for each trophic level to account for potential biomagnification of some chemicals in aquatic food webs and broad physiological differences between trophic levels that may influence bioaccumulation. Because lipid content of aquatic organisms and the amount of organic carbon in the water column have been shown to affect bioaccumulation of nonionic organic chemicals, EPA's national BAFs are adjusted to reflect the lipid content of commonly consumed fish and shellfish and the freely dissolved fraction of the chemical in ambient water for these chemicals.

5.1.3 Changes to the 1980 Methodology

Numerous scientific advances have occurred in the area of bioaccumulation since the publication of the 1980 Methodology for deriving AWQC for the protection of human health (USEPA, 1980). These advances have significantly increased our ability to assess and predict the bioaccumulation of chemicals in aquatic biota. As a result, EPA has revised the bioaccumulation portion of the 1980 Methodology to reflect the current state of the science and to improve accuracy in assessing bioaccumulation for setting 304(a) criteria for the protection of human health. The changes contained in the bioaccumulation portion of the 2000 Human Health Methodology are mostly designed to:

- Improve the ability to incorporate chemical exposure from sediments and aquatic food webs in assessing bioaccumulation potential,

- Expand the ability to account for site-specific factors which affect bioaccumulation, and

- Incorporate new data and assessment tools into the bioaccumulation assessment process.

A summary of the key changes that have been incorporated into the bioaccumulation portion of the 2000 Human Health Methodology and appropriate comparisons to the1980 Methodology are provided below.

5.1.3.1 Overall Approach

The 1980 Methodology for deriving 304(a) criteria for the protection of human health emphasized the assessment of bioconcentration (uptake from water only) through the use of the BCF. Based on the 1980 Methodology, measured BCFs were usually determined from laboratory data unless field data demonstrated consistently higher or lower accumulation compared with laboratory data. In these cases, "field BCFs" (currently termed field-measured BAFs) were recommended for use. For lipophilic chemicals where lab or field-measured data were unavailable, EPA recommended predicting BCFs from the octanol-water partition coefficient and the following equation from Veith et al. (1979): "log BCF = (0.85 log K_{ow}) - 0.70".

The 2000 Human Health Methodology revisions contained in this chapter emphasize the measurement of bioaccumulation (uptake from water, sediment, and diet) through the use of the BAF. Consistent with the 1980 Methodology, measured data are preferred over predictive approaches for determining the BAF (i.e., field-measured BAFs are generally preferred over predicted BAFs). However, the 2000 Human Health Methodology contains additional methods for deriving a national BAF that were not available in 1980. The preference for using the BAF methods also differs depending on the type and properties of the chemical. For example, the BAF derivation procedure differs for each of three broadly defined chemical categories: (1) nonionic organic, (2) ionic organic, and (3) inorganic and organometallic chemicals. Furthermore, within the category of nonionic organic chemicals, different procedures are used to derive the BAF depending on a chemicals' hydrophobicity and extent of chemical metabolism that would be expected to occur in aquatic biota.

5.1.3.2 Lipid Normalization

In the 1980 Methodology, BCFs for lipophilic chemicals were normalized by the lipid fraction in the tissue of fish and shellfish used to determine the BCF. Lipid normalization enabled BCFs to be averaged across tissues and organisms. Once the average lipid-normalized BCF was determined, it was adjusted by the consumption-weighted lipid content of commonly consumed aquatic organisms in the United States to obtain an overall consumption-weighted BCF. A similar procedure has been retained in the 2000 Human Health Methodology, whereby BAFs for nonionic organic chemicals are lipid normalized and adjusted by the consumption-weighted lipid content of commonly consumed organisms to obtain a BAF for criteria calculations. However, the 2000 Human Health Methodology uses more up-to-date lipid data and consumption data for deriving the consumption-weighted BAFs.

5.1.3.3 <u>Bioavailability</u>

Bioconcentration factors derived according to the 1980 Methodology were based on the total concentration of the chemical in water, for both lipophilic and nonlipophilic chemicals. In the 2000 Human Health Methodology, BAFs for nonionic organic chemicals are derived using the most bioavailable fraction (i.e., the freely dissolved fraction) to account for the influence of particulate and dissolved organic carbon on a chemical's bioavailability. Such BAFs are then adjusted to reflect the expected bioavailability at the sites of interest (i.e., by adjusting for organic carbon concentrations at the sites of interest). Procedures for accounting for the effect of organic carbon on bioaccumulation were published previously by EPA under the Great Lakes Water Quality Initiative (GLWQI or GLI) rulemaking (USEPA, 1995a,b). Bioavailability is also considered in developing BAFs for the other chemical classes defined in the 2000 Human Health Methodology (e.g., ionic organics, inorganics/organometallics) but is done so on a chemical-by-chemical basis.

5.1.3.4 <u>Trophic Level Considerations</u>

In the 1980 Methodology, BCFs were determined and used for criteria derivation without explicit regard to the trophic level of the aquatic organism (e.g., benthic filter feeder, forage fish, predatory fish). Over the past two decades, much information has been assembled which demonstrates that an organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. In order to account for the variation in bioaccumulation that is due to trophic position of the organism, the 2000 Human Health Methodology recommends that BAFs be determined and applied on a trophic level-specific basis.

5.1.3.5 <u>Site-Specific Adjustments</u>

The 1980 Methodology contained little guidance for making adjustments to the national BCFs to reflect site- or region-specific conditions. The 2000 Human Health Methodology has greatly expanded the guidance to States and authorized Tribes for making adjustments to national BAFs to reflect local conditions. This guidance is contained in the Bioaccumulation TSD. In the Bioaccumulation TSD, guidance and data are provided for adjusting national BAFs to reflect the lipid content in locally consumed aquatic biota and the organic carbon content in the waterbodies of concern. This guidance also allows the use of appropriate bioaccumulation models for deriving site-specific BAFs. EPA also plans to publish detailed guidance on designing and conducting field bioaccumulation studies for measuring BAFs and biota-sediment accumulation factors (BSAFs). In general, EPA encourages States and authorized Tribes to make site-specific modifications to EPA's national BAFs provided such adjustments are scientifically defensible and adequately protect the designated use of the waterbody.

While the aforementioned revisions are new to EPA's Methodology for deriving national 304(a) criteria for the protection of human health, many of these refinements have been incorporated in prior Agency guidance and regulations. For example, the use of food chain multipliers to account for the biomagnification of nonionic organic chemicals in aquatic food webs when measured data are unavailable was introduced by EPA in three documents*: Technical Support Document for Water Quality-Based Toxics Control* (USEPA, 1991), a draft document entitled *Assessment and Control of Bioconcentratable Contaminants in Surface Waters* (USEPA, 1993), and in the *Great Lakes Water Quality Initiative* (GLI) (USEPA, 1995b). Similarly, procedures for predicting BAFs using BSAFsand incorporating the effect of organic carbon on bioavailability were used to derive water quality criteria under the GLI.

5.1.4 Organization of This Section

The methodology for deriving national BAFs for use in deriving National 304(a) Human Health AWQC is provided in the following sections. Important terms used throughout this chapter are defined in Section 5.2. Section 5.3 provides an overview of the BAF derivation guidelines. Detailed procedures for deriving national BAFs are provided in Section 5.4 for nonionic organic chemicals, in Section 5.5 for ionic organic chemicals, and in Section 5.6 for inorganics and organometallic chemicals. Literature cited is provided in Section 5.7.

5.2 DEFINITIONS

The following terms and definitions are used throughout this chapter.

Bioaccumulation. The net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioconcentration. The net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water, through gill membranes or other external body surfaces.

Bioaccumulation Factor (BAF). The ratio (in L/kg-tissue) of the concentration of a substance in tissue to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time. The BAF is calculated as:

$$BAF = \frac{C_t}{C_w} \qquad \text{(Equation 5-2)}$$

where:

C_t = Concentration of the chemical in the specified wet tissue
C_w = Concentration of chemical in water

Bioconcentration Factor (BCF). The ratio (in L/kg-tissue) of the concentration of a substance in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time. The BCF is calculated as:

$$BCF = \frac{C_t}{C_w} \qquad \text{(Equation 5-3)}$$

where:

C_t = Concentration of the chemical in the specified wet tissue
C_w = Concentration of chemical in water

Baseline BAF (BAF_{ℓ}^{fd}). For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), a BAF (in L/kg-lipid) that is based on the concentration of freely dissolved chemical in the ambient water and the lipid normalized concentration in tissue.

Baseline BCF (BCF_{ℓ}^{fd}). For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), a BCF (in L/kg-lipid) that is based on the concentration of freely dissolved chemical in the ambient water and the lipid normalized concentration in tissue.

Biomagnification. The increase in tissue concentration of a chemical in organisms at successive trophic levels through a series of predator-prey associations, primarily through the mechanism of dietary accumulation.

Biomagnification Factor (BMF). The ratio (unitless) of the tissue concentration of a chemical in a predator at a particular trophic level to the tissue concentration in its prey at the next lower trophic level for a given waterbody and chemical exposure. For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), a BMF can be calculated using lipid-normalized concentrations in the tissue of organisms at two successive trophic levels as:

$$BMF_{(TL,\ n)} = \frac{C_{\ell\ (TL,\ n)}}{C_{\ell\ (TL,\ n-1)}} \qquad \text{(Equation 5-4)}$$

where:

$C_{\ell\ (TL,\ n)}$ = Lipid-normalized concentration in appropriate tissue of predator organism at a given trophic level (TL "n")

$C_{\ell\ (TL,\ n\text{-}1)}$ = Lipid-normalized concentration in appropriate tissue of prey organism at the next lower trophic level from the predator (TL "n-1")

For inorganic, organometallic, and certain ionic organic chemicals where lipid and organic carbon partitioning does not apply, a BMF can be calculated using chemical concentrations in the tissue of organisms at two successive trophic levels as:

$$BMF_{(TL,\ n)} = \frac{C_{t\ (TL,\ n)}}{C_{t\ (TL,\ n-1)}} \qquad \text{(Equation 5-5)}$$

where:

$C_{t\ (TL,\ n)}$ = Concentration in appropriate tissue of predator organism at trophic level "n" (may be either wet weight or dry weight concentration so long as both the predator and prey concentrations are expressed in the same manner)

$C_{t\ (TL,\ n\text{-}1)}$ = Concentration in appropriate tissue of prey organism at the next lower trophic level from the predator (may be either wet weight or dry weight concentration so long as both the predator and prey concentrations are expressed in the same manner)

Biota-Sediment Accumulation Factor (BSAF). For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), the ratio of the lipid-normalized concentration of a substance in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment (expressed as kg of sediment organic carbon per kg of lipid), in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism. The BSAF is defined as:

$$BSAF = \frac{C_{\ell}}{C_{soc}} \qquad \text{(Equation 5-6)}$$

where:

C_{ℓ} = The lipid-normalized concentration of the chemical in tissues of the biota (µg/g lipid)

C_{soc} = The organic carbon-normalized concentration of the chemical in the surface sediment (µg/g sediment organic carbon)

Depuration. The loss of a substance from an organism as a result of any active or passive process.

Food Chain Multiplier (FCM). For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), the ratio of a baseline BAF_{ℓ}^{fd} for an organism of a particular trophic level to the baseline BCF_{ℓ}^{fd} (usually determined for organisms in trophic level one). For inorganic, organometallic, and certain ionic organic chemicals where lipid and organic carbon partitioning does not apply, a FCM is based on total (wet or dry weight) concentrations of the chemical in tissue.

Freely Dissolved Concentration. For nonionic organic chemicals, the concentration of the chemical that is dissolved in ambient water, excluding the portion sorbed onto particulate or dissolved organic carbon. The freely dissolved concentration is considered to represent the most bioavailable form of an organic chemical in water and, thus, is the form that best predicts bioaccumulation. The freely dissolved concentration can be determined as:

$$C_w^{fd} = (C_w^t) \cdot (f_{fd}) \qquad \text{(Equation 5-7)}$$

where:

C_w^{fd} = Freely dissolved concentration of the organic chemical in ambient water
C_w^t = Total concentration of the organic chemical in ambient water
f_{fd} = Fraction of the total chemical in ambient water that is freely dissolved

Hydrophilic. A term that refers to the extent to which a chemical is attracted to partitioning into the water phase. Hydrophilic organic chemicals have a greater tendency to partition into polar phases (e.g., water) compared to chemicals of hydrophobic chemicals.

Hydrophobic. A term that refers to the extent to which a chemical avoids partitioning into the water phase. Highly hydrophobic organic chemicals have a greater tendency to partition into nonpolar phases (e.g., lipid, organic carbon) compared with chemicals of lower hydrophobicity.

Lipid-normalized Concentration (C_{ℓ}). The total concentration of a contaminant in a tissue or whole organism divided by the lipid fraction in that tissue or whole organism. The lipid-normalized concentration can be calculated as:

$$C_{\ell} = \frac{C_t}{f_{\ell}} \qquad \text{(Equation 5-8)}$$

where:

C_t = Concentration of the chemical in the wet tissue (either whole organism or specified tissue)

f_ℓ = Fraction lipid content in the organism or specified tissue

Octanol-water Partition Coefficient (K_{ow}). The ratio of the concentration of a substance in the n-octanol phase to its concentration in the aqueous phase in an equilibrated two-phase octanol-water system. For log K_{ow}, the log of the octanol-water partition coefficient is a base 10 logarithm.

Organic Carbon-normalized Concentration (C_{soc}). For sediments, the total concentration of a contaminant in sediment divided by the fraction of organic carbon in sediment. The organic carbon-normalized concentration can be calculated as:

$$C_{soc} = \frac{C_s}{f_{oc}} \qquad \text{(Equation 5-9)}$$

where:

C_s = Concentration of chemical in sediment
f_{oc} = Fraction organic carbon in sediment

Uptake. Acquisition by an organism of a substance from the environment as a result of any active or passive process.

5.3 FRAMEWORK FOR DETERMINING NATIONAL BIOACCUMULATION FACTORS

5.3.1 Four Different Methods

Bioaccumulation factors used to derive national BAFs can be measured or predicted using some or all of the following four methods, depending on the type of chemical and its properties. These methods are:

(1) a measured BAF obtained from a field study (i.e., a field-measured BAF);

(2) a BAF predicted from a field-measured BSAF;

(3) a BAF predicted from a laboratory-measured BCF (with or without adjustment by an FCM); and

(4) a BAF predicted from a chemical's octanol-water partition coefficient (K_{ow}), with or without adjustment using an FCM.

A brief summary of each of the four methods is provided below. Additional details on the use of these four methods is provided in Section 5.4 (for nonionic organics), Section 5.5 (for ionic organics) and Section 5.6 (for inorganics and organometallics).

1. **Field-Measured BAF.** Use of a field-measured BAF, which is the most direct measure of bioaccumulation, is the only method that can be used to derive a national BAF for all types of chemicals (i.e., nonionic organic, ionic organic, and inorganic and organometallic chemicals). A field-measured BAF is determined from a field study using measured chemical concentrations in the aquatic organism and its surrounding water. Because field studies are conducted in natural aquatic ecosystems, a field-measured BAF reflects an organism's exposure to a chemical through all relevant exposure pathways (i.e., water, sediment, and diet). A field-measured BAF also reflects any metabolism of a chemical that might occur in the aquatic organism or its food web. Therefore, field-measured BAFs are appropriate for all chemicals, regardless of the extent of chemical metabolism in biota.

2. **Field-measured BSAF.** For nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies), a BAF can also be predicted from BSAFs. A BSAF is similar to a field-measured BAF in that the concentration of a chemical in biota is measured in the field and reflects an organism's exposure to all relevant exposure routes. A BSAF also reflects any chemical metabolism that might occur in the aquatic organism or its food web. However, unlike a field-measured BAF which references the biota concentration to the water concentration, a BSAF references the biota concentration to the sediment concentration. Use of the BSAF procedure is restricted to organic chemicals which are classified as being moderately to highly hydrophobic.

3. **Lab-measured BCF.** A laboratory-measured BCF can also be used to estimate a BAF for organic and inorganic chemicals. However, unlike a field-measured BAF or a BAF predicted from a field-measured BSAF, a laboratory-measured BCF only reflects the accumulation of chemical through the water exposure route. Laboratory-measured BCFs may therefore under estimate BAFs for chemicals where accumulation from sediment or dietary sources is important. In these cases, laboratory-measured BCFs can be multiplied by a FCM to reflect accumulation from non-aqueous (i.e., food chain) pathways of exposure. Since a laboratory-measured BCF is determined using the measured concentration of a chemical in an aquatic organism and its surrounding water, a laboratory-measured BCF reflects any metabolism of the chemical that occurs in the organism, but not in the food web.

4. **K_{ow}.** A chemical's octanol-water partition coefficient, or K_{ow}, can also be used to predict a BAF for nonionic organic chemicals. This procedure is appropriate only for nonionic organic chemicals (and certain ionic organic chemicals where similar lipid and organic carbon partitioning behavior applies). The K_{ow} has been extensively correlated with the BCF for nonionic organic chemicals that are poorly metabolized by aquatic organisms. Therefore, where substantial metabolism is known to occur in biota, the K_{ow} is not used

to predict the BAF. For nonionic organic chemicals where chemical exposure through the food web is important, use of the K_{ow} alone will under predict the BAF. In such cases, the K_{ow} is adjusted with a FCM similar to the BCF procedure above.

5.3.2 Overview of BAF Derivation Framework

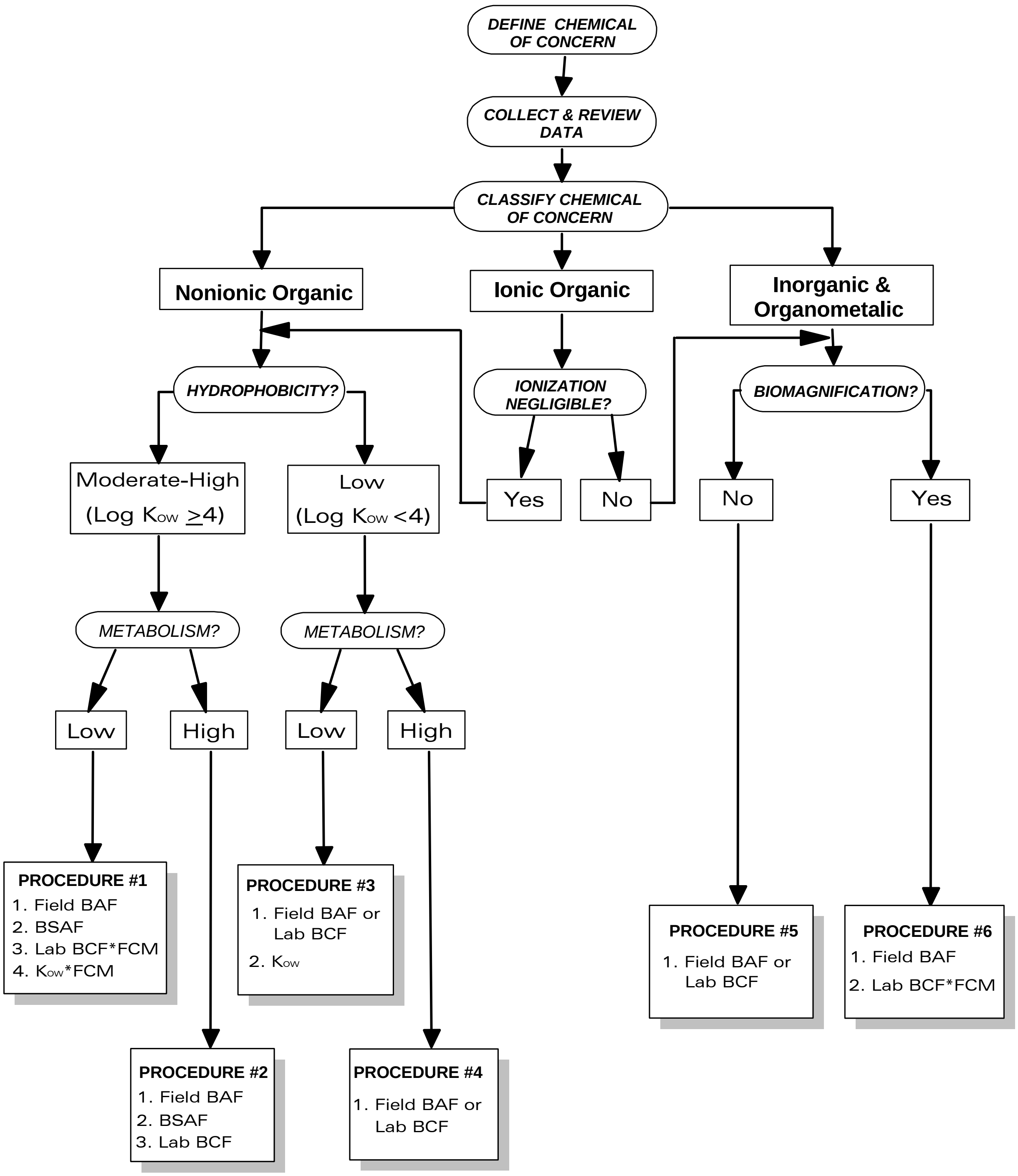
Although up to four methods can be used to derive a BAF as described in the previous section, it is evident that these methods do not apply equally to all types of chemicals. In addition, experience demonstrates that the required data will usually not be available to derive a BAF value using all of the applicable methods. As a result, EPA has developed the following guidelines to direct users in selecting the most appropriate method(s) for deriving a national BAF.

Figure 5-1 shows the overall framework of EPA's national BAF methodology. This framework illustrates the major steps and decisions that will ultimately lead to calculating a national BAF using one of six hierarchical procedures shown at the bottom of Figure 5-1. Each procedure contains a hierarchy of the BAF derivation methods discussed above, the composition of which depends on the chemical type and certain chemical properties (e.g., its degree of hydrophobicity and expected degree of metabolism and biomagnification). The number assigned to each BAF method within a procedure indicates its general order of preference for deriving a national BAF value. The goal of the framework and accompanying guidelines is to enable full use of available data and methods for deriving a national BAF value while appropriately restricting the use of certain methods to reflect their inherent limitations.

The first step in the framework is to define the chemical of concern. As described in Section 5.3.3, the chemical used to derive the national BAF should be consistent with the chemical used to derive the critical health assessment value. The second step is to collect and review all relevant data on bioconcentration and bioaccumulation of the chemical of concern (see Section 5.3.4). Once pertinent data are reviewed, the third step is to classify the chemical of concern into one of three broadly defined chemical categories: (1) nonionic organic chemicals, (2) ionic organic chemicals, and (3) and inorganic and organometallic chemicals. Guidance for classifying chemicals into these three categories is provided in Section 5.3.5.

After a chemical has been classified into one of the three categories, other information is used to select one of six hierarchical procedures to derive the national BAF. The specific procedures for deriving a BAF for each chemical group are discussed in Section 5.4 for nonionic organics, Section 5.5 for ionic organics, and Section 5.6 for inorganics and organometallics.

Figure 5-1. Framework for Deriving a National BAF



Detailed guidance concerning the first three steps of the derivation process (i.e, defining the chemical of concern, collecting and reviewing data, and classifying the chemical of concern) is provided in the following three sections.

5.3.3 Defining the Chemical of Concern

Defining the chemical of concern is the first step in deriving a national BAF. This step involves precisely defining the form(s) of the chemical upon which the national BAF value will be derived. Although this step is usually straightforward for single chemicals, complications can arise when the chemical of concern occurs as a mixture. The following guidelines should be followed for defining the chemical of concern.

1. Information for defining the chemical of concern should be obtained from the health and exposure assessment portions of the criteria derivation effort. The chemical(s) used to derive the national BAF should be consistent with the chemical(s) used to derive the reference dose (RfD), point of departure/uncertainty factor (POD/UF), or cancer potency factor.

2. In most cases, the RfD, POD/UF, or cancer potency factor will be based on a single chemical. In some cases, the RfD, POD/UF, or cancer potency factor will be based on a mixture of compounds, typically within the same chemical class (e.g., toxaphene, chlordane). In these situations, the national BAF should be derived in a manner that is consistent with the mixture used to express the health assessment.

    a. If sufficient data are available to reliably assess the bioaccumulation of each relevant compound contained in the mixture, then the national BAF(s) should be derived using the BAFs for the individual compounds of the mixture and appropriately weighted to reflect the mixture composition used to establish the RfD, POD/UF, or cancer potency factor. An example of this approach is shown in the derivation of BAFs for PCBs in the GLI Rulemaking (USEPA, 1997).

    b. If sufficient data are not available to reliably assess the bioaccumulation of individual compounds of the mixture, then the national BAF(s) should be derived using BAFs for the same or appropriately similar chemical mixture as that used to establish the RfD, POD/UF, or cancer potency value.

5.3.4 Collecting and Reviewing Data

The second step in deriving a national BAF is to collect and review all relevant bioaccumulation data for the chemical of concern. The following guidance should be followed for collecting and reviewing bioaccumulation data for deriving national BAFs.

1. All data on the occurrence and accumulation of the chemical of concern in aquatic animals and plants should be collected and reviewed for adequacy.

2. A comprehensive literature search strategy should be used for gathering bioaccumulation-related data. An example of a comprehensive literature search strategy is provided in the Bioaccumulation TSD.

3. All data that are used should contain sufficient supporting information to indicate that acceptable measurement procedures were used and that the results are probably reliable. In some cases it may be appropriate to obtain additional written information from the investigator.

4. Questionable data, whether published or unpublished, should not be used. Guidance for assessing the acceptability of bioaccumulation and bioconcentration studies is found in Sections 5.4, 5.5, and 5.6.

5.3.5 Classifying the Chemical of Concern

The next step in deriving a national BAF consists of classifying the chemical of concern into one of three categories: nonionic organic, ionic organic, and inorganic and organometallic (Figure 5-1). This step helps to determine which of the four methods described in Section 5.3.1 are appropriate for deriving BAFs. The following guidance applies for classifying the chemical of concern.

1. **Nonionic Organic Chemicals.** For the purposes of the 2000 Human Health Methodology, nonionic organic chemicals are those organic compounds that do not ionize substantially in natural bodies of water. These chemicals are also referred to as neutral or nonpolar organics in the scientific literature. Due to their neutrality, nonionic organic chemicals tend to associate with other neutral (or near neutral) compartments in aquatic ecosystems (e.g., lipid, organic carbon). Examples of nonionic organic chemicals which have been widely studied in terms of their bioaccumulation include polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins and furans, many chlorinated pesticides, and polynuclear aromatic hydrocarbons (PAHs). Procedures for deriving a national BAF for nonionic organic chemicals are provided in Section 5.4.

2. **Ionic Organic Chemicals.** For the purposes of the 2000 Human Health Methodology, ionic organic chemicals are considered to include those chemicals that contain functional groups with exchangeable protons such as hydroxyl, carboxylic, and sulfonic groups and functional groups that readily accept protons such as amino and aromatic heterocyclic nitrogen (pyridine) groups. Ionic organic chemicals undergo ionization in water, the extent of which depends on pH and the pKa of the chemical. Because the ionized species of these chemicals behave differently from the neutral species, separate guidance is provided for deriving BAFs for ionic organic chemicals. Procedures for deriving national BAFs for ionic organic chemicals are provided in Section 5.5.

3. **Inorganic and Organometallic Chemicals.** The inorganic and organometallic category is considered to include inorganic minerals, other inorganic compounds and elements, metals (e.g., copper, cadmium, chromium, zinc), metalloids (selenium, arsenic) and

organometallic compounds (e.g., methylmercury, tributyltin, tetraalkyllead). Procedures for deriving BAFs for inorganic and organometallic chemicals are provided in Section 5.6.

5.4 NATIONAL BIOACCUMULATION FACTORS FOR NONIONIC ORGANIC CHEMICALS

5.4.1 Overview

This section contains the methodology for deriving national BAFs for nonionic organic chemicals as defined in Section 5.3.5. The four general steps of this methodology are:

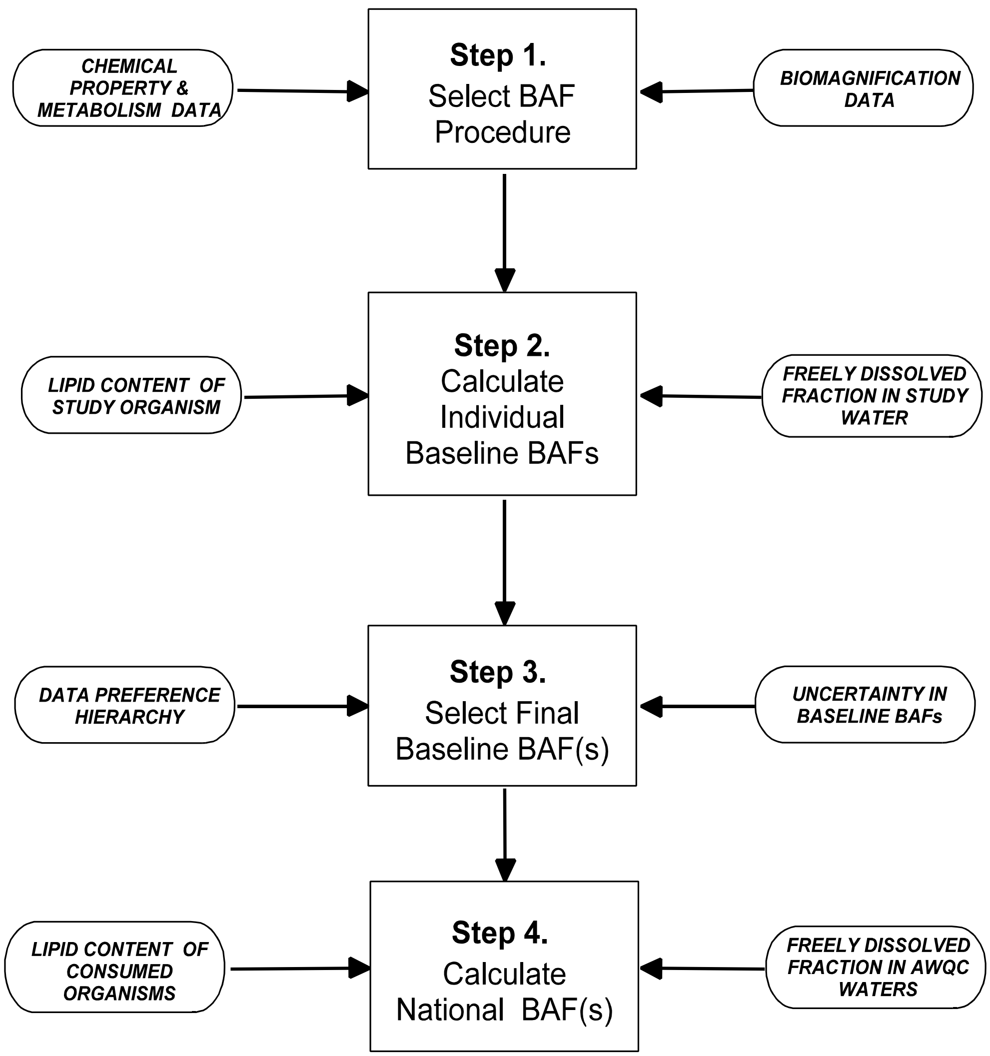
1. Selecting the BAF derivation procedure,
2. Calculating individual baseline BAF_{ℓ}^{fd}s,
3. Selecting the final baseline BAF_{ℓ}^{fd}s, and
4. Calculating the national BAFs from the final baseline BAF_{ℓ}^{fd}s.

A schematic of this four-step process is shown in Figure 5-2.

Step 1 of the methodology (selecting the BAF derivation procedure) determines which of the four BAF procedures summarized in Figure 5-1 will be appropriate for deriving the national BAF. Step 2 involves calculating individual, species-specific BAF_{ℓ}^{fd}s using all of the methods available within the selected BAF derivation procedure. Calculating the individual baseline BAF_{ℓ}^{fd}s involves using data from the field site or laboratory where the original data were collected to account for site-specific factors which affect the bioavailability of the chemical to aquatic organisms (e.g., lipid content of study organisms and freely dissolved concentration in study water). Step 3 of the methodology consists of selecting the final baseline BAF_{ℓ}^{fd}s from the individual baseline BAF_{ℓ}^{fd}s by taking into account the uncertainty in the individual BAFs and the data preference hierarchy selected in Step 1. The final step is to calculate a BAF (or BAFs) that will be used in the derivation of 304(a) criteria (i.e., referred to as the national BAF). This step involves adjusting the final baseline BAF_{ℓ}^{fd}(s) to reflect certain factors that affect bioavailablity of the chemical to aquatic organisms in waters to which the national 304(a) criteria will apply (e.g., the freely dissolved fraction expected in U.S. waters and the lipid content of consumed aquatic organisms). Baseline BAF_{ℓ}^{fd}s are not used directly in the derivation of the 304(a) criteria because they do not reflect the conditions that affect bioavailability in U.S. waters.

Section 5.4.2 below provides detailed guidance for selecting the appropriate BAF derivation procedure (Step 1 of the process). Guidance on calculating individual baseline BAF_{ℓ}^{fd}s, selecting the final baseline BAF, and calculating the national BAF (Steps 2 through 4 of the process) is provided in separate sections under each of the four BAF derivation procedures.

Figure 5-2. BAF Derivation for Nonionic Organic Chemicals



5.4.2 Selecting the BAF Derivation Procedure

This section describes the decisions that should be made to select one of the four available hierarchical procedures for deriving a national BAF for nonionic organic chemicals (Procedures #1 through #4 of Figure 5-1). As shown in Figure 5-1, two decision points exist in selecting the BAF derivation procedure. The first decision point requires knowledge of the chemical's hydrophobicity (i.e., the K_{ow} of the chemical). Guidance for selecting the K_{ow} for a chemical is provided in the Bioaccumulation TSD. The K_{ow} provides an initial basis for assessing whether biomagnification may be a concern for nonionic organic chemicals. The second decision point is based on the rate of metabolism for the chemical in the target organism. Guidance for assessing whether a high or low rate of metabolism is likely for a chemical of concern is provided below in Section 5.4.2.3. With the appropriate information for these two decision points, the BAF derivation procedure should be selected using the following guidelines.

5.4.2.1 <u>Chemicals with Moderate to High Hydrophobicity</u>

1. For the purposes of the 2000 Human Health Methodology, nonionic organic chemicals with log K_{ow} values equal to or greater than 4.0 should be classified as moderately to highly hydrophobic. For moderately to highly hydrophobic nonionic organic chemicals, available data indicate that exposure through the diet and other non-aqueous routes can become important in determining chemical residues in aquatic organisms (e.g., Russell et al., 1999; Fisk et al., 1998; Oliver and Niimi, 1983; Oliver and Niimi, 1988; Niimi, 1985; Swackhammer and Hites, 1988). Dietary and other non-aqueous exposure can become extremely important for those nonionic organic chemicals that are poorly metabolized by aquatic biota (e.g., certain PCB congeners, chlorinated pesticides, and polychlorinated dibenzo-p-dioxins and furans).

2. **Procedure #1** should be used to derive national BAFs for moderately to highly hydrophobic nonionic organic chemicals in cases where:

   (a) the rate of chemical metabolism by target aquatic organisms is expected to be sufficiently low such that biomagnification is of concern, or

   (b) the rate of chemical metabolism by target aquatic organisms is not sufficiently known.

   Procedure #1 accounts for non-aqueous exposure and the potential for biomagnification in aquatic food webs through the use of field-measured values for bioaccumulation (i.e., field measured BAF or BSAF) and FCMs when appropriate field data are unavailable. Guidance on deriving national BAFs using Procedure #1 is found below in Section 5.4.3.

3. **Procedure #2** should be used to derive the national BAFs for moderately to highly hydrophobic nonionic organic chemicals in cases where:

   (a) the rate of chemical metabolism by target aquatic organisms is expected to be sufficiently high such that biomagnification is not of concern.

Procedure #2 relaxes the requirement of using FCMs and eliminates the use of K_{ow}-based estimates of the BAF, two procedures that are most appropriate for poorly metabolized nonionic organic chemicals. Guidance on deriving national BAFs using Procedure #2 is found below in Section 5.4.4.

5.4.2.2 <u>Chemicals with Low Hydrophobicity</u>

1. For the purposes of these guidelines, nonionic organic chemicals with log K_{ow} values less than 4.0 should be classified as exhibiting low hydrophobicity. For nonionic organic chemicals that exhibit low hydrophobicity (i.e., log K_{ow} < 4.0), available information indicates that non-aqueous exposure to these chemicals is not likely to be important in determining chemical residues in aquatic organisms (e.g., Fisk et al., 1998; Gobas et al., 1993; Connolly and Pedersen, 1988; Thomann, 1989). For this group of chemicals, laboratory-measured BCFs and K_{ow}-predicted BCFs do not require adjustment with FCMs for determining the national BAF (Procedures #3 and #4), unless other appropriate data indicate differently.

   Other appropriate data include studies clearly indicating that non-aqueous exposure is important such that use of a BCF would substantially underestimate residues in aquatic organisms. In these cases, Procedure #1 should be used to derive the BAF for nonionic organic chemicals with log K_{ow} < 4.0. Furthermore, the data supporting the K_{ow} determination should be carefully reviewed for accuracy and appropriate interpretation, since the apparent discrepancy may be due to errors in determining K_{ow}.

2. **Procedure #3** should be used to derive national BAFs for nonionic organic chemicals of low hydrophobicity in cases where:

   (a) the rate of chemical metabolism by target aquatic organisms is expected to be negligible, such that tissue residues of the chemical of concern are not substantially reduced compared to an assumption of no metabolism, or

   (b) the rate of chemical metabolism by target aquatic organisms is not sufficiently known.

   Procedure #3 includes the use of K_{ow}-based estimates of the BCF to be used when lab or field data are absent. Guidance on deriving national BAFs using Procedure #3 is found below in Section 5.4.5.

3. **Procedure #4** should be used to derive national BAFs for nonionic organic chemicals of low hydrophobicity in cases where:

   (a) the rate of chemical metabolism by target aquatic organisms is expected to be sufficiently high, such that tissue residues of the chemical of concern are substantially reduced compared with an assumption of no metabolism.

Procedure #4 eliminates the option of using K_{ow}-based estimates of the BAF because the K_{ow} may over-predict accumulation when a chemical is metabolized substantially by an aquatic organism. Guidance on deriving national BAFs using Procedure #4 is found below in Section 5.4.6.

5.4.2.3 <u>Assessing Metabolism</u>

Currently, assessing the degree to which a chemical is metabolized by aquatic organisms is confounded by a variety of factors. First, conclusive data on chemical metabolism in aquatic biota are largely lacking. Such data include whole organism studies where the metabolic rates and breakdown products are quantified in fish and other aquatic organisms relevant to human consumption. However, the majority of information on metabolism is derived from *in vitro* liver microsomal preparations in which primary and secondary metabolites may be identified and their rates of formation may or may not be quantified. Extrapolating results from *in vitro* studies to the whole organism involves considerable uncertainty. Second, there are no generally accepted procedures for reliably predicting chemical metabolism by aquatic organisms in the absence of measured data. Third, the rate at which a chemical is metabolized by aquatic organisms can be species and temperature dependent. For example, PAHs are known to be metabolized readily by vertebrate aquatic species (primarily fish), although at rates much less than those observed for mammals. However, the degree of metabolism in invertebrate species is generally much less than the degree in vertebrate species (James, 1989). One hypothesis for this difference is that the invertebrate species lack the detoxifying enzymes and pathways that are present in many vertebrate species.

Given the current limitations on assessing the degree of chemical metabolism by aquatic organisms, the assessment of metabolism should be made on a case-by-case basis using a weight-of-evidence approach. When assessing a chemical's likelihood to undergo substantial metabolism in a target aquatic organism, the following data should be carefully evaluated:

(1) *in vivo* chemical metabolism data,
(2) bioconcentration and bioaccumulation data,
(3) data on chemical occurrence in target aquatic biota, and
(4) *in vitro* chemical metabolism data.

1. ***In vivo* Data.** *In vivo* data on metabolism in aquatic organisms are from studies of chemical metabolism using whole organisms. These studies are usually conducted using large fish from which blood, bile, urine, and individual tissues can be collected for the identification and quantification of metabolites formed over time. *In vivo* studies are considered the most useful for evaluating a chemical's degree of metabolism in an organism because both oxidative (Phase I) and conjugative (Phase II) metabolism can be assessed in these studies. Mass-balance studies, in which parent compound elimination is quantified separately from biotransformation and elimination of metabolites, allow calculation of conversion rate of parent to metabolite as well as metabolite elimination. This information might be used to estimate loss due to metabolism separately from that due to elimination of the parent compound for adjustment of K_{ow}-predicted BAFs. However, due to the analytical and experimental challenges these studies pose, data of

this type are limited. Less rigorous *in vivo* metabolism studies might include the use of metabolic blockers to demonstrate the influence of metabolism on parent compound kinetics. However, caution should be used in interpretation of absolute rates from these data due to the lack of specificity of mammalian derived blockers in aquatic species (Miranda et al., 1998).

2. **Bioconcentration or Bioaccumulation Data.** Data on chemical bioconcentration or bioaccumulation in aquatic organisms can be used indirectly for assessing metabolism. This assessment involves comparing acceptable lab-measured BCFs or field-measured BAFs (after converting to baseline values using procedures below) with the chemical's predicted value based on K_{ow}. The theoretical basis of bioconcentration and bioaccumulation for nonionic organic chemicals indicates that a chemical's baseline BCF should be similar to its K_{ow}-predicted value if metabolism is not occurring or is minimal (see the Bioaccumulation TSD). This theory also indicates that baseline BAFs should be similar to or higher than the K_{ow} for poorly metabolized organic chemicals, with highly hydrophobic chemicals often exhibiting higher baseline BAFs than K_{ow} values. Thus, if a chemical's baseline BCF or BAF is substantially lower than its K_{ow}, this may be an indication that the chemical is being metabolized by the aquatic organism of concern. Note, however, that this difference may also indicate problems in the experimental design or analytical chemistry, and that it may be difficult to discern the difference.

3. **Chemical Occurrence Data.** Although by no means definitive, data on the occurrence of chemicals in aquatic biota (i.e., residue studies) may offer another useful line of evidence for evaluating a chemical's likelihood to undergo substantial metabolism. Such studies are most useful if they have been conducted repeatedly over time and over wide geographical areas. Such studies might indicate a chemical is poorly metabolized if data show that the chemical is being biomagnified in the aquatic food web (i.e., higher lipid-normalized residues in successive trophic levels). Conversely, such studies might indicate a chemical is being metabolized substantially if residue data show a decline in residues with increasing trophic level. Again, other reasons for increases or decreases in concentrations with increasing trophic level might exist and should be carefully evaluated (e.g., incorrect food web assumptions, differences in exposure concentrations).

4. ***In vitro* Data.** *In vitro* metabolism data include data from studies where specific sub-cellular fractions (e.g., microsomal, cytosolic), cells, or tissues from an organism are tested outside the body (i.e., in test-tubes, cell- or tissue-culture). Compared with *in vivo* studies of chemical metabolism in aquatic organisms, *in vitro* studies are much more plentiful in the literature, with the majority of studies characterizing oxidative (Phase I) reactions de-coupled from conjugative (Phase II) metabolism. Cell, tissue, or organ level *in vitro* studies are less common but provide a more complete assessment of metabolism. While such studies are particularly useful for identifying the pathways, rates of formation, and metabolites formed, as well as the enzymes involved and differences in the temperature dependence of metabolism across aquatic species, they suffer from uncertainty when results are extrapolated to the whole organism. This uncertainty results from the fact that dosimetry (i.e., delivery of the toxicant to, and removal of metabolite

from, the target tissue) cannot currently be adequately reproduced in the laboratory or easily modeled.

When assessing chemical metabolism using the above information, the following guidelines apply.

a. A finding of substantial metabolism should be supported by two or more lines of evidence identified using the data described above.

b. At least one of the lines of evidence should be supported by either *in vivo* metabolism data or acceptable bioconcentration or bioaccumulation data.

c. A finding of substantial metabolism in one organism should not be extrapolated to another organism or another group of organisms unless data indicate similar metabolic pathways exist (or are very likely to exist) in both organisms. *In vitro* data may be particularly useful in cross-species extrapolations.

d. Finally, in situations where sufficient data are not available to properly assess the likelihood of significant metabolism in aquatic biota of concern, the chemical should be assumed to undergo little or no metabolism. This assumptions reflects a policy decision by EPA to err on the side of public health protection when sufficient information on metabolism is lacking.

5.4.3 Deriving National BAFs Using Procedure #1

This section contains guidance for calculating national BAFs for nonionic organic chemicals using Procedure #1 shown in Figure 5-1. The types of nonionic organic chemicals for which Procedure #1 is most appropriate are those that are classified as moderately to highly hydrophobic and subject to low (or unknown) rates of metabolism by aquatic biota (see Section 5.4.2 above). Non-aqueous contaminant exposure and subsequent biomagnification in aquatic food webs are of concern for chemicals that are classified in this category. Some examples of nonionic organic chemicals for which Procedure #1 is considered appropriate include:

- tetra-, penta- & hexachlorobenzenes;
- PCBs;
- octachlorostyrene;
- hexachlorobutadiene;
- endrin, dieldrin, aldrin;
- mirex, photomirex;
- DDT, DDE, DDD; and
- heptachlor, chlordane, nonachlor.

Under Procedure #1, the following four methods may be used in deriving a national BAF:

- using a BAF from an acceptable field study (i.e., a field-measured BAF);
- predicting a BAF from an acceptable field-measured BSAF;

- predicting a BAF from an acceptable laboratory-measured BCF and FCM; and
- predicting a BAF from an acceptable K_{ow} and FCM.

As shown in Figure 5-2, once the derivation procedure has been selected, the next steps in deriving a national BAF for a given trophic level include: calculating individual baseline BAF_{ℓ}^{fd}s (step 2), selecting the final baseline BAF_{ℓ}^{fd} (step 3), and calculating the national BAF from the final baseline BAF_{ℓ}^{fd} (step 4). Each of these three steps is discussed separately below.

5.4.3.1 Calculating Individual Baseline BAF_{ℓ}^{fd}s

Calculating an individual baseline BAF_{ℓ}^{fd} involves normalizing the field-measured BAF_{T}^{t} (or laboratory-measured BCF_{T}^{t}) which are based on total concentrations in tissue and water by the lipid content of the study organisms and the freely dissolved concentration in the study water. Both the lipid content in the organism and the freely dissolved concentration (as influenced by organic carbon in water) have been shown to be important factors that influence the bioaccumulation of nonionic organic chemicals (e.g., Mackay, 1982; Connolly and Pederson, 1988; Thomann, 1989, Suffet et al., 1994). Therefore, baseline BAF_{ℓ}^{fd}s (which are expressed on a freely dissolved and lipid-normalized basis) are considered more amenable to extrapolating between different species and bodies of water compared to BAFs expressed using the total concentration in the tissue and water. Because bioaccumulation can be strongly influenced by the trophic position of aquatic organisms (either due to biomagnification or physiological differences), extrapolation of baseline BAF_{ℓ}^{fd}s should not be performed between species of different trophic levels.

1. For each species for which acceptable data are available, calculate all possible baseline BAF_{ℓ}^{fd}s using each of the four methods shown above for Procedure #1.

2. Individual baseline BAF_{ℓ}^{fd}s should be calculated from field-measured BAF_{T}^{t}s, field-measured BSAFs, laboratory BCF_{T}^{t}s, and the K_{ow} according to the following procedures.

A. Baseline BAF_{ℓ}^{fd}s from Field-Measured BAFs

A baseline BAF_{ℓ}^{fd} should be calculated from each field-measured BAF_{T}^{t} using information on the lipid fraction in the tissue of concern for the study organism and the fraction of the total chemical that is freely dissolved in the study water.

1. **Baseline BAF_{ℓ}^{fd} Equation.** For each acceptable field-measured BAF_{T}^{t}, calculate a baseline BAF_{ℓ}^{fd} using the following equation:

$$\text{Baseline } BAF_{\ell}^{fd} = \left[\frac{\text{Measured } BAF_{T}^{t}}{f_{fd}} - 1 \right] \left(\frac{1}{f_{\ell}} \right) \qquad \text{(Equation 5-10)}$$

where:

Baseline BAF_{ℓ}^{fd}	=	BAF expressed on a freely dissolved and lipid-normalized basis
Measured BAF_{T}^{t}	=	BAF based on total concentration in tissue and water
f_{ℓ}	=	Fraction of the tissue that is lipid
f_{fd}	=	Fraction of the total chemical that is freely dissolved in the ambient water

The technical basis of Equation 5-10 is provided in the Bioaccumulation TSD. Guidance for determining each component of Equation 5-10 is provided below.

2. **Determining the Measured BAF_{T}^{t}.** The field-measured BAF_{T}^{t} shown in Equation 5-10 should be calculated based on the total concentration of the chemical in the appropriate tissue of the aquatic organism and the total concentration of the chemical in ambient water at the site of sampling. The equation to derive a measured BAF_{T}^{t} is:

$$\text{Measured } BAF_{T}^{t} = \frac{C_t}{C_w} \qquad \text{(Equation 5-11)}$$

where:

C_t	=	Total concentration of the chemical in the specified wet tissue
C_w	=	Total concentration of chemical in water

The data used to calculate a field-measured BAF_{T}^{t} should be reviewed thoroughly to assess the quality of the data and the overall uncertainty in the BAF value. The following general criteria apply in determining the acceptability of field-measured BAFs that are being considered for deriving national BAFs using Procedure #1.

a. Aquatic organisms used to calculate a field-measured BAF_{T}^{t} should be representative of aquatic organisms that are commonly consumed in the United States. An aquatic organism that is not commonly consumed in the United States can be used to calculate an acceptable field-measured BAF_{T}^{t} provided that the organism is considered to be a reasonable surrogate for a commonly consumed organism. Information on the ecology, physiology, and biology of the organism should be reviewed when assessing whether an organism is a reasonable surrogate of a commonly consumed organism.

b. The trophic level of the study organism should be determined by taking into account its life stage, diet, size, and the food web structure at the study location. Information from the study site (or similar sites) is preferred when evaluating trophic status. If such information is lacking, general information for assessing trophic status of aquatic organisms can be found in USEPA (2000a,b,c).

c. The percent lipid of the tissue used to determine the field-measured BAF^t_T should be either measured or reliably estimated to permit lipid-normalization of the chemical's tissue concentration.

d. The study from which the field-measured BAF^t_T is derived should contain sufficient supporting information from which to determine that tissue and water samples were collected and analyzed using appropriate, sensitive, accurate, and precise analytical methods.

e. The site of the field study should not be so unique that the BAF cannot be reasonably extrapolated to other locations where the BAF and resulting criteria will apply.

f. The water concentration(s) used to derive the BAF should reflect the average exposure of the aquatic organism that corresponds to the concentration measured in its tissue of concern. For nonionic organic chemicals, greater temporal and spatial averaging of chemical concentrations is required as the K_{ow} increases. In addition, as variability in water concentrations increase, greater temporal and spatial averaging is also generally required. Greater spatial averaging is also generally required for more mobile organisms.

g. The concentrations of particulate organic carbon and dissolved organic carbon in the study water should be measured or reliably estimated.

EPA is currently developing guidance for designing and conducting field studies for determining field-measured BAF^t_Ts, including recommendations for minimum data requirements. A more detailed discussion of factors that should be considered when determining field-measured BAF^t_Ts is provided in the Bioaccumulation TSD.

3. **Determining the Fraction Freely Dissolved (f_{fd}).** As illustrated by Equation 5-10, the fraction of the nonionic organic chemical that is freely dissolved in the study water is required for calculating a baseline BAF^{fd}_{ℓ} from a field-measured BAF^t_T. The freely dissolved fraction is the portion of the nonionic organic chemical that is not bound to particulate organic carbon or dissolved organic carbon. Together, the concentration of a nonionic organic chemical that is freely dissolved, bound to dissolved organic carbon, and bound to particulate organic carbon constitute its total concentration in water. As discussed further in the Bioaccumulation TSD, the freely dissolved fraction of a chemical is considered to be the best expression of the bioavailable form of nonionic organic chemicals to aquatic organisms (e.g., Suffet et al., 1994; USEPA, 1995b). Because the fraction of a nonionic organic chemical that is freely dissolved may vary among different bodies of water as a result of differences in dissolved and particulate organic carbon in the water, the bioavailability of the total chemical concentration in water is expected to vary from one body of water to another. Therefore, BAFs which are based on the freely dissolved concentration in water (rather than the total concentration in water) are considered to be more reliable for extrapolating and aggregating BAFs among different bodies of water. Currently, availability of BAFs based on measured freely dissolved

concentrations is very limited, partly because of difficulties in analytically measuring the freely dissolved concentration. Thus, if a BAF based on the total water concentration is reported in a given study, the fraction of the chemical that is freely dissolved should be predicted using information on the organic carbon content in the study water.

a. **Equation for Determining the Freely Dissolved Fraction.** If reliable measured data are unavailable to directly determine the freely dissolved fraction of the chemical in water, the freely dissolved fraction should be estimated using the following equation.

$$f_{fd} = \frac{1}{[1 + (POC \cdot K_{ow}) + (DOC \cdot 0.08 \cdot K_{ow})]} \qquad \text{(Equation 5-12)}$$

where:

POC	=	concentration of particulate organic carbon (kg/L)
DOC	=	concentration of dissolved organic carbon (kg/L)
K_{ow}	=	n-octanol water partition coefficient for the chemical

In Equation 5-12, K_{ow} is being used to estimate the partition coefficient to POC (i.e., K_{POC} in L/kg) and $0.08 \cdot K_{ow}$ is being used to estimate the partition coefficient to DOC (i.e., the K_{DOC} in L/kg). A discussion of the technical basis, assumptions, and uncertainty associated with the derivation and application of Equation 5-12 is provided in the Bioaccumulation TSD.

b. **POC and DOC Values.** When converting from the total concentration of a chemical to a freely dissolved concentration using Equation 5-12 above, the POC and DOC concentrations should be obtained from the original study from which the field-measured BAF is determined. If POC and DOC concentrations are not reported in the BAF study, reliable estimates of POC and DOC might be obtained from other studies of the same site used in the BAF study or closely related site(s) within the same water body. When using POC/DOC data from other studies of the same water body, care should be taken to ensure that environmental and hydrological conditions that might affect POC or DOC concentrations (i.e., runoff events, proximity to ground water or surface water inputs, sampling season) are reasonably similar to those in the BAF study. Additional information related to selecting POC and DOC values is provided in the Bioaccumulation TSD.

In some cases, BAFs are reported using the concentration of the chemical in filtered or centrifuged water. When converting these BAFs to a freely dissolved basis, the concentration of POC should be set equal to zero when using Equation 5-12. Particulates are removed from water samples by filtering or centrifuging the sample.

c. **Selecting K_{ow} Values.** A variety of techniques are available to measure or predict K_{ow} values. The reliability of these techniques depends to a large extent on the K_{ow} of the chemical. Because K_{ow} is an important input parameter for calculating the freely dissolved concentration of nonionic organic chemicals and for deriving BAFs using the other three methods of Procedure #1, care should be taken in selecting the most reliable K_{ow} value. The value of K_{ow} for use in estimating the freely dissolved fraction and other procedures used to derive national BAFs should be selected based on the guidance presented in the Bioaccumulation TSD.

4. **Determining the Fraction Lipid (f_ℓ).** Calculating a baseline BAF_ℓ^{fd} for a nonionic organic chemical using Equation 5-10 also requires that the total chemical concentration measured in the tissue used to determine the field-measured BAF_T^t be normalized by the lipid fraction (f_ℓ) in that same tissue. Lipid normalization of tissue concentrations reflects the assumption that BAFs (and BCFs) for nonionic organic chemicals are directly proportional to the percent lipid in the tissue upon which they are based. This assumption means that an organism with a two percent lipid content would be expected to accumulate twice the amount of a chemical at steady state compared with an organism with one percent lipid content, all else being equal. The assumption that aquatic organisms accumulate nonionic organic chemicals in proportion to their lipid content has been extensively evaluated in the literature (Mackay, 1982; Connell, 1988; Barron, 1990) and is generally accepted. Because the lipid content in aquatic organisms can vary both within and across species, BAFs that are expressed using the lipid-normalized concentration (rather than the total concentration in tissue) are considered to be the most reliable for aggregating multiple BAF values for a given species. Additional discussion of technical basis, assumptions, and uncertainties involved in lipid normalization is provided in the Bioaccumulation TSD.

a. The lipid fraction f_ℓ, is routinely reported in bioaccumulation studies involving nonionic organic chemicals. If the lipid fraction is not reported in the BAF study, it can be calculated using the following equation if the appropriate data are reported:

$$f_\ell = \frac{M_\ell}{M_t} \qquad \text{(Equation 5-13)}$$

where:

M_ℓ = Mass of lipid in specified tissue
M_t = Mass of specified tissue (wet weight)

b. Because lipid content can vary within an aquatic organism (and among tissues within that organism) due to several factors including the age and sex of the organism, changes in dietary composition, season of sampling and reproductive status, the lipid fraction used to calculate a baseline BAF_ℓ^{fd} should be measured in the same tissue and organisms used to determine the field-measured BAF^{t}_{T}, unless comparability is demonstrated across organisms.

c. Experience has shown that different solvent systems used to extract lipids for analytical measurement can result in different quantities of lipids being extracted and measured in aquatic organisms (e.g., Randall et al.,1991, 1998). As a result, lipid measurements determined using different solvent systems might lead to apparent differences in lipid-normalized concentrations and lipid-normalized BAFs. The extent to which different solvent systems might affect lipid extractions (and lipid-normalized concentrations) is thought to vary depending on the solvent, chemical of concern, and lipid composition of the tissue being extracted. Guidance on measurement of lipid content, including the choice of solvent system and how different solvent systems may affect lipid content, is provided in the Bioaccumulation TSD.

B. Baseline BAF^{fd}_{ℓ} Derived from BSAFs

The second method of determining a baseline BAF^{fd}_{ℓ} for the chemical of concern in Procedure #1 involves the use of BSAFs. Although BSAFs may be used for measuring and predicting bioaccumulation directly from concentrations of chemicals in surface sediment, they may also be used to estimate BAFs (USEPA, 1995b; Cook and Burkhard, 1998). Since BSAFs are based on field data and incorporate effects of chemical bioavailability, food web structure, metabolism, biomagnification, growth, and other factors, BAFs estimated from BSAFs will incorporate the net effect of all these factors. The BSAF approach is particularly beneficial for developing water quality criteria for chemicals which are detectable in fish tissues and sediments, but are difficult to detect or measure precisely in the water column.

As shown by Equation 5-14 below, predicting baseline BAF^{fd}_{ℓ}s using BSAFs requires that certain types of data be used for the chemicals of interest (for which BAFs are to be determined) and reference chemicals (for which BAFs are measured) from a common sediment-water-organism data set. Differences between BSAFs for different organic chemicals are good measures of the relative bioaccumulation potentials of the chemicals. When calculated from a common organism-sediment sample set, chemical-specific differences in BSAFs reflect the net effect of biomagnification, metabolism, food chain, bioenergetics, and bioavailability factors on the degree of each chemical's equilibrium/disequilibrium between sediment and biota. At equilibrium, BSAFs are expected to be approximately 1.0. However, deviations from 1.0 (reflecting disequilibrium) are common due to: conditions where water is not at equilibrium with surface sediment; differences in organic carbon content of water and sediment; kinetic limitations for chemical transfer between sediments and water associated with specific biota; biomagnification; or biological processes such as growth or biotransformation. BSAFs are most useful (i.e., most predictable from one site to another) when measured under steady-state (or near steady-state) conditions. The use of non-steady-state BSAFs, such as found with new chemical loadings or rapid increases in loadings, increases uncertainty in this method for the relative degree of disequilibrium between the reference chemicals and the chemicals of interest. In general, the fact that concentrations of hydrophobic chemicals in sediment are less sensitive than concentrations in water to fluctuations in chemical loading and distribution makes the BSAF method robust for estimating BAFs. Results from validation of the BAF procedure in Lake Ontario, the Fox River and Green Bay, Wisconsin, and the Hudson River, New York, demonstrate good agreement between observed and BSAF-predicted BAFs in the vast majority of comparisons made. Detailed results of the validation studies for the BSAF procedure are provided in the Bioaccumulation TSD.

Baseline BAF_{ℓ}^{fd}s should be calculated using acceptable BSAFs for chemicals of interest and appropriate sediment-to-water fugacity (disequilibrium) ratios $(\Pi_{socw})_r/(K_{ow})_r$ for reference chemicals under the following guidelines.

1. **Baseline $\mathbf{BAF_{\ell}^{fd}}$ Equation.** For each species with an acceptable field measured $(BSAF)_I$, a baseline BAF_{ℓ}^{fd} for the chemical of interest may be calculated using the following equation with an appropriate value of $(\Pi_{socw})_r/(K_{ow})_r$:

$$(Baseline\ BAF_{\ell}^{fd})_i = (BSAF)_i \frac{(D_{i/r})\ (\Pi_{socw})_r\ (K_{ow})_i}{(K_{ow})_r} \qquad \text{(Equation 5-14)}$$

where:

$(Baseline\ BAF_{\ell}^{fd})_I$	=	BAF expressed on a freely dissolved and lipid-normalized basis for chemical of interest "I"
$(BSAF)_I$	=	Biota-sediment accumulation factor for chemical of interest "I"
$(\Pi_{socw})_r$	=	sediment organic carbon to water freely dissolved concentration ratio of reference chemical "r"
$(K_{ow})_I$	=	octanol-water partition coefficient for chemical of interest "I"
$(K_{ow})_r$	=	octanol-water partition coefficient for the reference chemical "r"
$D_{i/r}$	=	ratio between Π_{socw}/K_{ow} for chemicals "I" and "r" (normally chosen so that $D_{i/r} = 1$)

The technical basis, assumptions, and uncertainties associated with Equation 5-14 are provided in the Bioaccumulation TSD. Guidance for determining each component of Equation 5-14 is provided below.

2. **Determining Field-Measured BSAFs.** BSAFs should be determined by relating lipid-normalized concentrations of chemicals in an organism (C_{ℓ}) to organic carbon-normalized concentrations of the chemicals in surface sediment samples (C_{soc}) using the following equation:

$$BSAF = \frac{C_{\ell}}{C_{soc}} \qquad \text{(Equation 5-15)}$$

a. **Lipid-Normalized Concentration.** The lipid-normalized concentration of a chemical in an organism should be determined by:

$$C_\ell = \frac{C_t}{f_\ell} \qquad \text{(Equation 5-16)}$$

where:

C_t = Concentration of the chemical in the wet tissue (either whole organism or specified tissue) (µg/g)
f_ℓ = Fraction lipid content in the tissue

b. **Organic Carbon-Normalized Concentration.** The organic carbon-normalized concentration of a chemical in sediment should be determined by:

$$C_{soc} = \frac{C_s}{f_{oc}} \qquad \text{(Equation 5-17)}$$

where:

C_s = Concentration of chemical in sediment (µg/g sediment)
f_{oc} = Fraction organic carbon in sediment

The organic carbon-normalized concentrations of the chemicals in surface sediment samples should be associated with the average exposure environment of the organism.

3. **Sediment-to-Water Partition Coefficient** $(\prod_{socw})_r$. Sediment-to-water partition coefficients for reference chemicals should be determined by:

$$(\prod_{socw})_r = \frac{(C_{soc})_r}{(C_w^{fd})_r} \qquad \text{(Equation 5-18)}$$

where:

$(C_{soc})_r$ = Concentration of a reference chemical in sediment normalized to sediment organic carbon
$(C_w^{fd})_r$ = Concentration of the reference chemical freely dissolved in water

4. **Selecting Reference Chemicals.** Reference chemicals with $(\prod_{socw}) / (K_{ow})$ similar to that of the chemical of interest are preferred for this method. Theoretically, knowledge of the

difference between sediment-to-water fugacity ratios for two chemicals, "I" and "r" ($D_{i/r}$), could be used when reliable reference chemicals that meet the fugacity equivalence condition are not available. Similarity of ($\prod_{socw}$) / (K_{ow}) for two chemicals can be indicated on the basis of similar physical-chemical behavior in water (persistence, volatilization), similar mass loading histories, and similar concentration profiles in sediment cores.

Validation studies have demonstrated that choosing reference chemicals with well quantified concentrations in water is important because the uncertainty associated with measurement of barely detected chemicals is large (see the Bioaccumulation TSD). Similarity between K_{ow} values of the reference and target chemicals is generally desirable, although recent validation studies indicate that the accuracy of the method is not substantially decreased through use of reference chemicals with large differences in K_{ow}, as long as the chemicals are structurally similar and have similar persistence behavior in water and sediments.

5. The following data, procedural, and quality assurance requirements should be met for predicting baseline BAF_{ℓ}^{fd}s using field-measured BSAFs:

   a. Data on the reference chemicals and chemicals of interest should come from a common organism-water-sediment data set at a particular site.

   b. The chemicals of interest and reference chemicals should have similar physicochemical properties and persistence in water and sediment.

   c. The loadings history of the reference chemicals and chemicals of interest should be similar such that their expected sediment-water disequilibrium ratios ($\prod_{socw}/K_{ow}$) would not be expected to be substantially different (i.e., $D_{i/r} \sim 1$).

   d. The use of multiple reference chemicals is generally preferred for determining the value of ($\prod_{socw})_r$ so long as the concentrations are well quantified and the aforementioned conditions for selecting reference chemicals are met. In some cases, use of a single reference chemical may be necessary because of limited data.

   e. Samples of surface sediments (0-1 cm is ideal) should be from locations in which sediment is regularly deposited and is representative of average surface sediment in the vicinity of the organism.

   f. The K_{ow} value for the target and reference chemicals should be selected as described in the Bioaccumulation TSD.

   g. All other data quality and procedural guidelines described earlier for determining field-measured BAFs in Section 5.4.3.1(A) should be met.

Further details on the requirements for predicting BAFs from BSAF measurements, including the data, assumptions, and limitations of this approach are provided in the Bioaccumulation TSD.

C. Baseline BAF_{ℓ}^{fd} from a Laboratory-Measured BCF_T^t and FCM

The third method in Procedure #1 consists of using a laboratory-measured BCF_T^t (i.e., a BCF based on total concentrations in tissue and water) and FCMs to predict a baseline BAF_{ℓ}^{fd} for the chemical of concern. The BCF_T^t is used in conjunction with an FCM because non-aqueous routes of exposure and subsequent biomagnification is of concern for the types of chemicals applicable to Procedure #1. A laboratory-measured BCF inherently accounts for the effects of chemical metabolism that occurs in the organism used to calculate the BCF, but does not account for metabolism which may occur in other organisms of the aquatic food web.

1. **Baseline BAF_{ℓ}^{fd} Equation.** For each acceptable laboratory-measured BCF_T^t, calculate a baseline BAF_{ℓ}^{fd} using the following equation:

$$\text{Baseline } BAF_{\ell}^{fd} = (FCM) \cdot \left[\frac{\text{Measured } BCF_T^t}{f_{fd}} - 1 \right] \cdot \left(\frac{1}{f_{\ell}} \right) \qquad \text{(Equation 5-19)}$$

where:

Baseline BAF_{ℓ}^{fd}	=	BAF expressed on a freely dissolved and lipid-normalized basis
Measured BCF_T^t	=	BCF based on total concentration in tissue and water
f_{ℓ}	=	Fraction of the tissue that is lipid
f_{fd}	=	Fraction of the total chemical in the test water that is freely dissolved
FCM	=	The food chain multiplier either obtained from Table 5-1 by linear interpolation for the appropriate trophic level, or from appropriate field data

The technical basis for Equation 5-19 is provided in the Bioaccumulation TSD. Guidance for determining each component of Equation 5-19 is provided below.

2. **Determining the Measured BCF_T^t.** The laboratory-measured BCF_T^t shown in Equation 5-19 should be calculated using information on the total concentration of the chemical in the tissue of the organism and the total concentration of the chemical in the laboratory test water. The equation to derive a measured BCF_T^t is:

$$\text{Measured } BCF_T^t = \frac{C_t}{C_w} \qquad \text{(Equation 5-20)}$$

where:

C_t = Total concentration of the chemical in the specified wet tissue
C_w = Total concentration of chemical in the laboratory test water

The data used to calculate a laboratory-measured BCF_T^t should be reviewed thoroughly to assess the quality of the data and the overall uncertainty in the BCF value. The following general criteria apply in determining the acceptability of laboratory-measured BCF_T^t.

a. The test organism should not be diseased, unhealthy, or adversely affected by the concentration of the chemical because these attributes may alter accumulation of chemicals compared with healthy organisms.

b. The total concentration of the chemical in the water should be measured and should be relatively constant during the exposure period.

c. The organisms should be exposed to the chemical using a flow-through or renewal procedure.

d. The percent lipid of the tissue used to normalize the BCF_T^t should be either measured or reliably estimated to permit lipid normalization of chemical concentrations.

e. The concentrations of particulate organic carbon and dissolved organic carbon in the study water should be measured or reliably estimated.

f. Aquatic organisms used to calculate a laboratory-measured BCF_T^t should be representative of those aquatic organisms that are commonly consumed in the United States. An aquatic organism which is not commonly consumed in the United States can be used to calculate an acceptable laboratory-measured BCF_T^t provided that the organism is considered to be a reasonable surrogate for a commonly consumed organism. Information on the ecology, physiology, and biology of the organism should be reviewed when assessing whether an organism is a reasonable surrogate of a commonly consumed organism.

g. BCFs may be based on measurement of radioactivity from radiolabeled parent compounds only when the BCF is intended to include metabolites, when there is confidence that there is no interference due to metabolites of the parent compounds, or when studies are conducted to determine the extent of metabolism, thus allowing for a proper correction.

h. The calculation of the BCF_T^t should appropriately address growth dilution, which can be particularly important in affecting BCF_T^t determinations for poorly depurated chemicals.

I. Other aspects of the methodology used should be similar to those described by the American Society of Testing and Materials (ASTM, 1999) and USEPA *Ecological Effects Test Guidelines* (USEPA, 1996).

j. In addition, the magnitude of the K_{ow} and the availability of corroborating BCF data should be considered. For example, if the steady-state method is used for the BCF_T^t determination, exposure periods longer than 28 days will generally be required for highly hydrophobic chemicals to reach steady state between the water and the organism.

k. If a baseline BCF_ℓ^{fd} derived from a laboratory-measured BCF_T^t consistently increases or decreases as the chemical concentration increases in the test solutions for the test organisms, the BCF_T^t should be selected from the test concentration(s) that would most closely correspond to the 304(a) criterion. Note: a BCF_T^t should not be calculated from a control treatment.

3. **Selecting Food Chain Multipliers.** An FCM reflects a chemical's tendency to biomagnify in the aquatic food web. Values of FCMs greater than 1.0 are indicative of biomagnification and typically apply to organic chemicals with log K_{ow} values between 4.0 and 9.0. For a given chemical, FCMs tend to be greater at higher trophic levels, although FCMs for trophic level three can be higher than those for trophic level four.

Food chain multipliers used to derive baseline BAF_ℓ^{fd}s using Procedure #1 can be selected from model-derived or field-derived estimates.

a. **Model-Derived FCMs.** For nonionic organic chemicals appropriate for Procedure #1, EPA has calculated FCMs for various K_{ow} values and trophic levels using the bioaccumulation model of Gobas (1993). The FCMs shown in Table 5-1 were calculated using the Gobas model as the ratio of the baseline BAF_ℓ^{fd}s for trophic levels 2, 3, and 4 to the baseline BCF_ℓ^{fd}.

EPA recommends using the biomagnification model by Gobas (1993) to derive FCMs for nonionic organic chemicals for several reasons. First, the Gobas model includes both benthic and pelagic food chains, thereby incorporating exposure of organisms to chemicals from both the sediment and the water column. Second, the input data needed to run the model can be readily defined. Third, the predicted BAFs using the model are in agreement with field-measured BAFs for chemicals, even those with very high log K_{ow}s. Finally, the model predicts chemical residues in benthic organisms using equilibrium partitioning theory, which is consistent with EPA's equilibrium partitioning sediment guidelines (USEPA, 2000d).

The Gobas model requires input of specific data on the structure of the food chain and the water quality characteristics of the water body of interest. For calculating national BAFs, a mixed pelagic/benthic food web structure consisting of four trophic levels is assumed. Trophic level 1 is phytoplankton, trophic level 2 is zooplankton, trophic level 3 is forage fish (e.g., sculpin and smelt), and trophic level 4 are predatory fish (e.g., salmonids). Additional assumptions are made regarding the composition of the aquatic species' diets (e.g., salmonids consume 10 percent sculpin, 50 percent alewives, and 40 percent smelt), the physical parameters of the aquatic species (e.g., lipid values), and the water quality characteristics (e.g., water temperature, sediment organic carbon).

A mixed pelagic/benthic food web structure has been assumed for the purpose of calculating FCMs because it is considered to be most representative of the types of food webs that occur in aquatic ecosystems. FCMs derived using the mixed pelagic/benthic structure are also about mid-range in magnitude between a 100% pelagic and 100% benthic driven food web (see the Bioaccumulation TSD). The validity of FCMs derived using the mixed pelagic/benthic food web structure has

Table 5-1
Food-Chain Multipliers for Trophic Levels 2, 3 and 4
(Mixed Pelagic and Benthic Food Web Structure and $\prod_{socw}$ / K_{OW} = 23)

Log K_{OW}	Trophic Level 2	Trophic Level 3	Trophic Level 4	Log K_{OW}	Trophic Level 2	Trophic Level 3	Trophic Level 4
4.0	1.00	1.23	1.07	6.6	1.00	12.9	23.8
4.1	1.00	1.29	1.09	6.7	1.00	13.2	24.4
4.2	1.00	1.36	1.13	6.8	1.00	13.3	24.7
4.3	1.00	1.45	1.17	6.9	1.00	13.3	24.7
4.4	1.00	1.56	1.23	7.0	1.00	13.2	24.3
4.5	1.00	1.70	1.32	7.1	1.00	13.1	23.6
4.6	1.00	1.87	1.44	7.2	1.00	12.8	22.5
4.7	1.00	2.08	1.60	7.3	1.00	12.5	21.2
4.8	1.00	2.33	1.82	7.4	1.00	12.0	19.5
4.9	1.00	2.64	2.12	7.5	1.00	11.5	17.6
5.0	1.00	3.00	2.51	7.6	1.00	10.8	15.5
5.1	1.00	3.43	3.02	7.7	1.00	10.1	13.3
5.2	1.00	3.93	3.68	7.8	1.00	9.31	11.2
5.3	1.00	4.50	4.49	7.9	1.00	8.46	9.11
5.4	1.00	5.14	5.48	8.0	1.00	7.60	7.23
5.5	1.00	5.85	6.65	8.1	1.00	6.73	5.58
5.6	1.00	6.60	8.01	8.2	1.00	5.88	4.19
5.7	1.00	7.40	9.54	8.3	1.00	5.07	3.07
5.8	1.00	8.21	11.2	8.4	1.00	4.33	2.20
5.9	1.00	9.01	13.0	8.5	1.00	3.65	1.54
6.0	1.00	9.79	14.9	8.6	1.00	3.05	1.06
6.1	1.00	10.5	16.7	8.7	1.00	2.52	0.721
6.2	1.00	11.2	18.5	8.8	1.00	2.08	0.483
6.3	1.00	11.7	20.1	8.9	1.00	1.70	0.320
6.4	1.00	12.2	21.6	9.0	1.00	1.38	0.210
6.5	1.00	12.6	22.8				

been evaluated in several different ecosystems including Lake Ontario, the tidally influenced Bayou D'Inde in Louisiana, the Fox River and Green Bay, Wisconsin, and the Hudson River in New York. Additional details of the validation of EPA's national default FCMs and the assumptions, uncertainties, and input parameters for the model are provided in the Bioaccumulation TSD.

Although EPA uses the FCMs in Table 5-1 to derive its national 304(a) criteria, EPA recognizes that food webs of other waterbodies might differ from the assumptions used to calculate national BAFs. In these situations, States and authorized Tribes may wish to use alternate food web structures for calculating FCMs for use in setting State or Tribal water quality criteria. Additional guidance on the use of alternate food web structures for calculating State, Tribal, or site-specific criteria is provided in the Bioaccumulation TSD.

b. **Field-Derived FCMs.** In addition to model-derived estimates of FCMs, field data may also be used to derive FCMs. Currently, the use of field-derived FCMs is the only method recommended for estimating FCMs for inorganic and organometalic chemicals because appropriate model-derived estimates are not yet available (see Section 5.6). In contrast to the model-based FCMs described previously, field-derived FCMs account for any metabolism of the chemical of concern by the aquatic organisms used to calculate the FCM.

Field-derived FCMs should be calculated using lipid-normalized concentrations of the nonionic organic chemical in appropriate predator and prey species using the following equations.

$$FCM_{TL2} = BMF_{TL2} \quad \text{(Equation 5-21)}$$

$$FCM_{TL3} = (BMF_{TL3})\,(BMF_{TL2}) \quad \text{(Equation 5-22)}$$

$$FCM_{TL4} = (BMF_{TL4})\,(BMF_{TL3})\,(BMF_{TL2}) \quad \text{(Equation 5-23)}$$

where:

FCM = Food chain multiplier for designated trophic level (TL2, TL3, or TL4)
BMF = Biomagnification factor for designated trophic level (TL2, TL3, or TL4)

The basic difference between FCMs and BMFs is that FCMs relate back to trophic level one (or trophic level two as assumed by the Gobas (1993) model), whereas BMFs always relate back to the next lowest trophic level. For nonionic organic chemicals, BMFs can be calculated from tissue residue concentrations determined in biota at a site according to the following equations.

$$BMF_{TL2} = (C_{\ell,TL2}) / (C_{\ell,TL1}) \quad \text{(Equation 5-24)}$$

$$BMF_{TL3} = (C_{\ell,TL3}) / (C_{\ell,TL2}) \quad \text{(Equation 5-25)}$$

$$BMF_{TL4} = (C_{\ell,TL4}) / (C_{\ell,TL3}) \quad \text{(Equation 5-26)}$$

where:

C_ℓ = Lipid-normalized concentration of chemical in tissue of appropriate biota that occupy the specified trophic level (TL2, TL3, or TL4)

In addition to the acceptability guidelines pertaining to field-measured BAFs, the following procedural and quality assurance requirements apply to field-measured FCMs.

(1) Information should be available to identify the appropriate trophic levels for the aquatic organisms and appropriate predator-prey relationships for the site from which FCMs are being determined. General information on determining trophic levels of aquatic organisms can be found in USEPA 2000a,b,c.

(2) The aquatic organisms sampled from each trophic level should reflect the most important exposure pathways leading to human exposure via consumption of aquatic organisms. For higher trophic levels (e.g., 3 and 4), aquatic species should also reflect those that are commonly consumed by humans.

(3) The studies from which the FCMs are derived should contain sufficient supporting information from which to determine that tissue samples were collected and analyzed using appropriate, sensitive, accurate, and precise methods.

(4) The percent lipid should be either measured or reliably estimated for the tissue used to determine the FCM.

(5) The tissue concentrations should reflect average exposure over the approximate time required to achieve steady-state in the target species.

D. Baseline BAF_ℓ^{fd} from a K_{ow} and FCM

The fourth method in Procedure #1 consists of using a K_{ow} and an appropriate FCM for estimating the baseline BAF_ℓ^{fd}. In this method, the K_{ow} is assumed to be equal to the baseline BCF_ℓ^{fd}. Numerous investigations have demonstrated a linear relationship between the logarithm of the BCF and the logarithm of the octanol-water partition coefficient (K_{ow}) for organic chemicals for fish and other aquatic organisms. Isnard and Lambert (1988) list various regression equations that illustrate this linear relationship. When the regression equations are constructed using lipid-normalized BCFs, the slopes and intercepts are not significantly different from one and zero, respectively (e.g., de Wolf, et al., 1992). The underlying assumption for the linear relationship between the BCF and K_{ow} is that the bioconcentration process can be viewed as the partitioning of a chemical between the lipid of the aquatic organisms and water and that the K_{ow} is a useful surrogate for this partitioning process (Mackay, 1982). To account for biomagnification, Procedure #1 requires the K_{ow} value be used in conjunction with an appropriate FCM.

1. **Baseline BAF_{ℓ}^{fd} Equation.** For each acceptable K_{ow} value and FCM for the chemical of concern, calculate a baseline BAF_{ℓ}^{fd} using the following equation.

$$\text{Baseline } BAF_{\ell}^{fd} = (FCM) \cdot (K_{ow}) \qquad \text{(Equation 5-27)}$$

where:

Baseline BAF_{ℓ}^{fd}	=	BAF expressed on a freely dissolved and lipid-normalized basis for a given trophic level
FCM	=	The food chain multiplier for the appropriate trophic level obtained from Table 5-1 by linear interpolation or from appropriate field data (used with Procedure #1 only)
K_{ow}	=	Octanol-water partition coefficient

The BCF-K_{ow} relationship has been developed primarily for nonionic organic chemicals that are not readily metabolized by aquatic organisms and thus is most appropriate for poorly-metabolized nonionic organic chemicals (i.e., Procedures #1 and #3 as depicted in Figure 5-1). For poorly-metabolized nonionic organic chemicals with large log K_{ow}s (i.e., > 6), reported log BCFs are often not equal to log K_{ow}. EPA believes that this nonlinearity is primarily due to not accounting for several factors which affect the BCF determination. These factors include not basing BCFs on the freely dissolved concentration in water, not accounting for growth dilution, not assessing BCFs at steady-state, inaccuracies in measurements of uptake and elimination rate constants, and complications from the use of solvent carriers in the exposure. Application of Equation 5-27 for predicting BAFs has been conducted in several different ecosystems including Lake Ontario, the tidally influenced Bayou D'Inde in Louisiana, the Fox River and Green Bay, Wisconsin, and the Hudson River in New York. Additional detail on the validation, technical basis, assumptions, and uncertainty associated with Equation 5-27 and is provided in the Bioaccumulation TSD.

2. **FCMs and K_{ow}s**. Food chain multipliers and K_{ow} values should be selected as described previously in Procedure #1.

5.4.3.2 Selecting Final Baseline BAF_{ℓ}^{fd}s

After calculating individual baseline BAF_{ℓ}^{fd}s using as many of the methods in Procedure #1 as possible, the next step is to determine a final baseline BAF_{ℓ}^{fd} for each trophic level from the individual baseline BAF_{ℓ}^{fd}s (see Figures 5-1 and 5-2). The final baseline BAF_{ℓ}^{fd} will be used in the last step to determine the national BAF for each trophic level. The final baseline BAF_{ℓ}^{fd} for each trophic level should be determined from the individual baseline BAF_{ℓ}^{fd}s by considering the data preference hierarchy defined by Procedure #1 and uncertainty in the data. The data preference hierarchy for Procedure #1 is (in order of preference):

1. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BAF (method 1)

2. a baseline BAF_{ℓ}^{fd} predicted from an acceptable field-measured BSAF (method 2),
3. a baseline BAF_{ℓ}^{fd} predicted from an acceptable BCF and FCM (method 3), or
4. a baseline BAF_{ℓ}^{fd} predicted from an acceptable K_{ow} and FCM (method 4).

This data preference hierarchy reflects EPA's preference for BAFs based on field-measurements of bioaccumulation (methods 1 and 2) over those based on laboratory-measurements and/or predictions of bioaccumulation (methods 3 and 4). However, this data preference hierarchy should not be considered inflexible. Rather, it should be used as a guide for selecting the final baseline BAF_{ℓ}^{fd}s when the uncertainty is similar among two or more baseline BAF_{ℓ}^{fd}s derived using different methods. The following steps and guidelines should be followed for selecting the final baseline BAF_{ℓ}^{fd}s using Procedure #1.

1. **Calculate Species-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method where more than one acceptable baseline BAF_{ℓ}^{fd} is available for a given species, calculate a species-mean baseline BAF_{ℓ}^{fd} as the geometric mean of all available individual baseline BAF_{ℓ}^{fd}s. When calculating a species-mean baseline BAF_{ℓ}^{fd}, individual baseline BAF_{ℓ}^{fd}s should be reviewed carefully to assess the uncertainty in the BAF values. For highly hydrophobic chemicals applicable to Procedure #1, particular attention should be paid to whether sufficient spatial and temporal averaging of water and tissue concentrations was likely achieved in the BAF, BSAF, or BCF study. Highly uncertain baseline BAF_{ℓ}^{fd}s should not be used. Large differences in individual baseline BAF_{ℓ}^{fd}s for a given species (e.g., greater than a factor of 10) should be investigated further. In such cases, some or all of the baseline BAF_{ℓ}^{fd}s for a given species might not be used. Additional discussion on evaluating acceptability of BAF values is provided in the Bioaccumulation TSD.

2. **Calculate Trophic-Level-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method where more than one acceptable species-mean baseline BAF_{ℓ}^{fd} is available within a given trophic level, calculate a trophic-level-mean baseline BAF_{ℓ}^{fd} as the geometric mean of acceptable species-mean baseline BAF_{ℓ}^{fd}s in that trophic level. Trophic-level-mean baseline BAF_{ℓ}^{fd}s should be calculated for trophic levels two, three, and four because available data on U.S. consumers of fish and shellfish indicate significant consumption of organisms in these trophic levels.

3. **Select a Final Baseline BAF_{ℓ}^{fd} for Each Trophic Level.** For each trophic level, select the final baseline BAF_{ℓ}^{fd} using best professional judgment by considering: (1) the data preference hierarchy shown previously, (2) the relative uncertainty in the trophic-level-mean baseline BAF_{ℓ}^{fd}s derived using different methods, and (3) the weight of evidence among the four methods.

   a. In general, when more than one trophic-level-mean baseline BAF_{ℓ}^{fd} is available for a given trophic level, the final trophic-level-mean baseline BAF_{ℓ}^{fd} should be selected from the most preferred BAF method defined by the data preference hierarchy for Procedure #1.

   b. If uncertainty in a trophic-level-mean baseline BAF based on a higher tier (more preferred) method is judged to be substantially greater than a trophic-level-mean baseline BAF from a lower tier method, and the weight of evidence among the various methods suggests that a BAF value from lower tier method is likely to be more accurate, then the final baseline BAF_{ℓ}^{fd} should be selected using a trophic level-mean baseline BAF_{ℓ}^{fd} from a lower tier method.

c. When considering the weight of evidence among the various BAF methods, greater confidence in the final baseline BAF_{ℓ}^{fd} is generally assigned when BAFs from a greater number of methods are in agreement for a given trophic level. However, lack of agreement among methods does not necessarily indicate less confidence if such disagreements can be adequately explained. For example, if the chemical of concern is metabolized by aquatic organisms represented by a BAF value, one would expect disagreement between a field-measured BAF (the highest priority data) and a predicted BAF using a K_{ow} and model-derived FCM. Thus, field-measured BAFs should generally be given the greatest weight among methods because they reflect direct measures of bioaccumulation and incorporate any metabolism which might occur in the organism and its food web.

d. The above steps should be performed for each trophic level until a final baseline BAF_{ℓ}^{fd} is selected for trophic levels two, three, and four.

5.4.3.3 Calculating National BAFs

The last step in deriving a national BAF for each trophic level is to convert the final baseline BAF_{ℓ}^{fd} determined in the previous step to a BAF that reflects conditions to which the national 304(a) criteria will apply (Figure 5-2). Since a baseline BAF_{ℓ}^{fd} is by definition normalized by lipid content and expressed on a freely dissolved basis, it needs to be adjusted to reflect the lipid fraction of aquatic organisms commonly consumed in the U.S. and the freely dissolved fraction expected in U.S. bodies of water. Converting a final baseline BAF_{ℓ}^{fd} to a national BAF requires information on: (1) the percent lipid of the aquatic organisms commonly consumed by humans, and (2) the freely dissolved fraction of the chemical of concern that would be expected in the ambient waters of interest. For each trophic level, a national BAF should be determined from a final baseline BAF_{ℓ}^{fd} according to the following guidelines.

1. **National BAF Equation.** For each trophic level, calculate a national BAF using the following equation.

$$\text{National BAF}_{(TL\ n)} = [(\text{Final Baseline BAF}_{\ell}^{fd})_{TL\ n} \cdot (f_{\ell})_{TL\ n} + 1] \cdot (f_{fd}) \qquad \text{(Equation 5-28)}$$

where:

Final Baseline BAF_{ℓ}^{fd} = Final trophic-level-mean baseline BAF expressed on a freely dissolved and lipid-normalized basis for trophic level "n"

$f_{\ell(TL\ n)}$ = Lipid fraction of aquatic species consumed at trophic level "n"

f_{fd} = Fraction of the total chemical in water that is freely dissolved

The technical basis of Equation 5-28 is provided in the Bioaccumulation TSD. Guidance for determining each component of Equation 5-28 is provided below.

2. **Determining the Final Baseline BAF_{ℓ}^{fd}.** The final trophic-level-mean baseline BAF_{ℓ}^{fd}s used in this equation are those which have been determined using the guidance presented in Section 5.4.3.2 for selecting the final baseline BAF_{ℓ}^{fd}s.

3. **Lipid Content of Commonly Consumed Aquatic Species.** As illustrated by Equation 5-28, the percent lipid of the aquatic species consumed by humans is needed to accurately characterize the potential exposure to a chemical from ingestion of aquatic organisms.

   a. **National Default Lipid Values.** For the purposes of calculating a national 304(a) criterion, the following national default values for lipid fraction should be used: 1.9% (for trophic level two organisms), 2.6% (for trophic level three organisms), and 3.0% (for trophic level four organisms).

   These national default values for lipid content reflect national per capita average patterns of fish consumption in the United States. Specifically, they were calculated using the consumption-weighted mean lipid content of commonly consumed fish and shellfish as identified by the USDA Continuing Survey of Food Intake by Individuals (CSFII) for 1994 through 1996. This same national survey data was used to derive national default values of fish consumption. To maintain consistency with the fish consumption assumptions, only freshwater and estuarine organisms were included in the derivation of the national default lipid values. Additional details on the technical basis, assumptions, and uncertainty in the national default values of lipid fraction are provided in the Bioaccumulation TSD.

   Although national default lipid values are used by EPA to set national 304(a) criteria, EPA encourages States and authorized Tribes to use local or regional data on lipid content of consumed aquatic species when adopting criteria into their water quality standards because local or regional consumption patterns (and lipid content) can differ from national consumption patterns. Additional guidance on developing site-specific values of lipid content, including a database of lipid content for many commonly consumed aquatic organisms, is found in the Bioaccumulation TSD.

4. **Freely Dissolved Fraction.** The third piece of information required for deriving a national BAF is the freely dissolved fraction of the chemical of concern that is expected

in waters of the United States. As noted previously, expressing BAFs on the freely dissolved concentration in water allows a common basis for averaging BAFs from several studies. However, for use in criteria development, these BAFs should be converted back to values based on the total concentration in the water to be consistent with monitored water column and effluent concentrations, which are typically based on total concentrations of chemicals in the water. This should be done by multiplying the freely dissolved baseline BAF_{ℓ}^{fd} by the fraction of the freely dissolved chemical expected in water bodies of the United States where criteria are to be applied, as shown in Equation 5-29.

$$f_{fd} = \frac{1}{[1 + (POC \cdot K_{ow}) + (DOC \cdot 0.08 \cdot K_{ow})]} \qquad \text{(Equation 5-29)}$$

where:

POC	=	national default value for the particulate organic carbon concentration (kg/L)
DOC	=	national default value for the dissolved organic carbon concentration (kg/L)
K_{ow}	=	n-octanol water partition coefficient for the chemical

Equation 5-29 is identical to Equation 5-12, which was used to determine the freely dissolved fraction for deriving baseline BAF_{ℓ}^{fd}s from field-measured BAFs. However, the POC and DOC concentrations used in Equation 5-29 reflect those values that are expected in U.S. bodies of water, not the POC and DOC values in the study water used to derive the BAF. Guidance for determining each component of Equation 5-29 follows.

a. **National Default Values of POC and DOC.** For estimating the freely dissolved fraction of the chemical of concern that is expected in U.S. water bodies, national default values of 0.5 mg/L (5×10^{-7} kg/L) for POC and 2.9 mg/L (2.9×10^{-6} kg/L) for DOC should be used. These values are 50th percentile values (medians) based on an analysis of over 110,000 DOC values and 85,000 POC values contained in EPA's STORET database from 1980 through 1999. These default values reflect a combination of values for streams, lakes and estuaries across the United States. Additional details on the technical basis, assumptions, and uncertainty in the derivation and application of the national default values of POC and DOC are provided in the Bioaccumulation TSD.

Although national default values of POC and DOC concentrations are used by EPA to set national 304(a) criteria as described by this document, EPA encourages States and authorized Tribes to use local or regional data on POC and DOC when adopting criteria into their water quality standards. EPA encourages States and Tribes to consider local or regional data on POC and DOC because local or regional conditions may result in differences in POC or DOC concentrations compared with the values used as national defaults. Additional guidance on developing local or regional values of POC and DOC, including a database of POC and DOC values segregated by waterbody type, is found in the Bioaccumulation TSD.

b. **K_{ow} Value.** The value selected for the K_{ow} of the chemical of concern should be the same value used in earlier calculations (e.g., for calculating baseline BAF_{ℓ}^{fd}s and FCMs). Guidance for selecting the K_{ow} value is found in the Bioaccumulation TSD.

5.4.4 Deriving National BAFs Using Procedure #2

This section provides guidance for calculating national BAFs for nonionic organic chemicals using Procedure #2 shown in Figure 5-1. The types of nonionic organic chemicals for which Procedure #2 is most appropriate are those that are classified as moderately to highly hydrophobic and subject to high rates of metabolism by aquatic biota (see Section 5.4.2 above). Non-aqueous contaminant exposure and subsequent biomagnification in aquatic food webs are not generally of concern for chemicals that are classified in this category. As a result, FCMs are not used in this procedure. In addition, K_{ow} -based predictions of bioconcentration are not used in this procedure since the K_{ow} /BCF relationship is primarily based on poorly metabolized chemicals. Some nonionic organic chemicals for which Procedure #2 is probably appropriate include certain PAHs which are believed to be metabolized substantially by fish (e.g., benzo[a]pyrene, phenanthrene, fluoranthene, pyrene, benzo[a]anthracene and chrysene/triphenylene; USEPA, 1980; Burkhard and Lukasewycz, 2000).

According to Procedure #2, the following three methods can be used in deriving a national BAF:

- using a BAF from an acceptable field study (i.e., a field-measured BAF) (method 1),
- predicting a BAF from an acceptable BSAF (method 2), and
- predicting a BAF from an acceptable BCF (method 3).

Each of these three methods relies on measured data for assessing bioaccumulation and therefore, includes the effects of chemical metabolism by the study organism in the BAF estimate. The field-measured BAF and BSAF methods also incorporate any metabolism which occurs in the aquatic food web.

As shown in Figure 5-2, the next steps in deriving a national BAF after selecting the derivation procedure are: (1) calculating individual baseline BAF_{ℓ}^{fd}s, (2) selecting the final baseline BAF_{ℓ}^{fd}s, and (3) calculating the national BAFs. Each of these three steps is discussed separately below.

5.4.4.1 Calculating Individual Baseline BAF_{ℓ}^{fd}s

As described previously in Procedure #1, calculating individual baseline BAF_{ℓ}^{fd}s involves normalizing the measured BAF_T^t or BCF_T^t (which are based on the total chemical in water and tissue) by the lipid content of the study organisms and the freely dissolved fraction of the chemical in the study water. Converting measured BAF_T^t (or BCF_T^t) values to baseline BAF_ℓ^{fd} (or BCF_ℓ^{fd}) values is designed to account for variation in measured BAF_T^ts that is caused by differences in lipid content of study organisms and differences in the freely dissolved fraction of chemical in study waters. Therefore, baseline BAF_ℓ^{fd}s are considered more amenable for extrapolating and averaging BAFs across different species and different study waters compared with total BAF_T^ts.

1. For each species where acceptable data are available, calculate all possible baseline BAF_ℓ^{fd}s using each of the three methods shown above for Procedure #2.

2. Individual baseline BAF_ℓ^{fd}s should be calculated from field-measured BAF_T^ts, field-measured BSAFs, and laboratory BCF_T^ts according to the following procedures.

A. Baseline BAF_ℓ^{fd} from Field-Measured BAFs

1. Except where noted below, a baseline BAF_ℓ^{fd} should be calculated from a field-measured BAF_T^t using the guidance and equations outlined in Section 5.4.3.1(A) for determining baseline BAF_ℓ^{fd}s from field-measured BAFs in Procedure #1.

2. Because nonionic organic chemicals applicable to Procedure #2 have relatively high rates of metabolism in aquatic organisms, they will tend to reach steady state more quickly than nonionic organic chemicals with similar K_{ow} values but which undergo little or no metabolism. Therefore, less temporal averaging of chemical concentrations would generally be required for determining field-measured BAF_T^ts with highly metabolizable chemicals compared with chemicals that are poorly metabolized by aquatic biota.

B. Baseline BAF_{ℓ}^{fd} Derived from Field-measured BSAFs

1. A baseline BAF_{ℓ}^{fd} should be calculated from a field-measured BSAF using the guidance and equations outlined in Section 5.4.3.1(B) for determining baseline BAF_{ℓ}^{fd}s from field-measured BSAFs in Procedure #1.

C. Baseline BAF_{ℓ}^{fd} from a Laboratory-Measured BCF

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from a laboratory-measured BCF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(c) for determining baseline BAF_{ℓ}^{fd}s from a laboratory-measured BCF and FCM in Procedure #1.

2. Because biomagnification is not an overriding concern for nonionic organic chemicals applicable to Procedure #2, food chain multipliers are not used in the derivation of a baseline BAF_{ℓ}^{fd} from a laboratory-measured BCF_{T}^{t} .

5.4.4.2 <u>Selecting Final Baseline BAF_{ℓ}^{fd}s</u>

After calculating individual, baseline BAF_{ℓ}^{fd}s using as many of the methods in Procedure #2 as possible, the next step is to determine a final baseline BAF_{ℓ}^{fd} for each trophic level from the individual baseline BAF_{ℓ}^{fd}s. The final baseline BAF_{ℓ}^{fd} will be used in the last step to determine the national BAF for each trophic level. A final baseline BAF_{ℓ}^{fd} for each trophic level should be determined from the individual baseline BAF_{ℓ}^{fd}s by considering the data preference hierarchy defined by Procedure #2 and uncertainty in the data. The data preference hierarchy for Procedure #2 is (in order of preference):

1. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BAF (method 1),
2. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BSAF (method 2), or
3. a baseline BAF_{ℓ}^{fd} from an acceptable laboratory-measured BCF (method 3).

This data preference hierarchy reflects EPA's preference for BAFs based on field-measurements of bioaccumulation (methods 1 and 2) over those based on laboratory-measurements (method 3). However, as explained in Procedure #1, this data preference hierarchy should not be considered inflexible. Rather, it should be used as a guide for selecting the final baseline BAF_{ℓ}^{fd}s when the underlying uncertainty is similar among two or more baseline BAF_{ℓ}^{fd}s derived using different methods. Although biomagnification is not generally a concern for chemicals subject to Procedure #2, trophic level differences in bioaccumulation might be substantial to the extent that the rate of chemical metabolism by organisms in different trophic levels differs. For example, certain PAHs have been shown to be metabolized to a much greater extent by some fish compared with some invertebrate species (James, 1989). Therefore, final baseline BAF_{ℓ}^{fd}s for chemicals applicable to Procedure #2 should be determined on a trophic-level-specific basis according to the following guidelines.

1. The final baseline BAF_{ℓ}^{fd}s in Procedure #2 should be selected according to the same steps described in Procedure #1 but with the substitution of the data preference hierarchy described above for Procedure #2. Specifically, the species-mean baseline BAF_{ℓ}^{fd}s,

trophic-level-mean baseline BAF_ℓ^{fd}s, and the final baseline BAF_ℓ^{fd}s should be determined according to the guidelines presented in Procedure #1 (Section 5.4.3.2, Steps 1, 2, and 3).

5.4.4.3 <u>Calculating the National BAFs</u>

As described in Procedure #1, the last step in deriving national BAFs for nonionic organic chemicals is to convert the final baseline BAF_ℓ^{fd}s determined in the previous step to BAFs which reflect conditions to which the national 304(a) criteria will apply (Figure 5-2).

1. For trophic levels two, three, and four, national BAFs should be calculated from the final baseline BAF_ℓ^{fd}s using the same equation and procedures described previously in Procedure #1 (see Section 5.4.3.3 entitled "Calculating the National BAFs").

5.4.5 Deriving National BAFs Using Procedure #3

This section provides guidance for calculating national BAFs for nonionic organic chemicals using Procedure #3 shown in Figure 5-1. The types of nonionic organic chemicals for which Procedure #3 is most appropriate are those that are classified as low in hydrophobicity (i.e., log K_{ow} values less than 4.0) and subject to low (or unknown) rates of metabolism by aquatic biota (see Section 5.4.2 above). Non-aqueous contaminant exposure and subsequent biomagnification in aquatic food webs are not generally of concern for chemicals that are classified in this category (Fisk et al., 1998; Gobas et al., 1993; Connolly and Pedersen, 1988; Thomann, 1989). As a result, FCMs are not used in this procedure.

According to Procedure #3, the following three methods can be used in deriving a national BAF:

- using a BAF from an acceptable field study (i.e., a field-measured BAF),
- predicting a BAF from an acceptable laboratory-measured BCF, and
- predicting a BAF from an acceptable K_{ow}.

After selecting the derivation procedure, the next steps in deriving a national BAF at a given trophic level for nonionic organic chemicals are: (1) calculating individual baseline BAF_ℓ^{fd}s, (2) selecting the final baseline BAF_ℓ^{fd}, and (3) calculating the national BAF (Figure 5-2). Each of these three steps is discussed separately below.

5.4.5.1 <u>Calculating Individual Baseline BAF_ℓ^{fd}s</u>

Calculating individual baseline BAF_ℓ^{fd}s involves normalizing each measured BAF_T^t or BCF_T^t (which are based on the total chemical in water and tissue) by the lipid content of the study organism and the freely dissolved fraction of the chemical in the study water. For additional discussion of the technical basis for calculating baseline BAF_ℓ^{fd}s, see Section 5.4.3.1 in Procedure #1.

1. For each species where acceptable data are available, calculate all possible baseline BAF_{ℓ}^{fd}s using each of the three methods shown above for Procedure #3.

2. An individual baseline BAF_{ℓ}^{fd} should be calculated from field-measured BAF_{T}^{t}s, laboratory-measured BCF_{T}^{t}s, and K_{ow} values according to the following procedures.

A. Baseline BAF_{ℓ}^{fd} from Field-Measured BAFs

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from a field-measured BAF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(A) in Procedure #1.

2. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), nonionic organic chemicals applicable to Procedure #3 are expected to remain almost entirely in the freely dissolved form in natural waters with dissolved and particulate organic carbon concentrations typical of most field BAF studies. Therefore, the freely dissolved fraction should be assumed to be equal to 1.0, unless the concentrations of DOC and POC are very high in the field BAF study. For studies with very high DOC or POC concentrations, (e.g., about 100 mg/L or higher for DOC or 10 mg/L or higher for POC), the freely dissolved fraction may be substantially lower than 1.0 and therefore should be calculated using Equation 5-12.

3. **Temporal Averaging of Concentrations.** Also due to their low hydrophobicity, nonionic organic chemicals appropriate to Procedure #3 will also tend to reach steady state quickly compared with those chemicals to which Procedure #1 applies. Therefore, the extent of temporal averaging of tissue and water concentrations is typically much less than that required for highly hydrophobic chemicals to which Procedure #1 is applied. In addition, field studies used to calculate BAFs for these chemicals should have sampled water and tissue at similar points in time because tissue concentrations respond more rapidly to changes in water concentrations. EPA will be providing additional guidance on appropriate BAF study designs for nonionic organic chemicals (including those appropriate to Procedure #3) in its forthcoming guidance document on conducting field BAF and BSAF studies.

B. Baseline BAF_{ℓ}^{fd} from a Laboratory-Measured BCF

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from a laboratory-measured BCF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(c) of Procedure #1.

2. **Food Chain Multipliers.** Because biomagnification is not an overriding concern for the minimally hydrophobic chemicals applicable to Procedure #3, FCMs are not used in the derivation of a baseline BAF_{ℓ}^{fd} from a laboratory-measured BCF_{T}^{t}.

3. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), nonionic organic chemicals to which Procedure #3 is applied are expected to remain

almost entirely in the freely dissolved form in waters containing dissolved and particulate organic carbon concentrations typical of laboratory BCF studies. Therefore, the freely dissolved fraction should usually be assumed equal to 1.0. The freely dissolved fraction will be substantially less than 1.0 only in situations where unusually high concentrations of DOC and POC are present in the laboratory BCF study (e.g., above about 100 mg/L for DOC or about 10 mg/L for POC). In this situation, the freely dissolved fraction should be calculated according to Equation 5-12.

C. Baseline BAF_{ℓ}^{fd} from a K_{ow}

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from an acceptable K_{ow} using the guidance and equations outlined in Section 5.4.3.1(D) in Procedure #1.

2. Because biomagnification is not an overriding concern for nonionic organic chemicals with low hydrophobicity (i.e., log K_{ow} < 4.0), food chain multipliers are not used in Procedure #3 for deriving the baseline BAF_{ℓ}^{fd} from a K_{ow}.

5.4.5.2 <u>Selecting Final Baseline BAF_{ℓ}^{fd}s</u>

After calculating individual baseline BAF_{ℓ}^{fd}s using as many of the methods in Procedure #3 as possible, the next step is to determine a final baseline BAF_{ℓ}^{fd} for each trophic level from the individual baseline BAF_{ℓ}^{fd}s (Figure 5-2). The final baseline BAF_{ℓ}^{fd} will be used in the last step to determine the national BAF for each trophic level. The final baseline BAF_{ℓ}^{fd} for each trophic level should be determined from the individual baseline BAF_{ℓ}^{fd}s by considering the data preference hierarchy defined by Procedure #3 and uncertainty in the data. The data preference hierarchy for Procedure #3 is (in order of preference):

1. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BAF or laboratory-measured BCF, or
2. a baseline BAF_{ℓ}^{fd} predicted from an acceptable K_{ow} value.

This data preference hierarchy reflects EPA's preference for BAFs that are based on measured data (field-measured BAFs and laboratory-measured BCFs) over BAFs based on predictive methods (K_{ow}). This data preference hierarchy should be used as a guide for selecting the final baseline BAF_{ℓ}^{fd}s when the uncertainty is similar among two or more baseline BAF_{ℓ}^{fd}s derived using different methods. Since bioaccumulation via dietary uptake and subsequent biomagnification generally are not of concern for chemicals subject to Procedure #3, field-measured BAFs and laboratory-measured BCFs are considered equally in determining the national BAF.

Final baseline BAF_{ℓ}^{fd}s should be selected for each trophic level using the following steps and guidelines.

1. **Calculate Species-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method (i.e., field-measured BAF, BAF from a lab-measured BCF, or BAF from a K_{ow}) where more than one

acceptable baseline BAF_{ℓ}^{fd} is available for a given species, calculate a species-mean baseline BAF_{ℓ}^{fd} according to the guidance described previously in Procedure #1.

2. **Calculate Trophic-Level-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method where more than one acceptable species-mean baseline BAF_{ℓ}^{fd} is available within a given trophic level, calculate the trophic-level-mean baseline BAF_{ℓ}^{fd} as the geometric mean of acceptable species-mean baseline BAF_{ℓ}^{fd}s in that trophic level.

3. **Select a Final Baseline BAF_{ℓ}^{fd} for Each Trophic Level.** For each trophic level, select the final baseline BAF_{ℓ}^{fd} using best professional judgment by considering: (1) the data preference hierarchy, (2) the relative uncertainties among trophic-level-mean baseline BAF_{ℓ}^{fd}s derived using different methods, and (3) the weight of evidence among the three methods.

   a. In general, when more than one trophic-level-mean baseline BAF_{ℓ}^{fd} is available within a given trophic level, the final baseline BAF_{ℓ}^{fd} should be selected from the most preferred BAF method defined by the data preference hierarchy for Procedure #3. Within the first data preference tier, field-measured BAFs and laboratory-measured BCFs are considered equally desirable for deriving a final trophic-level-mean baseline BAF_{ℓ}^{fd} using Procedure #3. If a trophic-level-mean baseline BAF_{ℓ}^{fd} is available from both a field-measured BAF and a laboratory-measured BCF, the final baseline BAF_{ℓ}^{fd} should be selected using the trophic-level-mean baseline BAF_{ℓ}^{fd} or BCF_{ℓ}^{fd} with the least overall uncertainty.

   b. If uncertainty in a trophic-level-mean baseline BAF_{ℓ}^{fd} based on a higher tier (more preferred) method is judged to be substantially greater than a trophic-level-mean baseline BAF_{ℓ}^{fd} from a lower tier method, then the final baseline BAF_{ℓ}^{fd} should be selected using a trophic-level-mean baseline BAF_{ℓ}^{fd} from a lower tier method.

   c. The above steps should be performed for each trophic level until a final baseline BAF_{ℓ}^{fd} is selected for trophic level two, three, and four.

5.4.5.3 <u>Calculating the National BAFs</u>

As described in Procedure #1, the last step in deriving a national BAF for a given trophic level for nonionic organic chemicals is to convert the final baseline BAF_{ℓ}^{fd} determined in the previous step to a BAF that reflect conditions to which the national 304(a) criterion will apply (Figure 5-2). Each national BAF should be determined from a final baseline BAF_{ℓ}^{fd} according to the following guidelines.

1. **National BAF Equation.** Except where noted below, national BAFs for trophic levels two, three, and four should be calculated from the final, trophic-level-mean baseline BAF_{ℓ}^{fd}s using Equation 5-28 and associated guidance described in Procedure #1 (see Section 5.4.3.3).

2. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), a freely dissolved fraction of 1.0 should be assumed for calculating national BAFs for nonionic organic chemicals using Procedure #3. A freely dissolved fraction of 1.0 should be assumed because at a log K_{ow} of less than 4.0, nonionic organic chemicals are expected to remain over 99 percent in the freely dissolved form at POC and DOC concentrations corresponding to national default values for U.S. bodies of water (i.e., 0.5 mg/L and 2.9 mg/L, respectively).

5.4.6 Deriving National BAFs Using Procedure #4

This section provides guidance for calculating national BAFs for nonionic organic chemicals using Procedure #4 shown in Figure 5-1. The types of nonionic organic chemicals for which Procedure #4 is most appropriate are those that are classified as having low hydrophobicity and subject to high rates of metabolism by aquatic biota (see Section 5.4.2 above). Non-aqueous contaminant exposure and subsequent biomagnification in aquatic food webs are not generally of concern for chemicals that are classified in this category. As a result, FCMs are not used in this procedure. In addition, K_{ow} -based predictions of bioconcentration are not used in this procedure since the K_{ow} /BCF relationship is primarily based on poorly metabolized chemicals. One example of a nonionic organic chemical for which Procedure #4 appears appropriate is butyl benzyl phthalate in fish. Using radiolabeling techniques with confirmation by chromatographic analysis, Carr et al. (1997) present evidence that indicates butyl benzyl phthalate is extensively metabolized in sunfish. Carr et al. (1997) also report measured BCFs (and subsequently lipid-normalized BCFs) which are substantially below predicted BCFs based on log $K_{ow.}$ In a study of chlorinated anilines (which would be essentially un-ionized at ambient pH), de Wolf et al. (1992) reported measured BCFs substantially lower than those predicted based on K_{ow}. The authors suggested that biotransformation (metabolism) involving the amine (NH_2) was responsible for the lower measured BCFs.

According to Procedure #4, the following two methods can be used in deriving a national BAF:

- using a BAF from an acceptable field study (i.e., a field-measured BAF), and
- predicting a BAF from an acceptable BCF.

After selecting the derivation procedure, the next steps in deriving a national BAF for a given trophic level for nonionic organic chemicals are: (1) calculating individual baseline BAF_{ℓ}^{fd}s, (2) selecting the final baseline BAF_{ℓ}^{fd}, and (3) calculating the national BAF (Figure 5-2). Each of these three steps is discussed separately below.

5.4.6.1 Calculating Individual Baseline BAF_{ℓ}^{fd}s

Calculating individual baseline BAF_{ℓ}^{fd}s involves normalizing the measured BAF_T^t or BCF_T^t (which are based on the total chemical in water and tissue) by the lipid content of the study organism and the freely dissolved fraction of the chemical in the study water. For additional discussion of the technical basis for calculating baseline BAF_{ℓ}^{fd}s, see Section 5.4.3.1 in Procedure #1.

1. For each species where acceptable data are available, calculate all possible baseline BAF_{ℓ}^{fd}s using each of the two methods shown above for Procedure #4.

2. Individual baseline BAF_{ℓ}^{fd}s should be calculated from field-measured BAF_{T}^{t}s and laboratory-measured BCF_{T}^{t}s according to the following procedures.

A. Baseline BAF_{ℓ}^{fd} from Field-Measured BAFs

1. A baseline BAF_{ℓ}^{fd} should be calculated from a field-measured BAF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(A) in Procedure #1.

2. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log $K_{ow} < 4.0$), nonionic organic chemicals applicable to Procedure #4 are expected to remain almost entirely in the freely dissolved form in natural waters with dissolved and particulate organic carbon concentrations typical of most field BAF studies. Therefore, the freely dissolved fraction should be assumed equal to 1.0 unless the concentrations of DOC and POC are very high in the field BAF study. For studies with very high DOC or POC concentrations, (e.g., about 100 mg/L or higher for DOC or 10 mg/L or higher for POC), the freely dissolved fraction may be substantially lower than 1.0 and therefore should be calculated using Equation 5-12.

3. **Temporal Averaging of Concentrations.** Also due to their low hydrophobicity, nonionic organic chemicals appropriate to Procedure #4 will also tend to reach steady-state quickly compared with those chemicals to which Procedure #1 applies. Therefore, the extent of temporal averaging of tissue and water concentrations is typically much less than that required for highly hydrophobic chemicals to which Procedure #1 is applied. In addition, field studies used to calculate BAFs for these chemicals should have sampled water and tissue at similar points in time because tissue concentrations should respond rapidly to changes in water concentrations. EPA will be providing additional guidance on appropriate BAF study designs for nonionic organic chemicals (including those appropriate to Procedure #4) in its forthcoming guidance document on conducting field BAF and BSAF studies.

B. Baseline BAF_{ℓ}^{fd} from a Laboratory-Measured BCF

1. Except where noted below, a baseline BAF_{ℓ}^{fd} should be calculated from a laboratory-measured BCF_{T}^{t} using the guidance and equations outlined in Section 5.4.3.1(c) of Procedure #1.

2. **Food Chain Multipliers.** Because biomagnification is not an important concern for the minimally hydrophobic chemicals applicable to Procedure #4, FCMs are not used in the derivation of a baseline BAF_{ℓ}^{fd} from a laboratory-measured BCF_{T}^{t}.

3. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log $K_{ow} < 4.0$), nonionic organic chemicals to which Procedure #4 is applied are expected to remain

almost entirely in the freely dissolved form in waters containing dissolved and particulate organic carbon concentrations typical of laboratory BCF studies. Therefore, the freely dissolved fraction should usually be assumed to be equal to 1.0. The freely dissolved fraction will be substantially less than 1.0 only in situations where unusually high concentrations of DOC and POC are present in the lab BCF study (e.g., above about 100 mg/L for DOC or about 10 mg/L for POC). In this situation, the freely dissolved fraction should be calculated according to Equation 5-12.

5.4.6.2 Selecting Final Baseline BAF_{ℓ}^{fd}s

After calculating individual baseline BAF_{ℓ}^{fd}s using as many of the methods in Procedure #4 as possible, the next step is to determine a final baseline BAF_{ℓ}^{fd} for a given trophic level from the individual baseline BAF_{ℓ}^{fd}s (Figure 5-2). The final baseline BAF_{ℓ}^{fd} will be used in the last step to determine the national BAF for each trophic level. A final baseline BAF_{ℓ}^{fd} should be determined for each trophic level from the individual baseline BAF_{ℓ}^{fd}s by considering the data preference hierarchy defined by Procedure #4 and uncertainty in the data. The data preference hierarchy for Procedure #4 is:

1. a baseline BAF_{ℓ}^{fd} from an acceptable field-measured BAF or predicted from an acceptable laboratory-measured BCF.

Since bioaccumulation via dietary uptake and subsequent biomagnification generally are not of concern for chemicals subject to Procedure #4, field-measured BAFs and laboratory-measured BCFs are considered equally in determining the national BAF.

Final baseline BAF_{ℓ}^{fd}s should be selected for each trophic level using the following steps and guidelines.

1. **Calculate Species-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method (i.e., field-measured BAF or a BAF from a lab-measured BCF) where more than one acceptable baseline BAF_{ℓ}^{fd} is available for a given species, calculate a species-mean baseline BAF_{ℓ}^{fd} according to the guidance described previously in Procedure #1.

2. **Calculate Trophic-Level-Mean Baseline BAF_{ℓ}^{fd}s.** For each BAF method where more than one acceptable species-mean baseline BAF_{ℓ}^{fd} is available within a given trophic level, calculate the trophic-level-mean baseline BAF_{ℓ}^{fd} as the geometric mean of acceptable species-mean baseline BAF_{ℓ}^{fd}s for that trophic level.

3. **Select a Final Baseline BAF_{ℓ}^{fd} for Each Trophic Level.** For each trophic level, select the final baseline BAF_{ℓ}^{fd} using best professional judgment by considering: (1) the data preference hierarchy, and (2) the relative uncertainties among trophic-level-mean BAFs derived using different methods.

    a. As discussed above, field-measured BAFs and laboratory-measured BCFs are considered equally desirable for deriving a final trophic-level-mean baseline

BAF_{ℓ}^{fd} using Procedure #4. If a trophic-level-mean baseline BAF_{ℓ}^{fd} is available from both a field-measured BAF and a laboratory-measured BCF, the final baseline BAF_{ℓ}^{fd} should be selected using the trophic-level-mean baseline BAF_{ℓ}^{fd} or BCF_{ℓ}^{fd} with the least overall uncertainty.

b. The above steps should be performed for each trophic level until a final baseline BAF_{ℓ}^{fd} is selected for trophic levels two, three, and four.

5.4.6.3 Calculating National BAFs

As described in Procedure #1, the last step in deriving a national BAF for a given trophic level for nonionic organic chemicals is to convert the final baseline BAF_{ℓ}^{fd} determined in the previous step to a BAF that reflects conditions to which the national 304(a) criterion will apply (Figure 5-2). Each national BAF should be determined from a final baseline BAF_{ℓ}^{fd} according to the following guidelines.

1. **National BAF Equation.** Except where noted below, national BAFs for trophic-levels two, three, and four should be calculated from the final, trophic-level-mean baseline BAF_{ℓ}^{fd}s using the same equation and procedures described previously in Procedure #1 (see Section 5.4.3.3 in Procedure #1).

2. **Freely Dissolved Fraction**. Due to their low hydrophobicity (i.e., log K_{ow} < 4.0), a freely dissolved fraction of 1.0 should be assumed for calculating national BAFs for nonionic organic chemicals using Procedure #4. A freely dissolved fraction of 1.0 should be assumed because at a log K_{ow} value of less than 4.0, nonionic organic chemicals are expected to remain over 99 percent in the freely dissolved form at POC and DOC concentrations corresponding to national default values for U.S. bodies of water (i.e., 0.5 mg/L and 2.9 mg/L, respectively).

5.5 NATIONAL BIOACCUMULATION FACTORS FOR IONIC ORGANIC CHEMICALS

This section contains guidelines for deriving national BAFs for ionic organic chemicals (i.e., organic chemicals which undergo significant ionization in water). As defined in Section 5.3.5, ionic organic chemicals contain functional groups which can either readily donate protons (e.g., organic acids with hydroxyl, carboxylic, and sulfonic groups) or readily accept protons (e.g., organic bases with amino and aromatic heterocyclic nitrogen groups). Some examples of ionic organic compounds include:

- chlorinated phenols (e.g., 2,4,6-trichlorophenol, pentachlorophenol),
- chlorinated phenoxyalkanoic acids (e.g., 2,4-dichlorophenoxyacetic acid [2,4-D]),
- nitrophenols (e.g., 2-nitrophenol, 2,4,6-trinitrophenol),
- cresols (e.g., 2,4-dinitro-*o*-cresol [DNOC]),
- pyridines (e.g., 2,4-dimethypyidine),
- aliphatic and aromatic amines (e.g., trimethylamine, aniline), and

- linear alkylbenzenesulfonate (LAS) surfactants.

Ionic organic chemicals are considered separately for deriving national BAFs because the anionic or cationic species of these chemicals behave much differently in the aquatic environment compared with their neutral (un-ionized) counterparts. The neutral species of ionic organic chemicals are thought to behave in a similar manner as nonionic organic compounds (e.g., partitioning to lipids and organic carbon as a function of hydrophobicity). However, the ionized (cationic, anionic) species exhibit a considerably more complex behavior involving multiple environmental partitioning mechanisms (e.g., ion exchange, electrostatic, and hydrophobic interactions) and a dependency on pH and other factors including ionic strength and ionic composition (Jafvert et al., 1990; Jafvert 1990; Schwarzenbach, et al., 1993). As a consequence, methods to predict the environmental partitioning of organic cations and anions are less developed and validated compared with methods for nonionic organic chemicals (Spacie, 1994; Suffet et al., 1994).

Given the current limitations in the state of the science for predicting the partitioning and bioaccumulation of the ionized species of ionic organic chemicals, procedures for deriving national BAFs for these chemicals differ depending on the extent to which the fraction of the total chemical is likely to be represented by the ionized (cationic, anionic) species in U.S. surface waters. When a significant fraction of the total chemical concentration is expected to be present as the ionized species in water, procedures for deriving the national BAF rely on empirical (measured) methods (i.e., Procedures #5 and 6 in Section 5.6). When an insignificant fraction of the total chemical is expected to be present as the ionized species (i.e., the chemical exists essentially in the neutral form), procedures for deriving the national BAF will follow those established for nonionic organic chemicals (e.g., Procedures #1 through #4 in Section 5.4). The following guidelines apply for assessing the occurrence of cationic and anionic forms at typical environmental pH ranges.

1. For the ionic organic chemical of concern, the dissociation constant, pK_a, should be compared to the range of pH values expected in fresh and estuarine waters of the U.S. At pH equal to the pK_a, 50% of the organic acid or base is expected to be present in the ionized species. The pH values for U.S. fresh and estuarine waters typically range between 6 and 9, although somewhat higher and lower values can occur in some bodies of water (e.g., acidic bogs and lakes, highly alkaline and eutrophic systems, etc.).

2. For organic acids, the chemical will exist almost entirely in its un-ionized form when pH is about 2 or more units below the pK_a. For organic bases, the chemical will exist almost entirely in its un-ionized form when pH is about 2 or more units above the pK_a. In these cases, the aqueous behavior of the chemical would be expected to be similar to nonionic organic chemicals. Therefore, national BAF should usually be derived using Procedures #1 through #4 in Section 5.4.

3. When pH is greater than the pK_a minus 2 for organic acids (or less than the pKa plus 2 for organic bases), the fraction of the total chemical that is expected to exist in its ionized form can become significant (i.e., $\geq$1% in the ionized). In these cases, the national BAF should usually be derived using Procedures #5 and #6 in Section 5.6.

4. In general, most organic acids (e.g., pentachlorophenol and silvex), exist primarily in the ionized form in ambient waters because their pK_a's (4.75 and 3.07, respectively) are much smaller than the pH of the ambient waters. Conversely, most organic bases, (e.g., aniline) exist mostly in the un-ionized form in ambient waters because their pK_a's (4.63 for aniline) are much smaller than the pH of the ambient waters.

5. The above guidelines are intended to be a general guide for deriving national BAFs for ionic organic chemicals, not an inflexible rule. Modifications to these guidelines should be considered on a case-by-case basis, particularly when such modifications are strongly supported by measured bioaccumulation or bioconcentration data. For example, initial models have been developed for predicting the solid and organic-phase partitioning of certain organic acids (e.g., Jafvert 1990, Jafvert et al., 1990). As these or other models become more fully developed and appropriately validated in the future, they should be considered in the development of national BAFs. In addition, since pH is a controlling factor for dissociation and subsequent partitioning of ionic organic chemicals, consideration should be given to expressing BAFs or BCFs as a function of pH (or other factors) where sufficient data exist to reliably establish such relationships.

5.6 NATIONAL BIOACCUMULATION FACTORS FOR INORGANIC AND ORGANOMETALLIC CHEMICALS

This section contains guidelines for deriving national BAFs for inorganic and organometallic chemicals as defined in Section 5.3.5. The derivation of BAFs for inorganic and organometallic chemicals differs in several ways from procedures for nonionic organic chemicals. First, lipid normalization of chemical concentrations in tissues does not generally apply for inorganic and organometallic chemicals. Thus, BAFs and BCFs cannot be extrapolated from one tissue to another based on lipid-normalized concentrations as is done for nonionic organic chemicals. Second, the bioavailability of inorganics and organometallics in water tends to be chemical-specific and thus, the techniques for expressing concentrations of nonionic organic chemicals based on the freely dissolved form do not generally apply. Third, at the present time there are no generic bioaccumulation models that can be used to predict BAFs for inorganic and organometallic chemicals as a whole, unlike the existence of K_{ow}-based models for nonionic organic chemicals. While some chemical-specific bioaccumulation models have been developed for inorganic and organometallic chemicals (e.g., Mercury Cycling Model by Hudson et. al, 1994), those models currently tend to require site-specific data for input to the model and are restricted to site-specific applications. As the models become more fully developed and validated in the future, they should be considered on a case-by-case basis in conjunction with the following procedures for deriving national BAFs.

5.6.1 Selecting the BAF Derivation Procedure

As shown in Figure 5-1, national BAFs can be derived using two procedures for inorganic and organometallic chemicals (Procedures #5 and #6). The choice of the BAF derivation procedure depends on whether or not the chemical undergoes biomagnification in aquatic food webs.

1. For many inorganic and organometallic chemicals, biomagnification does not occur and the BCF will be equal to the BAF. For these types of chemicals, Procedure #5 should be used to derive the national BAF. Procedure #5 considers BAFs and BCFs to be of equal value in determining the national BAF and does not require the use of FCMs with BCF measurements. Guidance for deriving BAFs using Procedure #5 is provided in Section 5.6.3.

2. For some inorganic and organometallic chemicals (e.g., methylmercury), biomagnification does occur and Procedure #6 should be used to determine the national BAF. Procedure #6 gives general preference to the use of field-measured BAFs over laboratory-measured BCFs and requires FCMs to be used with BCF measurements for predicting BAFs. Guidance for deriving BAFs using Procedure #6 is provided in Section 5.6.4.

3. Determining whether or not biomagnification occurs for inorganic and organometallic chemicals requires chemical-specific data on measured concentrations of the chemical in aquatic organisms and their prey. Concentrations in aquatic organisms that increase substantially at successive trophic levels of a food web suggest that biomagnification is

occurring. Concentrations in aquatic organisms that remain about the same or decrease at successive trophic levels of a food web suggest that biomagnification is not occurring. When comparing tissue concentrations for assessing biomagnification, care should be taken to ensure that the aquatic organisms chosen actually represent functional predator-prey relationships and that all major prey species are considered in the comparisons.

5.6.2 Bioavailability

The chemical-specific nature of inorganic and organometallic bioavailability is likely due in part to chemical-specific differences in several factors which affect bioavailability and bioaccumulation. These factors include differences in the mechanisms for chemical uptake by aquatic organisms (e.g., passive diffusion, facilitated transport, active transport), differences in sorption affinities to biotic and abiotic ligands, and differences in chemical speciation in water. Some inorganic and organometallic chemicals exist in multiple forms and valence states in aquatic ecosystems that can differ in their bioavailability to aquatic organisms and undergo conversions between forms. For example, selenium can exist in various forms in aquatic ecosystems, including inorganic selenite($^{+4}$) and selenate($^{+6}$) oxyanions, elemental selenium (^{0}) under reducing conditions (primarily in sediments), and organoselenium compounds of selenide ($^{-2}$). Dominant forms of mercury in natural, oxic waters include inorganic ($^{+2}$) mercury compounds and methylmercury; the latter is generally considered to be substantially more bioavailable than inorganic mercury compounds to higher trophic level organisms. Although a generic analogue to the "freely dissolved" conversion for nonionic organic chemicals does not presently exist for inorganic and organometallic chemicals as a whole, the occurrence and bioavailability of different forms of these chemicals should be carefully considered when deriving national BAFs.

1. If data indicate that: (1) a particular form (or multiple forms) of the chemical of concern largely governs its bioavailability to target aquatic organisms, and (2) BAFs are more reliable when derived using the bioavailable form(s) compared with using other form(s) of the chemical of concern, then BAFs and BCFs should be based on the appropriate bioavailable form(s).

2. Because different forms of many inorganic and organometallic chemicals may interconvert once released to the aquatic environment, regulatory and mass balance considerations typically require an accounting of the total concentration in water. In these cases, sufficient data should be available to enable conversion between total concentrations and the other (presumably more bioavailable) forms in water.

5.6.3 Deriving BAFs Using Procedure #5

This section contains guidance for calculating national BAFs for inorganic and organometallic chemicals using Procedure #5 as shown in Figure 5-1. The types of inorganic and organometallic chemicals for which Procedure #5 is appropriate are those that are not likely to biomagnify in aquatic food webs (see Section 5.1 above). In Procedure #5, two methods are available to derive the national BAF for a given trophic level:

- using a BAF from an acceptable field study (i.e., field-measured BAF), or
- predicting a BAF from an acceptable laboratory-measured BCF.

Individual BAFs should be determined from field-measured BAFs or laboratory-measured BCFs according to the following guidelines.

5.6.3.1 Determining Field-Measured BAFs

1. Except where noted below, field-measured BAFs should be determined using the guidance provided in Section 5.4.3.1(A) of Procedure #1.

2. As described previously, conversion of field-measured BAFs to baseline BAF_{ℓ}^{fd}s based on lipid-normalized and freely-dissolved concentrations does not apply for inorganic and organometallic chemicals. Therefore, the guidance and equations provided in Procedure #1 which pertain to converting field-measured BAFs to baseline BAF_{ℓ}^{fd}s and subsequently to national BAFs do not generally apply to inorganic chemicals. As discussed in Section 5.6.2 above, an analogous procedure in concept might be required for converting total BAFs to BAFs based on the most bioavailable form(s) for some inorganic and organometallic chemicals of concern. Such procedures should be applied on a chemical-specific basis.

3. BAFs should be expressed on a wet-weight basis; BAFs reported on a dry-weight basis can be used only if they are converted to a wet-weight basis using a conversion factor that is measured or reliably estimated for the tissue used in the determination of the BAF.

4. BAFs should be based on concentrations in the edible tissue(s) of the biota unless it is demonstrated that whole-body BAFs are similar to edible tissue BAFs. For some finfish and shellfish species, whole body is considered to be the edible tissue.

5. The concentrations of an inorganic or organometallic chemical in a bioaccumulation study should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccumulation of an inorganic or organometallic chemical that is essential to the nutrition of aquatic organisms might be overestimated if concentrations are at or below normal background levels due to selective accumulation by the organisms to meet their nutritional requirements.

5.6.3.2 **Determining Laboratory-Measured BCFs**

1. Except where noted below, BAFs should be predicted from laboratory-measured BCFs using the guidance provided in Section 5.4.3.1(c) of Procedure #1.

2. As described previously, conversion of laboratory-measured BCFs to baseline BCF_{ℓ}^{fd}s based on lipid-normalized and freely dissolved concentrations does not apply for inorganic and organometallic chemicals. Therefore, the guidance and equations provided in Procedure #1 which pertain to converting laboratory-measured BCFs to baseline BCF_{ℓ}^{fd}s and subsequently to national BCFs do not generally apply to inorganic and organometallic chemicals. As discussed in Section 5.6.2 above, an analogous procedure in concept might be required for converting total BCFs to BCFs based on the most bioavailable form(s) of some inorganic and organometallic chemicals of concern. Such procedures should be applied on a chemical-specific basis. In addition, the use of FCMs with BCFs does not apply to chemicals applicable to Procedure #5.

3. BCFs should be expressed on a wet-weight basis; BCFs reported on a dry-weight basis can be used only if they are converted to a wet-weight basis using a conversion factor that is measured or reliably estimated for the tissue used in the determination of the BCF.

4. BCFs should be based on concentrations in the edible tissue(s) of the biota unless it is demonstrated that whole-body BCFs are similar to edible tissue BCFs. For some finfish and shellfish species, whole body is considered to be the edible tissue.

5. The concentrations of an inorganic or organometallic chemical in a bioconcentration test should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccumulation of an inorganic or organometallic chemical that is essential to the nutrition of aquatic organisms might be overestimated if concentrations are at or below normal background levels due to selective accumulation by the organisms to meet their nutritional requirements.

5.6.3.3 **Determining the National BAFs**

After calculating individual BAFs using as many of the methods in Procedure #5 as possible, the next step is to determine national BAFs for each trophic level from the individual BAFs. The national BAFs will be used to determine the national 304(a) criteria. The national BAFs should be determined from the individual BAFs by considering the data preference hierarchy defined for Procedure #5 and uncertainty in the data. The data preference hierarchy for Procedure #5 is:

1. a BAF from an acceptable field-measured BAF or predicted from an acceptable laboratory-measured BCF.

Since bioaccumulation via dietary uptake and subsequent biomagnification are not of concern for chemicals subject to Procedure #5, field-measured BAFs and laboratory-measured

BCFs are considered equally in determining the national BAFs. The national BAFs should be selected for each trophic level using the following steps and guidelines.

1. **Calculate Species-Mean BAFs.** For each BAF method where more than one acceptable field-measured BAF (or a BAF predicted from a BCF) is available for a given species, calculate the species-mean BAF as the geometric mean of all acceptable individual measured or BCF-predicted BAFs. When calculating species-mean BAFs, individual measured or BCF-predicted BAFs should be reviewed carefully to assess uncertainties in the BAF values. Highly uncertain BAFs should not be used. Large differences in individual BAFs for a given species (e.g., greater than a factor of 10) should be investigated further and in such cases, some or all of the BAFs for a given species might not be used. Additional discussion on evaluating the acceptability of BAF and BCF values is provided in the Bioaccumulation TSD.

2. **Calculate Trophic-Level-Mean BAFs.** For each BAF method where more than one acceptable species-mean BAF is available within a given trophic level, calculate the trophic-level-mean BAF as the geometric mean of acceptable species-mean BAFs in that trophic level. Trophic-level-mean BAFs should be calculated for trophic levels two, three and four because available data on U.S. consumers of fish and shellfish indicate significant consumption of organisms in these trophic levels.

3. **Select a Final National BAF for Each Trophic Level.** For each trophic level, select the final national BAF using best professional judgment by considering: (1) the data preference hierarchy in Procedure #5, and (2) the relative uncertainties among trophic level-mean BAFs derived using different methods.

    a. As discussed above, field-measured BAFs and laboratory-measured BCFs are considered equally desirable for deriving a final national BAF using Procedure #5. If a trophic-level-mean BAF is available from both a field-measured BAF and a laboratory-measured BCF, the final national BAF should be selected using the trophic-level-mean BAF with the least overall uncertainty.

    b. The above steps should be performed for each trophic level until a national BAF is selected for trophic levels two, three, and four.

5.6.4 Deriving BAFs Using Procedure #6

This section contains guidance for calculating national BAFs for inorganic and organometallic chemicals using Procedure #6 as shown in Figure 5-1. The types of inorganic and organometallic chemicals for which Procedure #6 is appropriate are those that are considered likely to biomagnify in aquatic food webs (see Section 5.6.1 above). Methylmercury is an example of an organometallic chemical to which Procedure #6 applies. In Procedure #6, two methods are available to derive the national BAF:

- using a BAF from an acceptable field study (i.e., field-measured BAF), or

- predicting a BAF from an acceptable laboratory-measured BCF and a FCM.

Individual BAFs should be determined from field-measured BAFs or laboratory-measured BCFs and FCMs according to the following guidelines.

5.6.4.1 Determining Field-Measured BAFs

1. Field-measured BAFs should be determined using the guidance provided in Section 5.6.3.1 of Procedure #5.

5.6.4.2 Determining Laboratory-Measured BCFs

1. Except where noted below, BAFs should be predicted from laboratory-measured BCFs using the guidance provided in Section 5.6.3.2 of Procedure #5.

2. Because biomagnification is of concern for chemicals applicable to Procedure #6, BAFs should be predicted from laboratory-measured BCF using FCMs. Currently, there are no generic models from which to predict FCMs for inorganic or organometallic chemicals. Therefore, FCMs should be determined using field data as described in the section entitled: "Field-Derived FCMs" in Section 5.4.3.1(c) of Procedure #1. Unlike nonionic organic chemicals, field-derived FCMs for inorganic and organometallic chemicals are not based on lipid-normalized concentrations in tissues. For calculating FCMs for inorganic and organometallic chemicals, concentrations in tissues should be based on the consistent use of either wet-weight or dry-weight concentrations in edible tissues. FCMs should be derived for trophic levels two, three, and four.

5.6.4.3 Determining the National BAF

After calculating individual BAFs using as many of the methods in Procedure #6 as possible, the next step is to determine national BAFs for each trophic level from the individual BAFs. The national BAFs will be used to determine the national 304(a) criteria. The national BAFs should be determined from the individual BAFs by considering the data preference hierarchy defined for Procedure #6 and uncertainty in the data. The data preference hierarchy for Procedure #6 is (in order of preference):

1. a BAF from an acceptable field-measured BAF, or
2. a predicted BAF from an acceptable laboratory-measured BCF and FCM.

This data preference hierarchy reflects EPA's preference for field-measured BAFs over BAFs predicted from a laboratory-measured BCF and FCM, because field-measured BAFs are direct measures of bioaccumulation and biomagnification in aquatic food webs. BAFs predicted from laboratory-measured BCFs and FCMs indirectly account for biomagnification through the use of the FCM. For each trophic level, the national BAFs should be determined using the following steps and guidelines.

1. **Calculate Species-Mean BAFs.** For each BAF method where more than one acceptable field-measured BAF or BAF predicted using a BCF and FCM is available, calculate a species-mean BAF according to the guidance described previously in Procedure #5.

2. **Calculate Trophic Level-Mean BAFs.** For each BAF method where more than one acceptable species-mean BAF is available within a given trophic level, calculate the trophic level-mean BAF according to guidance described previously in Procedure #5.

3. **Select a Final National BAF for Each Trophic Level.** For each trophic level, select the final national BAF using best professional judgment by considering: (1) the data preference hierarchy in Procedure #6, and (2) the relative uncertainties among trophic level-mean BAFs derived using different methods.

    a. When a trophic-level mean BAF is available using both methods for a given trophic level (i.e., a field-measured BAF and a BAF predicted from a BCF and FCM), the national BAF should usually be selected using the field-measured BAF which is the preferred BAF method in the data preference hierarchy in Procedure #6.

    b. If uncertainty in the trophic-level mean BAF derived using field-measured BAFs is considered to be substantially greater than a trophic-level mean BAF derived using a BCF and FCM, the national BAF for that trophic level should be selected from the second tier (BCF · FCM) method.

    c. The above steps should be performed for each trophic level until a national BAF is selected for trophic levels two, three, and four.

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Fish Consumption Rates & Risk Levels for Carcinogens Used in Human Health Criteria Calculations

*A Compilation of Fish Consumption Rates (FCR) and Risk Levels for Carcinogens used by Assorted States and Tribes to Calculate Surface Water Quality Human Health Criteria**

** Data compiled from information provided to Ecology by the Environmental Protection Agency, Region 10, in January 2013.*

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Alabama	4	**30**		**10^{-6}**	Except for Arsenic, which uses 10^{-5}
Alaska	10	**6.5**	Criteria in National Toxics Rule are also applicable.	**10^{-5}**	
Arizona	9	**17.5**		**10^{-6}**	
Arkansas	6	**7.5**		**10^{-5}**	
Bad River Band of Lake Superior Tribe of Chippewa Indians of the Bad River Reservation (WI)	5	**142.4**		**None Listed**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
California	9	**6.5**	Mercury criterion is 18.7 grams/day (fresh water, enclosed bays and estuaries) and 19.5 grams/day (ocean waters). More recent site-specific mercury criteria in CA apply the methymercury tissue criterion and a rate of 32 grams/day. Criteria in the National Toxics Rule and California Toxics Rule are also applicable.	**10^{-6}**	
Colorado	8	**17.5**		**10^{-6}**	
Confederated Salish and Kootenai Tribes of the Flathead Indian Reservation	8	**17.5**		**10^{-6}**	
Confederated Tribes of the Chehalis Reservation	10	**6.5**		**10^{-6}**	
Confederated Tribes of the Colville Reservation	10	**narrative criteria**		**N/A**	
Confederated Tribes of the Umatilla Indian Reservation of Oregon	10	**389**		**10^{-6}**	
Confederated Tribes of the Warm Springs Indian Reservation of Oregon	10	**170**		**10^{-6}**	
Connecticut	1	**17.5** or **6.5**	17.5 grams/day used for most parameters.	**10^{-6}**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Coeur d'Alene	10	**17.5**	Initial WQS submission - EPA has not acted on the submission.	**10^{-6}**	
Delaware	3	**17.5**		**10^{-6}**	
District of Columbia	3	**17.5**		**10^{-6}**	
Florida	4	**6.5**	Florida is proposing to update criteria with an approach that calculates the criterion level necessary to achieve the minimum risk to Florida's population. This approach is currently being reviewed as part of the public comment process.	**10^{-6}**	
Georgia	4	**17.5**		**10^{-6}**	
Grand Portage Band of the Minnesota Chippewa Tribe	5	**142.4**		**10^{-6}**	Concentrations of carcinogenic chemicals from point or non-point sources, singly or in mixtures, must not exceed risk levels of one chance in 1,000,000 in surface waters.
Hawaii	9	**19.9**		**10^{-6}**	
Idaho	10	**6.5**	Idaho proposed a rate of 17.5 grams/day in 2006, which was disapproved by EPA in 2012.	**10-^{6}**	
Illinois	5	**15** (Great Lakes Basin); **20** (outside Great Lakes Basin)		**10^{-5}**	Great Lakes Initiative

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Indiana	5	**15** (Great Lakes Basin); **6.5** (outside Great Lakes Basin)		**10^{-5}**	Great Lakes Initiative
Iowa	7	**17.5**		**10^{-5}**	
Kalispel Indian Community of the Kalispel Reservation	10	**17.5**	Nickel, arsenic, and chloroform use a FCR of 6.5 g/day.	**10^{-6}**	
Kansas	7	**6.5** or **17.5**	Criteria in National Toxics Rule are also applicable. Kansas is proposing to adopt updated criteria based on EPA's recommended §304(a) criteria in its current revision.	**10^{-6}**	
Kentucky	4	**17.5**		**10^{-6}**	
Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation	5	**32**		**10^{-6}**	
Louisiana	6	**20**	6.5 grams/day for Monte Sano Bayou.	**10^{-6}**	Except for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) and hexachlorocyclohexane (lindane, gamma BHC), in which case 10^{-5} is used.
Lummi Nation	10	**142.4**		**10^{-6}**	

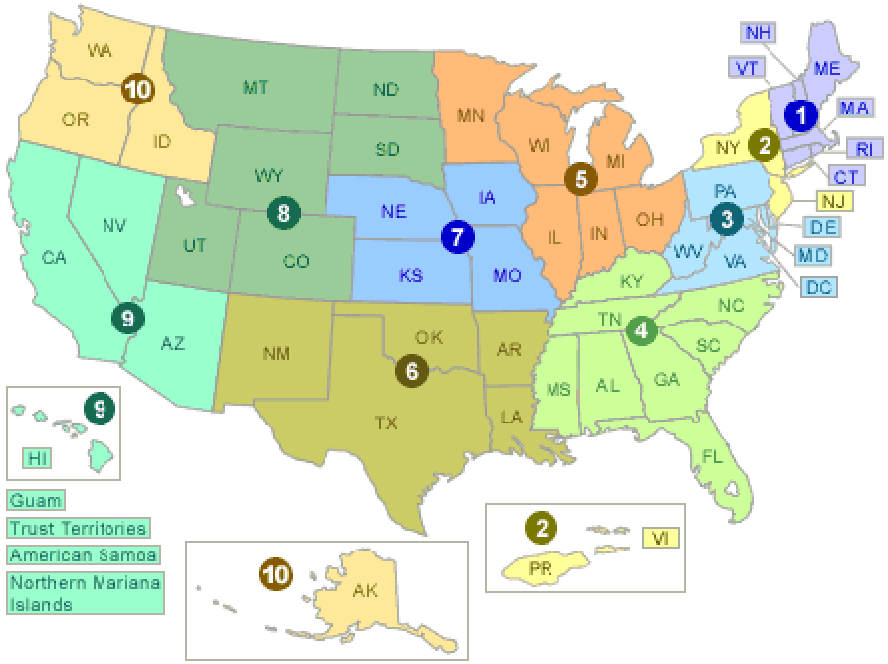
Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Maine	1	**32.2**		**10^{-6}**	Maine recently adopted new arsenic criteria based on a 10^{-4} cancer risk level and a FCR of 138 g/day.
Makah Tribe	10	**142.4**		**10^{-6}**	
Maryland	3	**17.5**		**10^{-5}**	
Massachusetts	1	**17.5** or **6.5**		**10^{-6}**	
Miccosukee Tribe Indians of Florida	4	**17.5**		**10^{-6}**	
Michigan	5	**15** (Great Lakes Basin); **15** (outside Great Lakes Basin)		**10^{-5}**	Great Lakes Initiative
Minnesota	5	**30**		**10^{-5}**	Great Lakes Initiative
Mississippi	4	**6.5**	Mississippi completed a WQS revision in June 2012, with criteria based on consumption rate of 17.5 grams/day (will be submitted to EPA).	**10^{-6}**	
Missouri	7	**6.5**		**10^{-6}**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Superior Tribe of the Chippewa Indians, Sokaogon Chippewa Community	5	**15**		**None Listed**	
Montana	8	**17.5**		**10^{-6}**	
Nebraska	7	**6.5**	Mercury criterion uses 32.4 grams/day	**10^{-6}**	
Nevada	9	**6.5**	Mercury criterion uses 18.7 grams/day. Criteria in National Toxics Rule are also applicable.	**10^{-5}**	
New Hampshire	1	**6.5**		**10^{-6}**	
New Jersey	2	**17.5**			
New Mexico	6	**17.5**		**10^{-5} and 10^{-6}**	
New York	2	**33**		**10^{-6}**	
North Carolina	4	**17.5**		**10^{-6}**	
North Dakota	8	**17.5**		**10^{-6}**	
Ohio	5	**15** (Great Lakes Basin); **6.5** (outside Great Lakes Basin)		**10^{-5}**	Great Lakes Initiative
Oklahoma	6	**6.5**	Oklahoma intends to update criteria using 17.5 grams/day in next triennial revision.	**10^{-5}**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
Oregon	10	**175**		**10^{-6}**	Except for arsenic which uses 10^{-5} for organism only and 10-4 for water + organism
Pennsylvania	3	**17.5**		**10^{-6}**	
Port Gamble S'Klallam Tribe	10	**142.4**		**10^{-6}**	
Puyallup Tribe of Indians	10	**6.5**	Puyallup Tribe has proposed rate of 142.4 grams/day, but has not submitted to EPA.	**10^{-6}**	
Rhode Island	1	**17.5**		**10^{-6}**	
Saint Regis Mohawk Tribe	2	**33**		**10^{-6}**	
South Carolina	4	**17.5**		**10^{-6}**	
South Dakota	8	**17.5**		**10^{-6}**	
Spokane Tribe of Indians	10	**86.3**	Spokane Tribe submitted revised standards to EPA in 2010 using rate of 865 grams/day, but EPA has not acted on this submittal.	**10^{-6}**	
Tennessee	4	**17.5**		**10^{-6}**	
Texas	6	**17.5** (carcinogens); **5.6** (non-carcinogens, childhood exposure factors)	Mercury criteria use 10 grams/day (fresh water) and 15 grams/day (salt water).	**10^{-5}**	

Entity	EPA Region	Fish Consumption Rate* *(measured in grams/day)*	Additional Information for FCR	Risk Level for Carcinogens*	Additional Information for Risk Levels
The Fond du Lac Band of the Minnesota Chippewa Tribe	5	**60**		**None Listed**	
Utah	8	**17.5**		**10^{-6}**	
Vermont	1	**6.5**		**10^{-6}**	
Virginia	3	**17.5**		**10^{-5}**	
Washington	10	**6.5**	Applicable human health criteria are in the National Toxics Rule.	**10^{-6}**	
West Virginia	3	**17.5**		**10^{-6}**	
Wisconsin	5	**20**		**10^{-5}**	Great Lakes Initiative
Wyoming	8	**17.5**		**10^{-6}**	

Environmental Protection Agency Regions



November 2002 (revised)

FISH CONSUMPTION AND ENVIRONMENTAL JUSTICE

A Report developed from the National Environmental Justice Advisory Council Meeting of December 3-6, 2001

A Federal Advisory Committee to the U.S. Environmental Protection Agency

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PREFACE

"[L]et everybody know that this environment belongs to all of us, and when you contaminate the water and contaminate the fish, you are contaminating all of us.

I tell you, I don't know if you know anything about Isaiah. Isaiah was a great prophet you know, and he said, "I have played, I have taught, and I have preached, and I wonder if anybody is listening." So I want to know if anybody is listening, and if you are listening I want to know what are you going to do about it?"

Remarks of Daisy Carter, Project AWAKE
Member of the NEJAC Fish Consumption Work Group
and its Air and Water Subcommittee

December 4, 2001
Meeting of the National Environmental Justice Advisory Council
Seattle, Washington

ACKNOWLEDGMENTS

The NEJAC acknowledges, with deep appreciation, the Fish Consumption Work Group and the NEJAC Report consultant, Catherine O'Neill, Associate Professor, Seattle University School of Law, for their outstanding contributions in developing this broad public policy issue report.

DISCLAIMER

This Report and recommendations have been written as part of the activities of the National Environmental Justice Advisory Council, a public advisory committee providing independent advice and recommendations on the issue of environmental justice to the Administrator and other officials of the United States Environmental Protection Agency (EPA).

This report has not been reviewed for approval by the EPA, and hence, its contents and recommendations do not necessarily represent the views and the policies of the Agency, nor of other agencies in the Executive Branch of the federal government.

INTERPRETIVE NOTES

The National Environmental Justice Advisory Council (NEJAC) is a federal advisory committee to the United States Environmental Protection Agency (EPA). This Report, therefore, focuses on those environmental justice issues raised by compromised aquatic ecosystems that EPA is empowered to address. That is to say, it examines, in the main, efforts that might be undertaken by EPA, as opposed to other agencies (whether federal, state, or tribal), and it focuses on sources of contamination and depletion within the United States, as opposed to global sources. This focus is not meant to suggest that NEJAC believes that the efforts of these other agencies and the contributions of these other sources are not important aspects of understanding and addressing compromised aquatic ecosystems; rather, it reflects NEJAC's role as a federal advisory committee to EPA.

This Report also examines the issues assuming a backdrop of the current state of the law. For example, in Chapter Two it discusses prevention, reduction, cleanup and restoration in light of existing environmental laws, and in Chapter Four it discusses the particular legal and political status of American Indian tribes and Alaska Native villages, given current interpretations of this status and the current enumeration of federally-recognized tribes. Again, this assumption is not meant to suggest that NEJAC supports in every respect these current enactments or interpretations; rather, it reflects a pragmatic choice, governed in part by considerations of scope.

Throughout, this Report discusses the impact of contaminated and depleted aquatic ecosystems on communities of color, low-income communities, tribes, and other indigenous peoples; Chapter Four, however, is devoted to those issues raised by the fact of American Indian tribes' and Alaska Native villages' unique status as sovereign governments. Thus, while the environmental justice issues posed by compromised aquatic ecosystems will often be common to each of these groups and their members, the NEJAC believes that separate treatment is warranted for tribes in their governmental capacity.

This Report uses the phrase "communities of color, low-income communities, tribes, and other indigenous peoples" in an effort to capture, in shorthand form, all of the various groups and subgroups that are affected by environmental injustice stemming from compromised aquatic ecosystems. It is meant to include all people of color, low-income people, American Indians, Alaska Natives, Native Hawaiians and other Pacific Islanders, and other indigenous people located within the jurisdictional boundaries of the United States. In an effort to avoid cumbersome repetition of this phrase, the Report also substitutes the phrases "affected communities and tribes" and "affected groups;" these shorter phrases are meant to be similarly inclusive.

Finally, this Report intends to address itself to the contamination and depletion of aquatic ecosystems and all of their components, including fish, shellfish, marine invertebrates, aquatic plants, and wildlife. This Report often refers simply to "fish" or "aquatic resources" or to some other shorthand term, but should be understood in each instance to refer to aquatic ecosystems and all of their components (unless the context suggests otherwise).

November 19, 2002

Administrator Christine Todd Whitman
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20004

Dear Administrator Whitman,

Please find attached a copy of the report entitled "**National Environmental Justice Advisory Council Fish Consumption and Environmental Justice,** *November 2002.*"

EPA, through its Office of Environmental Justice, requested the National Environmental Justice Advisory Council (NEJAC) in its meeting of December 3-6, 2001 to provide advice and recommendations on how EPA could improve the quality, quantity, and integrity of our Nation's aquatic ecosystems in order to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife.

This report reflects the advice and recommendations that resulted from pre-meeting preparation, on-site discussions, public comments and subsequent analysis. Individuals and organizations with varied backgrounds and interests offered comments, suggestions and recommendations on how EPA should address fish consumption issues.

This report proposes six overarching consensus recommendations to the EPA as follows:

(1) Require states, territories, and authorized tribes to consider specific uses, including the use of the waterbody or waterbody segment for subsistence fishing, when designating uses for a waterbody, and to set water quality criteria that support the specific designated use; *provided* that where human health criteria are established based upon consumption of toxic chemicals that bioaccumulate in fish, regulators should employ appropriate human fish consumption rates and bioaccumulation factors, including cultural practices (*e.g.*, species, fish parts used, and manner of cooking and preparation) of tribes and other indigenous and environmental justice communities using the waterbody; *provided further* that EPA should encourage and provide financial and technical support for states, territories, and authorized tribes to control effectively all sources, including both point sources and nonpoint sources, to achieve the criteria;

(2) Work expeditiously to prevent and reduce the generation and release of those contaminants to the Nation's waters and air that pose the greatest risk of harm to human health and aquatic resources, including but not limited to persistent bioaccumulative toxics (PBTs) (*e.g.*, mercury, dioxins, and polychlorinated biphenyls (PCBs)) and other toxic chemicals, and to clean up and restore aquatic ecosystems contaminated by pollutants;

(3) Protect the health of populations with high exposure to hazards from contaminated fish, aquatic organisms and plants, and wildlife, including communities of color, low income communities, tribes, and other indigenous peoples, by making full use of authorities under the federal environmental laws and accounting for the cultural, traditional, religious, historical , economic, and legal contexts in which these affected groups consume and use aquatic and terrestrial resources;

(4) Ensure that fish and other aquatic organism consumption advisories are used by regulators as a short-term, temporary strategy for informing those who consume and use fish, aquatic organisms and plants, and wildlife of risks while water quality standards are being attained and while prioritizing and pursuing the cleanup of contamination by appropriate parties; agencies must evaluate and address such risks~~;~~ and require risk-producers to prevent, reduce, and clean up contamination of waters and aquatic ecosystems;

(5) Because many American Indian and Alaska Native (AI/AN) communities are particularly prone to environmental harm due to their dependence on subsistence fishing, hunting, and gathering, conduct environmental research, fish consumption surveys, and monitoring, in consultation with federally recognized tribes and with the involvement of concerned tribal organizations, to determine the effects on, and ways to mitigate adverse effects on the health of AI/AN communities resulting from contaminated water sources and/or the food chain; and

(6) Consistent with the 1988 *EPA Indian Policy for the Administration of Environmental Programs on Indian Reservations*, the federal trust responsibility to federally recognized tribes, and federal policies recognizing tribal sovereignty and promoting self-determination and self-sufficiency, provide equitable funding and technical support for tribal programs to protect AI/AN communities and tribal resources from harm caused by contaminated water and aquatic resources and, until tribes are able to assume responsibility for such programs, implement and require compliance with the federal environmental laws within Indian country; *provided* that, in consultation with tribes, EPA should promptly develop effective and appropriate regulatory strategies for setting, implementing, and attaining water quality standards within Indian country; and *provided further* that, EPA should work with Alaska Native villages to address the special circumstances that exist in Alaska and to protect the health of Alaska Natives from environmental threats associated with their extensive subsistence lifeways.

The NEJAC is pleased to present this report to you for your review, consideration, response and action. In addition, the NEJAC appreciates any assistance you can provide in processing the recommendations in this report through the Office of Water with consultation as appropriate with the American Indian Environmental Office and the Office of Environmental Justice.

Sincerely,

/s/ /s/

Peggy Shepard — Jana Walker
Chair — Vice Chair

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FISH CONSUMPTION AND ENVIRONMENTAL JUSTICE

NATIONAL ENVIRONMENTAL JUSTICE ADVISORY COUNCIL (NEJAC)

Summary

This Report has been compiled after deliberation during the December, 2001 meeting of the National Environmental Justice Advisory Council (NEJAC) regarding the following overarching policy question:

> **How should EPA improve the quality, quantity, and integrity of our Nation's aquatic ecosystems in order to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?**

This Report works to identify and discuss the particular issues that this question raises when – as is often the case – those affected by contaminated and depleted aquatic ecosystems are communities of color, low-income communities, American Indian tribes/Alaskan Native villages and their members, and other indigenous peoples.

This report proposes six overarching consensus recommendations to the EPA as follows:[1]

(1) Require states, territories, and authorized tribes to consider specific uses, including the use of the waterbody or waterbody segment for subsistence fishing, when designating uses for a waterbody, and to set water quality criteria that support the specific designated use; *provided* that where human health criteria are established based upon consumption of toxic chemicals that bioaccumulate in fish, regulators should employ appropriate human fish consumption rates and bioaccumulation factors, including cultural practices (*e.g.*, species, fish parts used, and manner of cooking and preparation) of tribes and other indigenous and environmental justice communities using the waterbody; *provided further* that EPA should encourage and provide financial and technical support for states, territories, and authorized tribes to control effectively all sources, including both point sources and nonpoint sources, to achieve the criteria;

(2) Work expeditiously to prevent and reduce the generation and release of those contaminants to the Nation's waters and air that pose the greatest risk of harm to human health and aquatic resources, including but not limited to persistent bioaccumulative toxics (PBTs) (*e.g.*, mercury, dioxins, and polychlorinated biphenyls (PCBs)) and other toxic chemicals, and to clean up and restore aquatic ecosystems contaminated by pollutants;

[1]NEJAC Executive Council member Kenneth J. Warren joins in support of the Report's six Consensus Recommendations and the Report's depiction of fish consumption impacts to communities and tribes. He believes, however, that the Report should provide a more focused and well-grounded substantiation for these recommendations.

(3) Protect the health of populations with high exposure to hazards from contaminated fish, aquatic organisms and plants, and wildlife, including communities of color, low income communities, tribes, and other indigenous peoples, by making full use of authorities under the federal environmental laws and accounting for the cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic and terrestrial resources;

(4) Ensure that fish and other aquatic organism consumption advisories are used by regulators as a short-term, temporary strategy for informing those who consume and use fish, aquatic organisms and plants, and wildlife of risks while water quality standards are being attained and while prioritizing and pursuing the cleanup of contamination by appropriate parties; agencies must evaluate and address such risks; and require risk-producers to prevent, reduce, and clean up contamination of waters and aquatic ecosystems;

(5) Because many American Indian and Alaska Native (AI/AN) communities are particularly prone to environmental harm due to their dependence on subsistence fishing, hunting, and gathering, conduct environmental research, fish consumption surveys, and monitoring, in consultation with federally recognized tribes and with the involvement of concerned tribal organizations, to determine the effects on, and ways to mitigate adverse effects on the health of AI/AN communities resulting from contaminated water sources and/or the food chain; and

(6) Consistent with the 1988 *EPA Indian Policy for the Administration of Environmental Programs on Indian Reservations*, the federal trust responsibility to federally recognized tribes, and federal policies recognizing tribal sovereignty and promoting self-determination and self-sufficiency, provide equitable funding and technical support for tribal programs to protect AI/AN communities and tribal resources from harm caused by contaminated water and aquatic resources and, until tribes are able to assume responsibility for such programs, implement and require compliance with the federal environmental laws within Indian country; *provided* that, in consultation with tribes, EPA should promptly develop effective and appropriate regulatory strategies for setting, implementing, and attaining water quality standards within Indian country; and *provided further* that, EPA should work with Alaska Native villages to address the special circumstances that exist in Alaska and to protect the health of Alaska Natives from environmental threats associated with their extensive subsistence lifeways.

The Report is organized into five chapters. An initial chapter provides background. The four succeeding chapters each address a more focused policy question and the issues it raises. These chapters are outlined below:

Background

This chapter explores the importance of having healthy aquatic ecosystems to address issues of environmental justice. It provides background on the perspectives of the various individuals, communities, tribes, and peoples affected by those aquatic ecosystems which are contaminated and depleted. This chapter begins with the observation that communities of color, low-income communities, tribes, and other indigenous peoples *depend* on healthy aquatic ecosystems and the fish, aquatic plants, and wildlife that these ecosystems support. While there are important differences among these various affected groups, their members generally depend on the fish, aquatic plants, and wildlife to a greater extent and in different ways than does the general population. These resources are consumed and used to meet nutritional and economic needs. For some groups, they are also consumed or used for cultural, traditional, or religious purposes. For members of these groups, the conventional understandings of the "health benefits" or "economic benefits" of catching, harvesting, preparing, and eating fish, aquatic plants, and wildlife do not adequately capture the significant value these practices have in their lives and the life of their culture. The harms caused by degradation of aquatic habitats and depletion of fisheries, moreover, do not only affect the present generation. They take their toll on future generations and on the transfer of knowledge from one generation to the next (e.g., ecological knowledge, customs and traditions surrounding harvest, preparation and consumption of aquatic resources).

Many of the rivers, streams, bayous, bays, lakes, wetlands, and estuaries that support these resources on which communities and tribes depend have become contaminated and depleted. Contamination is causing the communities' and tribes' everyday practices – their ways of living – to serve as a source of exposure to a host of substances toxic to humans and other living things. The depletion of aquatic environments and resources also threatens these groups' subsistence, economic, cultural, traditional, and religious practices. Aquatic ecosystems are contaminated with mercury, PCBs, dioxins, DDT and other pesticides, lead and other metals, sediments, fecal coliform and other bacterial and viral contaminants – in short, a host of toxins, most of which are particularly troubling because they *persist* in the environment for great lengths of time and because they *bioaccumulate* in the tissues of fish, aquatic plants, and wildlife, existing in greater quantities higher up the food chain.

For many communities of color, low-income communities, tribes, and other indigenous peoples, there are no real alternatives to eating and using fish, aquatic plants, and wildlife. For many members of these groups it is entirely impractical to "switch" to "substitutes" when the fish and other resources on which they rely have become contaminated. There are numerous and often insurmountable obstacles to seeking alternatives (e.g., fishing "elsewhere," throwing back "undesirable" species of fish, adopting different preparation methods, or substituting beef, chicken or tofu). For some, not fishing and not eating fish are unimaginable for cultural, traditional, or religious reasons. For the fishing peoples of the Pacific Northwest, for example, fish and fishing are necessary for survival as a people – they are vital as a matter of cultural flourishing and self-determination.

When health and environmental agencies respond to contamination and its impacts, they typically employ one or both of two general strategies: *risk avoidance*, whereby risk-bearers are encouraged or required to change the practices that expose them to contamination (e.g., through fish consumption advisories, directed to those who eat fish) or *risk reduction*, whereby risk-producers are required to cleanup, reduce, or prevent contamination (e.g., through water quality standards, applied to industrial sources that discharge contaminants into surrounding waters). In either event, agencies rely on assumptions about fish consumption rates, practices, and needs that reflect the circumstances of the general population, but often are not reflective enough of the circumstances of affected communities and tribes. Agencies' approaches to risk assessment, risk management, and risk communication similarly fall short of taking into account that affected groups consume and use fish, aquatic plants, and wildlife in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American." These observations have policy implications that are taken up in the remaining chapters.

Chapter One: **Research Methods and Risk Assessment Approaches**

Chapter One focuses on the tools that agencies use to define, evaluate, and respond to the adverse health impacts from contaminated aquatic environments. It examines the research methods that agencies use to obtain information about the lives, practices, and circumstances of affected communities and tribes. It also examines the risk assessment approaches that agencies employ to evaluate and address these health impacts.

This chapter begins by noting that agencies typically focus on "adverse impacts to human health" that tend to focus narrowly on individuals and physiological harms. Some affected groups, by contrast, may view the harms from contamination more broadly: they are not only physiological, but psychological, social, and cultural; which may not only impact an individual, but a group overall.

This chapter then devotes considerable discussion to differences in various groups' circumstances of exposure. It documents the marked differences in how much fish is eaten (measured by fish consumption rates) between the general population and higher-consuming "subpopulations" such as communities of color, low-income communities, tribes, and other indigenous peoples. It canvases agencies' standard assumptions about the fish, shellfish, plant, and wildlife species that people consume and use; the parts of these species they use; and the preparation methods they employ. It points out that these assumptions often do not reflect the practices among the various affected groups. It observes the different cultural, traditional, religious, historical, economic, and legal contexts in which many affected groups consume and use aquatic resources. It takes up the issues of aggregate or multiple exposures and cumulative risks, noting that whereas agencies' current methods proceed as if humans were exposed to a single contaminant at a time, humans are actually often exposed to multiple contaminants at a time or in succession, and often by more than one route and pathway of exposure. This is especially likely to be the case for many members of communities of color, low-income communities, tribes, and other indigenous peoples. Each of the considerations raised here contributes to the observation that agencies currently underestimate the extent to which members of these groups are exposed to environmental contaminants. The result is that standards set or advisories issued based on these estimates will not be sufficiently protective of these affected groups.

This chapter next considers the different susceptibilities and "co-risk" factors that may characterize affected groups and their members, noting again that these differences are unlikely to be accounted for by current agency approaches.

This chapter then explores suppression effects and their implications. A suppression effect occurs when a fish consumption rate for a given subpopulation reflects a current level of consumption that is artificially diminished from an appropriate baseline level of consumption for that subpopulation. The more robust baseline level of consumption is "suppressed," inasmuch as is does not get captured by the fish consumption rate. Suppression effects may arise as a result of contaminated aquatic ecosystems, depleted aquatic ecosystems and fisheries, or both. When agencies set environmental standards using a fish consumption rate based upon an artificially diminished consumption level, they may set in motion a downward spiral whereby the resulting standards permit further contamination and/or depletion of the fish and aquatic resources. This chapter discusses the policy implications of suppression effects.

This chapter then addresses research methods relevant to risk assessment, risk management, and risk communication. Much of the preceding discussion is brought to bear, as it underscores the fact that it will often be crucial to the relevance, accuracy, and acceptability of research in these areas that the affected community or tribe be central to the process throughout. This is not only a matter of community access or tribal consultation, but, importantly, a matter of scientific defensibility. There are currently sizeable gaps in the data and methods that EPA and other agencies use to assess, manage, and communicate risk, and it is often the case that these gaps can only be filled by community- and tribally-based research. As the large literature on "participatory research" documents, affected communities and tribes have expertise that is simply not going to be able to be replicated by non-member researchers. Notably, it will be important to ensure that this community participation and tribal consultation is adequately funded and supported technically. This chapter also discusses the need for research that seeks not only to describe affected groups' exposure, but also to connect exposure to sources of contaminants in aquatic environments.

Finally, this chapter examines efforts to refine current risk assessment methods in order to address issues raised by these methods for communities of color, low-income communities, tribes, and other indigenous peoples, and discusses efforts to reevaluate the use of current risk assessment approaches in light of alternative approaches, particularly those that focus on prevention and precaution.

Chapter Two: Using Existing Legal Authorities

Chapter Two discusses agencies' risk reduction efforts, that is, strategies that look to risk-producers to prevent or reduce contamination in the first place, and to cleanup and restore those environments that are already contaminated. It examines the legal authorities that might be invoked more effectively to sustain healthy aquatic ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife.

This chapter begins by providing background on the contaminants of greatest concern, not only from the perspectives of health and environmental agencies, but also from the perspective of affected groups and their members. Chief among the contaminants of concern are mercury, PCBs, dioxins, DDT, and chlordane. In addition to these five contaminants, at least eight others are a source of concern, given that they are highly *toxic*; they are *persistent* once released into the environment; and they *bioaccumulate* in the tissues of fish and wildlife. These eight are: aldrin, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene, and furans. Finally, a host of other contaminants are troubling here, including: lead and other metals; numerous other pesticides; fecal coliform, marine biotoxins and various other bacterial and viral contaminants; sediment and silt loadings; and numerous others. This chapter outlines briefly the health effects of each of the major contaminants of concern, as well as its sources in the environment.

This chapter discusses how EPA might better prevent and reduce contamination in the first place, focusing primarily on efforts under the Clean Water Act (CWA) and secondarily on efforts under other legal authorities, such as the Clean Air Act (CAA). It then turns its discussion to how EPA might better clean up and restore those aquatic ecosystems that are already contaminated. Again, it looks first to the authority provided by the Clean Water Act, and then discusses other legal authorities, such as "Superfund," the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

Chapter Three: **Fish Consumption Advisories**

Chapter Three discusses agencies' risk avoidance strategies, focusing on fish and wildlife consumption advisories in particular and on risk communication in general. It asks what role fish consumption advisories should play in efforts to protect more effectively the health and safety of people consuming or using these resources. It considers how agencies can identify, acknowledge, and meet the real needs of those who are affected – how they can work to make affected groups whole once the fish, aquatic plants, and wildlife on which they depend have already become contaminated.

The chapter first takes up the question of the advisories' proper role. Drawing on the observations presented above about the impracticality and/or unimaginability of reducing fish consumption or of altering practices connected with catching, harvesting, preparing and eating fish, this chapter notes that the answer to the question of fish consumption advisories' role will likely be different for different communities or tribes. Importantly, it should be for the affected group to determine what will be appropriate from its perspective. Tribes' particular political and legal status as sovereign nations must also be taken into account here, as tribes will be in the position, in their governmental capacities, of deciding for themselves what role fish consumption advisories should play in their environmental protection efforts.

This chapter next explores fish consumption advisories' "effectiveness." It discusses briefly the potential differences in how "effective" might be defined by various agencies and by various affected communities and tribes. It reviews the current state of research regarding how those to whom advisories are directed respond to this information, observing that the available evidence suggests that low-income, people of color, those with limited English proficiency, and those with relatively little formal education are less likely to be aware of advisories.

In light of this evidence, and in view of current EPA efforts to this end, this chapter then devotes considerable attention to the matter of improving the effectiveness of risk communication and fish consumption advisories. As a general matter, it observes that if risk communication is truly to be a "two-way street" – if *communication* is actually to occur, - affected groups must be involved as partners or co-managers at every point in the risk communication process. All of the elements of effective advisories – including "audience identification," "needs assessment," message content, media choice, implementation, and evaluation – will fall into place if agencies and affected communities or tribes consider together the questions and answers. In general, EPA and other agencies should work to reconceptualize risk communication approaches from large-scale, abstract, one-time efforts to develop and disseminate various communication "products" (e.g., developing and posting fish advisory signs) to local, contextually-supported, ongoing efforts to establish and maintain relationships with a particular affected community or tribe.

More specifically, it will be important for EPA and other agencies to recognize the diverse contexts, interests, and needs that characterize the various affected groups – including, but not limited to groups with limited English proficiency; groups with limited or no literacy; low-income communities; immigrant and refugee communities; African American communities; various Asian and Pacific Islander communities and subcommunities (e.g., Mien, Lao, Khmu, and Thadium communities within the larger Laotian community in West Contra County, CA); various Hispanic communities and subcommunities (e.g., Carribean-American communities in the Greenpoint/Williamsburg area of Brooklyn, NY); various Native Americans, Native Hawaiians, and Alaska Natives (including members of tribes and villages, members of non-federally recognized tribes, and urban Native people).

"Affected groups" also refers to subgroups within these larger groups, including but not limited to nursing infants; children; pregnant women and women of childbearing age; elders; traditionalists versus modernists in terms of practices surrounding fish consumption; and subgroups defined by geographical region. Affected group involvement in aiding identification and understanding of the diverse contexts, interests, and needs of these various groups will, perhaps unsurprisingly, be essential. The content of the message and the media selected need to be effective and appropriate from the perspective of the affected group, and this chapter examines several specific considerations to this end. Implementation efforts, too, must be effective and appropriate from the perspective of those affected, who will be particularly well-positioned to take the lead in implementing an advisory and outreach strategy that has been developed by and for their group. Evaluation will also be most usefully conducted together with members of the affected group, whose ability to help define and measure "success" will again often be unparalleled.

Additionally, this chapter observes that capacity-building or capacity-augmentation is in and of itself and environmental justice issue, for both communities and tribes. Involvement by those affected at each point in the risk communication process would go far toward enabling them to shape the process so that it is not only relevant and appropriate, but also useful and empowering from the perspective of the community or tribe.

Finally, this chapter notes that here again, as in the context of research in general, financial and technical support will be crucial to enabling communities and tribes fully to be involved.

Chapter Four: **American Indian Tribes and Alaskan Native Villages**

Chapter Four addresses issues unique to American Indian tribes, Alaskan Native villages, and their members. Although tribes and their members share many of the concerns discussed in the preceding chapters, tribes' political and legal status is unique among affected groups and so warrants separate treatment. Tribes are governmental entities, recognized as possessing broad inherent authority over their members, territories, and resources. As sovereigns, federally recognized tribes have a government-to-government relationship with the federal government and its agencies, including the EPA. Tribes' unique legal status includes a trust responsibility on the part of the federal government. For many tribes, it also includes treaty rights. Other laws and executive commitments, too, shape the legal obligations owed to American Indian tribes and Alaska Native tribes and their members.

This chapter describes the EPA's Indian Policy for the Administration of Environmental Programs on Indian Reservations; tribes' efforts to assume responsibilities for administering environmental programs on their reservations under various federal environmental laws – notably, the Safe Drinking Water Act, the Clean Water Act, the Clean Air Act, and CERCLA; and tribes' work as co-managers of cleanup and restoration efforts and/or as Natural Resource Damage Trustees. In these and other roles, tribes will have environmental justice concerns of a different and complex nature.

The chapter then outlines the ways in which the political and legal status of Alaska Native villages has been interpreted to be both similar to and different from the status of tribes in the forty-eight contiguous states, and notes briefly some of the circumstances unique to Alaska Natives that are likely to raise particular concerns for this group.

Finally, this chapter outlines the particular circumstances of tribes and their members with respect to susceptibilities and co-risk factors; these have implications, as discussed more generally in Chapter One, for agencies' risk assessment, risk management, and risk communication approaches.

FISH CONSUMPTION AND ENVIRONMENTAL JUSTICE

BACKGROUND CHAPTER

The National Environmental Justice Advisory Council (NEJAC) is a federal advisory committee of the U.S. Environmental Protection Agency (EPA). Under its charter, the NEJAC's mission is to provide advice and recommendations to the EPA Administrator on matters related to environmental justice. In July, 2000, EPA requested that NEJAC address issues raised by the relationship between fish consumption, water quality, and environmental justice. This issue was the focus of the NEJAC's December 3-6, 2001 meeting in Seattle, Washington.

This Report focuses on the following question:

How should EPA improve the quality, quantity, and integrity of our Nation's aquatic ecosystems in order to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?

This chapter provides background necessary to address adequately the above policy question. This chapter seeks to explain why contaminated and depleted aquatic ecosystems are an environmental justice issue. Importantly, this chapter seeks to present the dimensions of the problem from the perspectives of the various individuals, communities, tribes, and other peoples affected.

This chapter begins in Part A by gathering the accounts of a number of different people who suffer the ill effects of contaminated and depleted aquatic ecosystems. Although these stories do not catalogue exhaustively the harms felt by all of those who are affected, it is hoped that, taken together, they will provide a sense of the breadth and enormity of the impacts on communities of color, low-income communities, tribes, and other indigenous peoples. And it is hoped that, in their diversity, they will provide a sense of the differing dimensions of the ill effects for these different affected groups. This chapter begins with these accounts because they are properly the starting point for any discussion of environmental justice policy: they present the *real* stories – the stories told from the perspectives of those on the ground, and not as they need to be told to fit into the bins and categories created by environmental laws and regulations. These accounts should *frame* the discussion – rather than be merely "inputs" into a discussion already framed in someone else's terms.

In order to speak to government agencies that work within the boundaries of environmental laws and regulations, however, it seems useful to work to "translate" these stories so that their relevance to agencies' efforts can be appreciated. NEJAC's attempt at translation will often mean breaking things down and naming their component parts in ways that are more likely to be understood by agencies, given agencies' current categories, programs, and approaches. So, for example, in seeking to convey the importance of salmon in his life, a member of the Fourteen

Confederated Tribes and Bands of the Yakama Nation may invoke terms and concepts familiar to agencies such as "nutrition," "health," "economy," "resource," "subsistence," "culture," and "treaty-protected;" he may refer to laws and programs that separately address the "air," "water quality," "water quantity," and "sediments" that together are home to the salmon.

This attempt at translation may entail loss, however: it may fail fully to capture the multiple and interrelated dimensions of what is at stake; or it may risk misunderstanding or *mis*translation Yet an attempt at translation may be necessary for those affected to convey their recommendations to agency decision makers. Nonetheless, it is crucial that agencies also work to *hear* the stories in their original, whole form and to consider what these stories have to teach them – how they might serve to reframe agencies' approaches altogether. It is important that agencies strive to reduce the gulf that must be bridged by translation and so to minimize the loss that accompanies translation. With these considerations in mind, the remainder of this Report looks to discuss the issues in the terms used by environmental agencies and in environmental laws and regulations, while at the same time referring often to the words of those affected as touchstones for deliberation.

Part B of this chapter then raises the question that is examined in the remainder of this Report, regarding the policy implications of the accounts set forth in Part A.

A. DIVERSE IMPACTS, MULTIPLE DIMENSIONS: THE ACCOUNTS OF ENVIRONMENTAL INJUSTICE

1. Communities of Color, Low-Income Communities, Tribes, and Other Indigenous Peoples Depend on Fish,[2] Aquatic Plants, and Wildlife

Put simply, communities of color, low-income communities, tribes, and other indigenous peoples *depend* on healthy aquatic ecosystems and the fish, aquatic plants, and wildlife that these ecosystems support. While there are important differences among the various affected communities of color, low-income communities, tribes, and other indigenous peoples, members of these groups depend on fish, aquatic plants, and wildlife to a greater extent and in different ways than does the general population.

[2]The term "fish," here and throughout this Report, is meant to include shellfish and marine invertebrates, unless the particular context suggests otherwise. Please see the Interpretive Notes at the outset of this Report for elaboration.

Fish are a healthful source of dietary protein and other nutrients for humans.[3] Fish are relatively low in fat, and are a good source of selenium. Fish, aquatic plants, and wildlife are major dietary staples for some individuals, and those who subsist chiefly or solely on fish, aquatic plants, and wildlife are more likely to be people of color, low-income individuals, tribal members, or other indigenous people. Thus, for example, a recent survey revealed that whereas 60% of "non-white" (primarily African-American) fishers on the Detroit River fished there to meet their needs for food or for a combination of food and recreation, only 21.7% of white fishers indicated that they fished for reasons combining food and recreation, and none indicated that they fished only to meet their needs for food.[4] In Alaska, "[a]mong Yupiks of Gambell, over one-half of their protein, iron, vitamin B-12, and omega-3 fatty acids come from subsistence foods."[5]

Fish, aquatic plants, and wildlife are important food sources for economic reasons: it generally costs less to purchase many kinds of fish than it costs to purchase other sources of animal protein,[6] and if someone can fish, gather, harvest, or hunt nearby, he or she can bypass altogether the need to get to a store and to purchase food. For some of these fishers, fishing provides not only food for their own consumption and consumption by relatives and neighbors, but also an important source of income and livelihood. As Delbert Frank, Sr., Warm Springs, explains:

> *I used to fish at Celilo falls before The Dalles Dam was built. We used to be able to fish all year long. We caught lots of different kinds of fish – spring chinook, summer chinook, bluebacks, fall chinook, steelhead, and coho. When the fish were coming in good, I could catch one ton of salmon a day. And, it didn't take a lot of fancy gear or expensive boats to fish. For the cost of one or two balls of twine, about 6 to 12 dollars, I could make the fishing gear necessary for me to catch enough fish to supply my family and many others for a whole year.*[7]

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[3]See, e.g., Yvonne Smith and Laura Berg, *Ancient Tradition, Modern Reality: Is There a Future for a Salmon-Based Culture?*, 1 Wana Chinook Tymoo 14 (1998); Renate D. Kimbrough, *Consumption of Fish: Benefits and Perceived Risk*, 33 Journal of Toxicology & Environmental Health 82-83 (1991).

[4]Patrick C. West, *Race and the Incidence of Environmental Hazards: A Time for Discourse* "Invitation to Poison? Detroit Minorities and Toxic Fish Consumption from the Detroit River"96, 98 (Bunyan Bryant and Paul Mohai, eds. 1992).

[5]Elizabeth D. Nobmann, *Nutritional Benefits of Subsistence Foods* (1997) available at www.nativeknowledge.org/db/files/aboutnt2.htm.

[6]See, e.g., Kimbrough, *supra* at 83.

[7]**Columbia River Inter-Tribal Fish Commission, *Celilo Falls*, available at www.critfc.org/text/CELILO.HTM.**

A low-income African-American fisher on the Detroit River observes:

> *I catch to eat fish. I catch a lot of fish and bring a lot home to eat. Bring home Perch and Bass. I eat more because I like fish and it is easier to feed a family because of money.*[8]

For some groups, fish, aquatic plants, and wildlife are consumed or used for cultural, traditional, or religious purposes as well. For members of these groups, conventional dominant society understandings of the "health benefits" or "economic benefits" of catching, harvesting, preparing, and eating fish, aquatic plants and wildlife do not adequately capture the place of these practices in their lives and the life of their culture. Cultural, traditional, and religious understandings will, of course, differ among various groups; the following excerpts provide but a few accounts. Winona LaDuke, Mississippi Band of Anishinaabeg, explains:

> *There are many wild rice lakes on the White Earth reservation in northern Minnesota; my community, the Anishinaabeg, calls the rice* Manoomin*, or a gift from the Creator.*
>
> *Every year, half our people harvest the wild rice, the fortunate ones generating a large chunk of their income from it. But wild rice is not just about money and food. It's about feeding the soul.*[9]

Similarly, Horace Axtell, Nez Perce, explains:

> *According to our religion, everything is based on nature. Anything that grows or lives, like plants and animals, is part of our religion. The most important element we have in our religion is water. At all of the Nez Perce ceremonial feasts the people drink water before and after they eat. The water is a purification of our bodies before we accept the gifts from the Creator. After the feast we drink water to purify all the food we have consumed. The next most important element in our religion is the fish because fish comes from water. It doesn't matter what kind of fish. If we have suckers or eels or steelhead or salmon, we honor it next after we drink the water. Then we name whatever fish we have, and then everyone takes a small bit before we eat the rest of the food. The next element is the game meat like deer, elk, and moose. That's how we honor the food we eat, especially the fish, because it is the next element after the water. The chinook salmon is more*

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[8] Pat West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low Income Afro-Americans from the Detroit River* 16 (forthcoming 2002) (listing fisher's income as \$5,000 - \$9,999).

[9] Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* 115 (1999).

favored because it is the strongest fish and the most tasty. Chinook Salmon is the fish we try to bring to the long house.[10]

As Hawaii's Thousand Friends relates:

> *Hawaiians, the indigenous people of these islands, rely on healthy aquatic ecosystems for their life-style. The depletion and contamination of these ecosystems has drastically impacted their health, food sources, economic well-being and ability to follow cultural, traditional and religious practices.*[11]

And, as Art Ivanoff, from the Alaska Native village of Unalakleet explains, their understandings of these practices – and of the very meaning of the term "subsistence" – are often quite different than the understanding of the dominant society:

> *We have a different definition [of subsistence]. Western society tends to look at it as something that's derogatory, before the poverty level. That's not how we define our lifestyle. It's something rich. It's spiritual. It's economic. It's social. It's getting together with your friends and your relatives going out there harvesting, and sharing with elders, sharing with widows, and that's a pride we get.*[12]

The harms occasioned by the degradation of aquatic habitats and the depletion of fisheries, moreover, are not only visited on the present generation. Part of the affront to the culture and social fabric of some communities and tribes for whom fish and fishing are vital comes from the diminished opportunities for inter-generational transfer of knowledge – especially ecological knowledge about places and natural systems – and for other aspects of inter-generational socialization. The acts of inter-generational transfer of customs and traditions surrounding catching, preparing, and consuming fish are themselves important to the maintenance of social and cultural health.[13] As an African-American fisher on the Detroit River explains:

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[10]Dan Landeen and Allen Pinkham, *Salmon and His People: Fish and Fishing in Nez Perce Culture* 55 (1999).

[11]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[12]Art Ivanoff, Alaska Native Village of Unalakleet, *Comments to the National Environmental Justice Advisory Council* Vol. III-17 (Annual meeting transcript December 4, 2001); accord, Mary Kancewick & Eric Smith, *Subsistence in Alaska: Towards a Native Priority*, 59 UMKC Law Review 645, 650 (1991) ("Alaska Natives speak of subsistence not in terms of minimalism, but in terms of wealth; not in terms of something to be risen above, but in terms of something to aspire to and hold onto: 'Subsistence living, a marginal way of life to most, has no such connotation to the Native people of southeast Alaska. The relationship between the Native population and the resources of the land and the sea is so close that an entire culture is reflected.'"(quoting testimony of Nelson Frank, Tlingit, Sitka)).

[13]See, e.g., Pat West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low Income Afro-Americans from the Detroit River* 9-10, 18-21 (forthcoming 2002)

My stepdad taught me how to fish. He is from a little town in Mississippi. Most people around here who fish were from the South and our parents were from the South and they were used to fishing and then they taught their kids. When I was little we used to eat fish a lot but that was when the water was clean. . . . I do eat the fish that I catch.[14]

The Columbia River Inter-Tribal Fish Commission, for example, describes the extensive tribal ecological knowledge that was "transmitted to succeeding generations as part of their inheritance," and notes that "[p]lants, animals, and especially places were . . . repositories for historical, social, and spiritual lessons."[15] The concept of "risk" then, should include "cultural risk:"

Cultural risk [includes] ecological impacts that reduce or impair the inter-generational transfer of ecological knowledge used for implementing traditional holistic environmental management practices.[16]

Indeed, for many members of communities of color, low-income communities, tribes, or other indigenous peoples, there are no real alternatives to depending on fish, aquatic plants, and wildlife. In some cases, for example, it is utterly impractical to suggest that people "switch" to "substitute sources of protein" when the fish on which they rely to put food on the table have become contaminated. Such suggestions are often unrealistic, given the many obstacles to the imagined alternatives: there may be no uncontaminated bays, lakes, or rivers for miles around; even if another fishing spot can be found just a little farther away, it may be difficult or impossible to reach without a car or other transportation – and it may cost too much for the gas or the bus or train ticket to get there; or another fishing spot may traditionally be someone else's fishing spot, such that it wouldn't be appropriate simply to go there; and there may be no adequate substitutes from other food sources at the grocery store – not being able to eat fish may mean having to look to foods that are poorer quality from a nutritional and health perspective. As Mark Davis, Coalition to Restore Coastal Louisiana, Baton Rouge, explains:

The advisories that are issued are just not relevant *to the people here . . . it's as if no one believes that there really are subsistence fishers. Suddenly it is* my *responsibility as a risk-bearer to figure out what the advisories mean, what my level of risk is . . . as if there*

(discussing importance of inter-generational socialization for African-American community members in Detroit, many of whom brought practices surrounding fish and fishing with them as they and their families moved from the rural south to the industrial north).

[14]Id. at 20.

[15]Columbia River Inter-Tribal Fish Commission, *Cultural Context* available at http://www.critfic.org/text/TRP_cul.htm.

[16]Columbia River Inter-Tribal Fish Commission, *Comments to EPA Administrator Carol Browner on the Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* 10 (January 14, 1999).

were a choice. People here walk or bike to a drainage ditch, to a bayou, to the Mississippi River – how can these people be expected to go fish somewhere else?[17]

An African-American fisher on the Detroit River explains:

> *I think that mostly black people fish on the river (due to lack of money); if they have the money they can go anywhere and fish – wherever they want. A lot of us don't have the boats or the cars to get to the good fish. We settle for the fish here but it's all good. I still get the fish. Some people fish because they have to fish. Fish is good food and it is cheap but river fish is the cheapest and I don't blame people for eating it.*[18]

According to Angela Wilson, Founder, Environmental Justice Action Group, Portland, Oregon:

> *It is unrealistic to think that the community members who fish in the Columbia Slough can simply "eat peanuts and tofu," as the agencies suggest.*[19]

Hawaii's Thousand Friends explains:

> *Fish, raw and cooked, is a staple of the Native Hawaiian diet. In an attempt to reduce the alarmingly high percentage of Native Hawaiians with high blood pressure, diabetes, heart disease and obesity, some physicians advocate returning to a historical Hawaiian diet, of which eating fish is a major component. The EPA recommendation of only 12 ounces of fish in one week is incompatible with most Native Hawaiian diets and with all those who follow the physician-recommended diet.*[20]

Yin Ling Leung, Executive Director of Asians and Pacific Islanders for Reproductive Health, California, summarizes:

> *To our communities, being able to fish means being able to either put food on the table, or basically eat a much less nutritious meal. I think that's a non-choice.*[21]

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[17]Telephone Interview with Mark Davis, Coalition to Restore Coastal Louisiana (August 22, 2001).

[18]Pat West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low Income Afro-Americans from the Detroit River* 16 (forthcoming 2002).

[19]Angela Wilson, Environmental Justice Action Group, Presentation at Public Interest Environmental Law Conference, University of Oregon (March, 2001).

[20]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[21]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 1 (1998).

In some cases, too, not fishing and not eating fish are unimaginable for cultural, traditional, or religious reasons. For the fishing peoples of the Pacific Northwest, for example, fish and fishing are necessary for survival as a people – to fish is to *be* Nez Perce.[22] Fish and fishing are vital as a matter of cultural flourishing and self-determination. The importance of fish, especially salmon, to these peoples is reflected in language, in treaties, in past and present tribal fisheries management and environmental restoration efforts, and in the ongoing political and legal struggles for the survival of the salmon and the way of life that is bound up with the salmon. Don Samson, Umatilla, Executive Director, Columbia River Inter-Tribal Fish Commission, explains:

> *The reason I've been fishing is more for my own subsistence, to bring fish home. But maybe more importantly now these days is to maintain the tradition of fishing – of going up to the mountains where my father, my elders fished before me. So it's something that we've got to carry on – that's really why I fish. We've got to pass it on to our children. We have to have that for them in order to be Indians – in order to survive and carry on the things that were placed here for us, and carry on what our elders tell us and teach us.*[23]

Billy Frank, Jr., Nisqually, Chairman, Northwest Indian Fisheries Commission, explains:

> *Fishing defines the tribes as a people. It was the one thing above all else that the tribes wished to retain during treaty negotiations with the federal government 150 years ago. Nothing was more vital to the tribal way of life then, and nothing is more important now. . . .The tribes have fought too hard for too long to let the salmon and their treaty rights to harvest salmon go extinct. This summer and fall you will see tribal fishermen doing what they have always done – fish.*[24]

Of course, for many communities of color, low-income communities, tribes, and other indigenous peoples, the nutritional, economic, and traditional or cultural aspects of fishing, preparing and eating fish are interrelated. Members of these groups thus in many cases depend on fish for a combination of the above reasons. For example, a recent survey of first- and second-generation Asian and Pacific Islanders in King County, Washington – including members of

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[22]See, e.g., Dan Landeen and Allen Pinkham, *Salmon and His People: Fish and Fishing in Nez Perce Culture* 156 (1999) (quoting Del White, Nez Perce: "People need to understand that the salmon is part of who the Nez Perce people are. It is just like a hand is a part of your body. The salmon have always been part of our religion. You can't separate the two.").

[23]Videotape: *My Strength is From the Fish* (Columbia River Inter-Tribal Fish Commission, 1994).

[24]Billy Frank, Jr., *A Statement from Billy Frank, Jr. a*vailable at www.nwifc.wa.gov/esa/start.htm.

Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese ethnic groups – observes:

> *[Asian and Pacific Islanders] consider seafood collection and consumption as healthy activities that reflect a homelike lifestyle and may fish for economic necessity.*[25]

Similarly, in Green Bay, Wisconsin:

> *Eating fish forms a regular part of the diet and culture for the Asians (Hmong and Laotians) living in the Green Bay area.*[26]

And, in the Greenpoint/Williamsburg ("G/W") community in the Borough of Brooklyn in New York City:

> *In G/W, some anglers consume as many as two meals per day of fish caught in the East River, which forms the western boundary of G/W. Approximately 38 percent of the G/W population lives below the poverty line, suggesting that many of the anglers fishing in this community may be urban subsistence anglers who rely on fish caught in the East River as a free source of nutrition. In addition, fishing is a way of life rooted in the cultural heritage for many of the black and Hispanic anglers observed fishing on the piers in G/W, many of whom come from Carribean fishing cultures.*[27]

Finally, the health of humans and the health of aquatic ecosystems are intimately related, such that compromised aquatic ecosystems are of concern in and of themselves, with the contamination of fish, aquatic plants, and wildlife but some of the devastating effects. Water of sufficient quality and quantity is vital to sustain all life. To allow waters to be degraded and depleted is to undermine health, traditions, cultures, and economies. To allow waters to be degraded and depleted is to neglect obligations, including the obligation to sustain tribal homelands as contemplated by federal Indian treaties and other laws. As Frank Tenorio, Governor, San Felipe Pueblo, explained:

> *There has been a lot said about the sacredness of our land which is our body; and the values of our culture which is our soul; but water is the blood of our tribes; and if its life-*

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[25]Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999).

[26]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[27]Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 3-1 (1999).

giving flow is stopped, or it is polluted, all else will die and the many thousands of years of our communal existence will come to an end.[28]

Consider in this vein, too, Langston Hughes's famous poem, "The Negro Speaks of Rivers:"

I've known rivers ancient as the
world and older than the flow of
blood in human veins.
My soul has grown deep like the rivers.
I bathed in the Euphrates when
dawns were young,
I built my hut near the Congo and
it lulled me to sleep,
I looked upon the Nile and raised
the pyramids above it,
I heard the singing of the Mississippi
when Abe Lincoln went down to
New Orleans,
And I've seen its muddy bosom turn
all golden in the sunset,
I've known rivers;
Ancient, dusky rivers;
My soul has grown deep like
the rivers.[29]

2. Contamination of Aquatic Ecosystems and the Fish, Plants, Wildlife, and People They Support

The rivers, streams, bayous, bays, lakes, wetlands, and estuaries that support the fish, aquatic plants, and wildlife on which communities and tribes depend have been allowed to become contaminated and depleted. The waters to which communities and tribes look to meet their nutritional, economic, traditional, cultural, religious and other needs also have become vectors of toxins. Contamination now renders communities' and tribes' everyday practices – their ways of living – a source of exposure to a host of substances toxic to humans and other living things. Depletion, too, threatens communities' and tribes' subsistence, traditional, cultural, and religious practices.

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[28]Elizabeth Cheechio and Bonnie G. Colby, *Indian Water Rights: Negotiating the Future* 1 (June 1993) (quoting Frank Tenorio, Governor, San Felipe Pueblo, *Indian Water Policy in a Changing Environment* 2 (1982)).

[29]Langston Hughes, *My Soul Has Grown Deep: Classics of Early African American Literature*, "The Negro Speaks of Rivers" (John Edgar Wideman ed.).

Yet toxic chemicals and other contaminants have been and continue to be permitted to be emitted, discharged, dumped, or leaked into the air, water, soils, and sediments that together make up home to all life. Once in the environment, these contaminants behave in various ways: some move – traveling over distances or cycling between air and water; some linger – persisting for months or years; some biodegrade – becoming more or less toxic chemical successors; some bioaccumulate in the tissues of aquatic organisms, fish and wildlife – existing in increasing quantities higher up the "food chain." Eventually, humans that consume and use fish, aquatic plants, and wildlife may be exposed to the toxins concentrated in their tissues.

Toxic chemicals and other contaminants also contribute to the depletion of aquatic resources. These other threats (e.g., from logging, mining, grazing, and agricultural operations; from hydropower; from development) compromise water quality and quantity, destroy habitat for fish, aquatic plants and wildlife, and otherwise contribute to the depletion of the resources on which communities and tribes depend.

As a result, aquatic ecosystems are damaged from the Penobscot River to the San Francisco Bay, from Bayou d'Inde to the Great Lakes, from the Columbia Slough to the St. James River. These aquatic ecosystems are contaminated when mercury is emitted to the air from coal-fired power plants and other sources of fossil fuel combustion or from medical waste incinerators – this mercury is then deposited to surface waters and to soils. They are contaminated when PCBs are allowed to remain in sediments without being cleaned up – these PCBs persist for long periods of time and are released to waters, air and soils. They are contaminated when dioxins are discharged to the water from the industrial production of chlorinated organic chemicals – these dioxins are often contained for long periods in sediments and may, in turn, be resuspended to surface waters. These and multiple other sources and contaminants have wreaked incalculable harms to aquatic ecosystems and the fish, aquatic plants and wildlife they support.

James Ransom, Director, Haudenosuanee Environmental Task Force, recounts the destruction of the portion of the St. Lawrence River that is Akwesasne, home to the St. Regis Mohawk:

> *Akwesasne or St. Regis is like most Native communities. We were a fishing, farming, hunting, trapping, and gathering community. These lifestyles helped to support an earth-based value system. . . . We were sustainable societies. Everything we needed was provided by the natural world. We followed the natural laws. It required that we only take from the natural world what we need and that we use all that we take. . . This all changed for the Mohawks of Akwesasne in the 1950s. . . .In 1958, the St. Lawrence-FDR Power Project was constructed on the St. Lawrence River just upriver from Akwesasne. Low-cost hydroelectric power allowed two new industries to open, Reynolds Metal company, an aluminum smelter, and General Motors Powertrain, an automobile parts manufacturer. It allowed a third industry, ALCOA, an aluminum smelter, to expand operations.*
>
> *By the early 1960s, cattle within the territories of the Mohawks began feeling the effects of flouride poisoning from the aluminum smelters. By 1981, PCB contamination of the*

General Motors site came to light. In 1983, it became a federal superfund site. By 1987, PCB problems at ALCOA and Reynolds became known as well. By 1989, a six-mile stretch of the Grasse River and a two-mile stretch of the St. Lawrence River became a federal superfund site because of PCB contamination. . . .

In 1986, a 67-inch length, 200 pound lake sturgeon was caught by Mohawk fishermen in the St. Lawrence river. Parts of it were sent for PCB analysis. The results were alarming as 3.41 parts per million (ppm) of PCBs were found in the meat, 7.95 ppm in the eggs, and 10.20 ppm in the liver. The New York State PCB fish standard for human consumption is 2.0 ppm. . . .

Contamination of the St. Lawrence River resulted in a destruction of a subsistence lifestyle for the Mohawk people. It destroyed hunting, fishing, farming, trapping, and gathering activities. . . .[30]

At a meeting of Alaskan Natives from the northwest arctic region, Herman Toolie, Savoonga, expresses his concerns and the concerns of others in his village:

They have those – what do you call it? – PCBs? A lot of those were in the village. They found gallons in the village around Northeast Cape. There were transformers that were leaking. We don't know if they took them out of the ground or not. I guess they took them out. There used to be a lot of fish right there. We had our camp there not more than a mile away from the site. There used to be lots of fish there but no more. There is a whole bunch of concerns that these elders have. I wish I had a tape recorder and could tape them.[31]

In introducing its tribally-conducted fish consumption study, the Suquamish Tribe recounts the importance of fish and shellfish, even in the face of the degraded water quality and habitat of the Puget Sound:

The Suquamish culture finds its fullest expression in the acknowledged relationship of the people with the land, air, water and all forms of life found within the natural system. River systems, lakes and numerous small creeks historically supported abundant coho, chinook, sockeye and chum runs, with other salmonids and marine fish available as well. The same forests which sustained life in the riparian zones also harbored deer, bear, and other wildlife. Vast expanses of intertidal habitat supported shellfish. By virtue of the Treaty of Point Elliott, Suquamish rights to fish and interests in their habitat were recognized to include the marine waters of Puget Sound from the northern tip of Vashon

[30] James Ransom, Director, Haudenosuanee Environmental Task Force, *Proceedings of the American Fisheries Society: Forum on Contaminants in Fish* 25 (1999).

[31] Alaska Traditional Knowledge and Native Foods Database, *Native Concerns* available at www.nativeknowledge.org/db/concerns.asp.

Island to the Fraser River in Canada, including Haro and Rosario Straits and streams draining into the western side of central Puget Sound.

Increased levels of development as well as pollutants from residential, industrial, and commercial uses have resulted in degraded habitats and harvesting restrictions. There were eleven Superfund sites within the immediate area of the Port Madison Indian Reservation at the time the fish consumption survey was conducted.

Despite degraded water quality and habitat, tribal members continue to rely on fish and shellfish as a significant part of their diet. All species of seafood are an integral component of the cultural fabric that weaves the people, the water, and the land together in an interdependent linkage which has been experienced and passed on for countless generations.[32]

And in recounting the harms of intense industrialization along the lower Mississippi River and in St. James Parish, Louisiana, the United Church of Christ Commission for Racial Justice reports:

Also presented as a negative economic impact of polluting industries by local residents was the significant loss of wildlife and vegetation, which contribute to the subsistence living of many St. James Parish residents. Fruiting trees such as pecan, fig, peach, and others have died off. Fish, crayfish and oyster beds have been poisoned. And wildlife important for subsistence hunting, such as rabbit and deer, have disappeared. Not only have important food sources disappeared, but the ability of residents to gather and sell these for cash has also gone. With the decline in the prosperity of local residents, many local businesses have also left the area. A number of residents complained that they must now commute great distances simply to buy groceries and other necessities.[33]

3. Different Exposure Circumstances and Contexts Characterize Communities of Color, Low-Income Communities, Tribes, and Other Indigenous Peoples

Consumption and use of contaminated fish, aquatic plants, and wildlife is the primary route by which humans are exposed to many toxic contaminants. For example, consumption of contaminated fish is considered to be the single greatest route of exposure to PCBs and a major route of exposure to mercury. Consumption of contaminated fish is similarly a significant route of exposure to chlordane, dioxins, DDT, toxaphene, and a litany of over 40 other contaminants. Indeed, any contaminant that *persists* in aquatic environments and *bioaccumulates* in the fish and wildlife that are supported by aquatic environments may find its way to humans when they

[32]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region* 4 (2000).

[33]Charles Lee, ed., United Church of Christ Commission for Racial Justice, *From Plantations to Plants: Report of the Emergency National Commission on Environmental and Economic Justice in St. James Parish, Louisiana* (1998).

consume or use these fish and wildlife. EPA has recognized that fish and wildlife consumption, in particular, is the chief route by which all humans are exposed to many of these "persistent and bioaccumulative toxins" or PBTs.

Consumption and use of contaminated fish, aquatic plants, and wildlife is an especially pressing concern for many communities of color, low-income communities, tribes, and other indigenous peoples, whose members may (1) consume fish, aquatic plants, and wildlife in greater quantities than does the general population; (2) consume and use different fish, aquatic plants, and wildlife than does the general population; (3) employ different practices in consuming and using fish, aquatic plants, and wildlife than does the general population; (4) consume and use fish, aquatic plants, and wildlife in cultural, traditional, religious, historical, economic, and legal contexts that differ from those of the general population.

When health and environmental agencies respond to the human health impacts from contaminated aquatic environments, they typically frame the issue as one of harm to individuals' physical health: the contaminants are carcinogens, or reproductive toxins, or endocrine disrupters, or have multiple human health "endpoints." Health and environmental agencies then manage these "health risks" by employing one or both of two general strategies: *risk avoidance* (whereby risk-bearers are encouraged or required to change the practices that expose them to environmental contamination, e.g. through fish consumption advisories, directed to those people who eat fish) or *risk reduction* (whereby risk-producers are required to cleanup, reduce, or prevent environmental contamination, e.g., through water quality standards, applied to industrial sources that discharge contaminants into surrounding waters). In both cases, agencies' decisions for the most part reflect the exposure circumstances and the cultural, traditional, religious, historical, economic, and legal contexts that describe members of the general population – the "average American" or "the typical U.S. consumer." Importantly, these decisions often do not reflect the exposure circumstances or the traditional, religious, historical, economic, and legal contexts that describe members of communities of color, low-income communities, tribes, or other indigenous peoples.

To illustrate briefly a few of these considerations:

The EPA until quite recently based its environmental decisions on the assumption that humans eat just 6.5 grams of fish per day – *roughly one 8-ounce fish meal per month*. Yet there is abundant evidence that people of color, low-income individuals, tribal members, and other indigenous people eat far greater quantities of fish. For example, a recent study by the Columbia River Inter-Tribal Fish Commission of members of four Columbia River tribes registered a mean fish consumption rate of 58.7 grams/day and a maximum fish consumption rate of 972.0 grams/day – well over one hundred times the EPA value.[34] A recent study of ten Asian and Pacific Islander

[34]Columbia River Inter-Tribal Fish Commission, Technical Report 94-3, A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin (1994); Columbia River Inter-Tribal Fish Commission, Comments to Administrator Browner on the Draft Revisions to the Methodology for Deriving Ambient water Quality Criteria for the Protection of Human Health 8 (1999).

groups in King County, Washington showed a mean fish consumption rate of 117.2 grams/day and a maximum values of 733.46 grams/day.[35] Similarly, studies of anglers in both Alabama and Michigan registered markedly higher fish consumption rates for low-income African-Americans – in Alabama, low-income African-Americans ate a mean of 63 grams/day;[36] in Michigan, low-income African-Americans (together with other "minority fishers and off-reservation Native Americans") consumed a mean of 43.1 grams/day;[37] a recent study of members of the Suquamish Tribe registered a mean fish consumption rate of 213.9 grams/day and a maximum fish consumption rate of 1,453.6 grams/day.[38] Although methodological differences in the various studies mean that these numbers cannot provide a precise basis for comparison, they nonetheless afford a sense of the large differences in the quantities of fish consumed by different groups. EPA has just revised its standard assumptions and now uses default values of 17.5 grams/day for the general population and 142.4 grams/day for subsistence populations. While these revised numbers are a marked improvement, they are still a source of concern for those groups whose members consume at the highest levels. The result is that when the fish are contaminated, those consuming at higher rates will be exposed to greater quantities of the contaminants that are present in the fish tissue.

EPA also typically makes assumptions about the species and parts consumed and about the methods of preparation that reflect that practices of the general population but often do not depict fully or accurately the practices of communities of color, low-income communities, tribes, or other indigenous peoples. For example, according to a recent survey of first- and second-generation Asian and Pacific Islanders in King County, Washington – including members of Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese ethnic groups:

> *[Asian and Pacific Islanders] consume a wide variety of seafood species, the most frequently consumed being shellfish. These seafood, depending on their feeding and habitat characteristics, and the tissue parts consumed pose varying chemical contaminant risks to APIs. For example, certain fat soluble chemicals, e.g., PCBs, are concentrated in the fat layer between the meat and the skin, potentially exposing such consumers to higher contaminant levels than those who simply eat the fillet. Eating the fillet with skin is clearly a common practice in the API community. . . . Overall, skin was consumed with the fillet 55% of the time. . . .*

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[35] Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999) [See Table 1 in Chapter One].

[36] Alabama Department of Environmental Management (1993) [See Table 1 in Chapter One].

[37] Patrick West, et al. (1995) [See Table 1 in Chapter One].

[38] Suquamish Indian Tribe (2000) [See Table 1 in Chapter One].

API community members appear to eat shellfish parts that are thought to contain higher concentrations of chemical contamination, e.g., clam stomachs or the hepatopancreas of crabs. Bivalve shellfish were consumed whole by 24% (geoduck) to 89% (mussels) of respondents depending on the species. The "butter" as well as the meat of crabs were consumed 43% of the time . . .Finally, cooking water, both for finfish and shellfish are commonly used in cooking or directly consumed.[39]

According to a study of the Greenpoint/Williamsburg ("G/W") community in the Borough of Brooklyn in New York City:

[Hispanics and Caribbean Americans] consume considerable quantities of fresh shellfish, including parts of the fish not typically consumed (e.g., the highly contaminated hepatopancreas of blue crabs).[40]

According to Hawaii's Thousand Friends:

Hawaii's diverse ethnic population led to a mixing of traditions and foods, including many fish dishes. Japanese sashimi and Hawaiian poke, both raw fish dishes, are mainstays at most parties and traditional gatherings.[41]

According to an account of subsistence fishing on the Upper Kobuk River in Alaska:

Each summer, families from Shungnak and Kobuk move to camps to harvest salmon, whitefish, and sheefish. . . . upper Kobuk residents preferred to camp in the sheefish spawning areas because sheefish caught there had eggs, a local delicacy. . . .Although sheefish are caught throughout the summer, local residents prefer to catch them late in the season because the sheefish are fat, the eggs are ripe, and the fish can be left to age and freeze, a storage method preferable to drying.

Aged, frozen sheefish, an upper Kobuk delicacy, were eaten later in winter without further processing or preparation. By spring, these fish were known as ui.laaq *(thawed, aged sheefish) a meal savored by upper Kobuk residents.*

[39] Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999)

[40] Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 2-21 (1999).

[41] Hawaii's Thousand Friends (Written Comments, March 11, 2002).

*Fresh sheefish were baked, boiled, or fried. The large intestines, full of fat, were boiled. Fish oil (*qaluum uqsruq*) was separated from the boiled water with a large spoon and served with cooked sheefish.*[42]

Ron Oatman, Nez Perce, recalls:

We used to collect the eggs from the suckers and Mom would fry them up with the rest of the fish. We always thought this quite good.[43]

Again, the result in many cases is that when the fish are contaminated, those consuming in accordance with different practices will be exposed to greater quantities of the contaminants.

Moreover, the approach employed by EPA and other environmental agencies proceeds as if humans were exposed to one contaminant at a time. However, members of communities of color, low-income communities, tribes, and other indigenous peoples are often exposed to multiple contaminants (and by multiple routes) at the same time; this is so to a greater extent than for the general population. For example, according to Barbara Harper, Fourteen Confederated Tribes and Bands of the Yakama Nation, and Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation:

[I]t is the norm, at least in the Columbia River system, for over 100 contaminants to be identified in fish tissues.[44]

Environmental agencies also proceed as if all humans similarly enjoyed relative health and access to basic health care and nutrition. However, members of communities of color, low-income communities, and tribes often have relatively poorer background health and lesser access to health care and nutrition than is enjoyed by the general population. Other "co-risk" factors, too, affect how humans respond when they are exposed to environmental contaminants and often these co-risk factors are different for members of affected communities and tribes.

Health and environmental agencies generally assume that all humans are similarly able to turn to substitutes when fish, aquatic plants, and wildlife have become contaminated. While this substitution may pose few difficulties for members of the general population, it may be impractical or impossible for economic, cultural, religious and/or other reasons for some members of communities of color, low-income communities and tribes. For example, for some tribal peoples,

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[42]Susan Georgette and Hannah Loon, *Subsistence and Sport Fishing of Sheefish on the Upper Kobuk River, Alaska* (1990) available at www.nativeknowledge.org/db/files/tp175.htm.

[43]Dan Landeen and Allen Pinkham, *Salmon and His People: Fish and Fishing in Nez Perce Culture* 95 (1999).

[44]Barbara Harper and Stuart Harris, *Proceedings of the American Fisheries Society: Contaminants in Fish,* "Tribal Technical Issues in Risk Reduction Through Fish Advisories" 19 (1999).

as Barbara Harper, Fourteen Confederated Tribes of the Yakama Nation, and Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, explain:

> *[T]here are likely to be no acceptable 'tradeoffs.' Tribal peoples may not have an option of avoiding fish consumption for cultural or religious reasons as well as economic reasons. . . . The cultural use of fish is not a 'perceived benefit of fish consumption.' It is a baseline situation that is not an option or a choice, but an absolute requirement.*[45]

These considerations and others place in question the appropriate role of fish consumption advisories in protecting those who would consume fish, aquatic plants, and wildlife from the serious harms of exposure – harms including the risk of cancer, neurological damage, endocrine disruption, and a host of other ills. To the extent that fish consumption advisories form an appropriate part of agencies' response to contaminated aquatic environments, however, there is reason to be concerned that health and environmental agencies generally employ the language and methods of communication that are likely to reach and be understood by the members of the general population, but often fail to reach and cannot be understood by members of affected communities. This is particularly likely when agencies distribute advisories in English to those who have limited English proficiency, or when agencies post advisories on the Internet but those affected cannot afford and do not otherwise have access to a computer. There has been recent progress here, however, as EPA and other agencies in some cases have translated their advisories into the language(s) of those affected and have sought to learn which methods of communication would be most likely to reach communities likely to be among the most exposed.

4. Environmental Agencies Have Made Considerable Progress; However, Many Aspirations and Obligations Remain Unfulfilled

EPA and other agencies have made considerable progress toward addressing degraded and depleted aquatic ecosystems, and, more recently, toward attending to the needs and rights of communities of color, low-income communities, tribes, and other indigenous peoples. Aquatic ecosystems are significantly less contaminated than they were three decades ago, when the Clean Water Act was passed. According to EPA estimates, whereas in 1972 only 36% of the rivers, lakes, and estuaries within the United States were clean enough to support "fishable-swimable" uses, today roughly 60% of lakes, rivers, and estuaries are clean enough to support these uses.[46] EPA and other agencies have also made progress in attending to the different circumstances of exposure that often describe members of communities of color, low-income communities, tribes, and other indigenous peoples; in evidencing awareness of their different languages, traditions, and cultures; and in addressing their claims to participation and consultation when EPA and other agencies make decisions affecting their lives and resources.

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[45]Id. at 21 (1999).

[46]Zygmunt J.B, Plater, et al., *Environmental Law and Policy: Nature, Law, and Society* 503 (2d ed. 1998).

Yet, by EPA's own account, there is much yet to be done. EPA's Strategic Plan issued in September 2000 (2000 EPA Strategic Plan) acknowledges that much more work is needed to protect effectively American's rivers, lakes, wetlands, aquifers, and coastal and ocean waters so that they will sustain fish, plants, and wildlife as well as recreational, subsistence, and economic activities.[47] There EPA notes that "[a]s of 1998, about 40 percent of the assessed waters in the United States were degraded to the point that they did not support their designated use."[48] Additionally, more than 50% of the Nation's wetlands--some 100 million acres--have been lost since European settlement.[49] And, "polluted water and degraded aquatic ecosystems threaten the viability of all living things and vigor of the nation's economy."[50] In 2000, the number of fish consumption advisories rose by 187, representing a 7% increase over 1999, and the number of acres of lakes under advisories increased from 20.4% in 1999 to 23% in 2000, a total of 63,288 lakes.[51] All of the Great Lakes and their connecting waters and 71% of coastal waterways were under advisory in 2000.[52]

Thus, EPA has yet to fulfill the aspirations set for it in the Clean Water Act and elsewhere. The CWA, for example, aspires "to restore and maintain the chemical, physical, and biological integrity of our Nation's waters;" it aspires to do this by, among other things, eliminating the discharge of pollution into navigable waters "by 1985."

EPA also has yet to uphold fully its obligations to communities of color, low-income communities, tribes, and other indigenous peoples under various treaties, the federal trust responsibility, Title VI of the Civil Rights Act of 1964, and Executive Order 12898.

B. WHAT ARE THE POLICY IMPLICATIONS OF THE ABOVE?

Together, the chapters of this Report respond to the policy charge to NEJAC:

> How should EPA improve the quality, quantity, and integrity of our Nation's aquatic ecosystems in order to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?

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[47] U.S. Environmental Protection Agency, Office of the Chief Financial Officer, *Strategic Plan* 19 (No. 190-R-00-002) (September 2000) available at www.epa.gov/ocfopage/plan/2000strategicplan.pdf.

[48] Id. Note that this figure does not include unassessed waters – some of which may not meet these standards.

[49] Id.

[50] Id.

[51] *U.S. Environmental Protection Agency Fact Sheet Update: National Listing of Fish and Wildlife Advisories* 1 (EPA-823-F-01-010) (April 2001).

[52] Id.

Chapter One focuses on the tools that environmental agencies use to define, evaluate and respond to the adverse health impacts from contaminated aquatic environments. It discuses the research methods agencies use to obtain information about the lives, practices, and circumstances of affected communities and tribes, as well as the risk assessment approaches agencies use to evaluate these impacts.

The next two chapters examine agencies' responses – the "risk management" approaches that they employ to address the health impacts of contaminated aquatic environments. Chapter Two discusses agencies' risk reduction strategies, whereby risk-producers are required to cleanup, reduce, or prevent environmental contamination. This chapter examines the legal authorities that might be invoked more effectively to sustain healthy aquatic ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife.

Chapter Three then discusses agencies' risk avoidance strategies, whereby risk-bearers are asked to change their lives and practices in order to avoid exposure to harmful contaminants. This chapter focuses on fish consumption advisories and asks what role they should play in efforts more effectively to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife. In so doing, it considers how agencies can identify, acknowledge and meet the real needs of those who are affected among communities of color, low-income communities, tribes, and other indigenous peoples. This chapter discusses means by which agencies can ensure community participation and tribal consultation. It also discusses ways agencies can work to make communities whole once the fish, aquatic plants, and wildlife on which they depend have already become contaminated. This chapter, in particular, responds to questions posed to the NEJAC by the EPA Office of Water in October, 2001, requesting advice on improving its risk communication efforts and on updating its *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume IV: Risk Communication.*[53] Various aspects of these questions are also addressed throughout the Report.

Chapter Four examines issues unique to American Indian tribes, Alaskan Native villages, and their members. Although tribes and their members share many of the concerns discussed in the first three chapters, their unique political and legal status warrants separate treatment.

[53]Memorandum from James Hanlon, Acting Deputy Assistant Administrator, Office of Water, to Barry Hill, Director, Office of Environmental Justice (October 4, 2001).

CHAPTER I: RESEARCH METHODS AND RISK ASSESSMENT APPROACHES

How should EPA improve its research methods and risk assessment approaches to address degradation of aquatic ecosystems and adverse impacts to human health from consuming or using contaminated fish, aquatic plants, and wildlife for subsistence, cultural, traditional, and religious activities and purposes?

When health and environmental agencies respond to the harms from contaminated aquatic environments, they typically frame the issue as one of "human health risks" – specifically, harm to individuals' physical health: the contaminants are carcinogens, or reproductive toxins, or endocrine disrupters, or have multiple human health "endpoints."

Health and environmental agencies then manage these "health risks" by employing one or both of two general strategies: *risk avoidance* (whereby risk-bearers are encouraged or required to change the practices that expose them to environmental contamination, e.g. through fish consumption advisories, directed to those people who eat fish) or *risk reduction* (whereby risk-producers are required to cleanup, reduce, or prevent environmental contamination, e.g., through water quality standards, applied to industrial sources that discharge contaminants into surrounding waters).[54] Risk reduction strategies will be the focus of discussion in Chapter 2; risk avoidance strategies will be the focus of discussion in Chapter 3.

For both strategies, agencies need to get a sense of the practices that expose humans to environmental contaminants (e.g., how much fish do they eat? what kinds of fish? how is it prepared?) and the underlying health and other circumstances of those exposed (e.g., are they young or old? do they have other preexisting health conditions? do they have access to adequate health care?). In gathering this information and, more generally, in fashioning their responses to contamination, agencies' efforts have until quite recently reflected the lives, practices, and circumstances of the "average American"or "the typical U.S. consumer."[55] Importantly, they often have not reflected the lives and circumstances of communities of color, low-income communities, tribes, and other indigenous peoples. That is, agencies' efforts overall have tended to reflect the cultural, traditional, religious, historical, economic, and legal contexts that describe members of the general population. Specifically, agencies' efforts have assumed (1) the exposure circumstances of members of the general population; and (2) the susceptibilities and co-risk factors of members of the general population.

[54]Catherine A. O'Neill, *Risk Avoidance and Environmental Justice* (forthcoming).

[55]See, e.g., U.S. Environmental Protection Agency, *Note to Correspondents: EPA Issues 1996 Fish Advisory Data* (1997) ("The typical U.S. consumer eating fish in moderation from a variety of sources and eating a variety of species is not believed to be at increased risk . . .").

This Chapter will focus on the tools environmental agencies use to define, evaluate and respond to the adverse health impacts from contaminated aquatic environments: the *research methods* agencies use to obtain information about the lives, practices, and circumstances of affected communities and tribes, and the *risk assessment approaches* agencies employ to evaluate and address these health impacts. Along the way, it will highlight issues that bear as well on agencies' approaches to *risk management* and *risk communication*, although these questions will be taken up at greater length later in the Report.

Part A of the chapter discusses briefly the prior question: what is meant by "adverse impacts to human health?" The next four parts examine exposure. Part B looks at fish consumption rates and how these differ as between the general population and higher-consuming "subpopulations" such as communities of color, low-income communities, tribes, and other indigenous peoples. Part C examines standard assumptions about the fish, plant and wildlife species people consume and use; the parts of these species they use; and the preparation methods they employ. It considers the differences in these practices among various affected groups and how this affects estimates of exposure. Part D raises the point that communities of color, low-income communities, tribes, and other indigenous peoples consume and use fish, plants and wildlife in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American." Part E takes up the issues of aggregate or multiple exposures and cumulative risks. Part F turns from exposure to issues of susceptibility and co-risk factors. Part G explores suppression effects and their implications. Part H addresses research methods relevant to risk assessment, management, and communication involving contaminated fish and aquatic environments. Finally, Part I considers refinements and alternatives to risk-based approaches.

A. DEFINING ADVERSE IMPACTS TO HUMAN HEALTH

How can EPA in its various functions ensure that cultural, traditional, religious practices are being considered in defining and evaluating health risks with respect to all people, including minority and low-income communities, and tribes?

When health and environmental agencies evaluate and respond to the human health risks from contaminated aquatic environments, they typically invoke a particular conception of "human health."[56] This conception tends to be that of the dominant society, for whom "human health" is taken in the narrow, individual and physiological sense of the term. So defined, agencies look to toxicological and epidemiological data that connect environmental contaminants such as mercury or PCBs to human health "endpoints" such as neurological damage or cancer. Agencies cite determinations (by legislatures, courts, or their own or other agencies) as to "acceptable" increases in the risk of occurrence of such "endpoints," and from there work backward to decide how much mercury to permit to be emitted into the air or what quantity of PCBs to allow to remain in

[56] Agencies also sometimes (although less often) respond to "ecological risks;" these are typically considered separately from human health risks, and do not include attention to social, cultural, or other related harms.

contaminated sediments after cleanup. These decisions then get incorporated into standards or permits or cleanup requirements.

This definition of the adverse impacts, however, may not reflect the perspectives of those affected. For some of those affected, the harms from contamination are not only physical, but psychological, social, and cultural. For some of those affected, the affront is not only to an individual but to a group – the threat is not only to the physical survival of a person, but to the cultural flourishing of a people. Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, and Barbara Harper, International Institute for Indigenous Resource Management, explain:

> *For example, Native American communities are inseparable from their lands and resources, so evaluation of their risks from contamination must integrate human physiological and mental health, ecological health, socio-economic health, and cultural and spiritual health within a single framework. This does not mean simply adding a quality of life component and calling it cultural risk, or using an exposure scenario that reflects additional routes of exposures. Rather, it means beginning the assessment by understanding the entire eco-cultural system (people and biota interlocked in a co-adapted system of behaviors and ecologies that is sustainable over time but which is now severely strained even without the addition of contamination). . . .*
>
> *The individual and collective well-being of tribal members is often derived from membership in a healthy community that has access to ancestral lands and traditional resources and from having the ability to satisfy personal responsibility to participate in traditional community activities and to help maintain the spiritual quality of our resources.*[57]

Environmental justice means noticing and acknowledging not only the harms that are perceived by the dominant society, but also the harms that are felt by communities of color, low-income communities, tribes, and other indigenous peoples. Often, these harms will have quite different dimensions than those felt by the dominant society and reflected in agencies' definition and evaluation of the problem. EPA and other agencies need to reexamine methods and models employed in evaluating adverse health impacts from environmental contamination.[58]

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[57]Stuart G. Harris and Barbara L. Harper, *Using Eco-Cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures*, 2 Environmental Science & Pollut. Res. 91, 91-92 (Special Issue, 2000).

[58]Elizabeth D. Nobmann, *Nutritional Benefits of Native Foods*, available at www.nativeknowledge.org/db/files/aboutnt2.htm (describing Alaskan Native's understanding of "nutrition" in the broadest sense and recounting a call for "models that addressed social, emotional, spiritual and cultural issues as well as physical health" by attendees of the Alaska-Russia Native People's Health and Social Issues Conference in 1992).

B. EXPOSURE: FISH CONSUMPTION RATES

Several factors determine (1) whether and how an individual comes in contact with environmental contaminants and (2) to what extent that individual suffers adverse health effects as a result of this contact. The first set of factors describes one's circumstances of *exposure*. The second set of factors describes one's *susceptibilities and co-risk factors*. Although more information needs to be gathered about the differences among various "subpopulations" with respect to both exposure and susceptibilities, existing data show important differences between the general population and communities of color, low-income communities, tribes, and other indigenous peoples. Questions of exposure will be addressed in Parts B, C, D and E, below; questions of susceptibility will be addressed in Part F.

Humans are exposed to environmental contaminants through a variety of routes: they inhale toxic air contaminants; they drink contaminated groundwater; they absorb pesticides through our skin; they eat fish that swim in and bioaccumulate toxins from contaminated surface water and sediments. As noted above, fish consumption is the primary route of exposure for many toxic contaminants, including those that are now present in and permitted to be released to aquatic environments. All else being equal, the higher the level of fish one consumes, the greater one's exposure to any contaminants in the environment that the fish uptake, and the greater one's risk of adverse health effects.

EPA and other agencies use exposure data to set environmental standards for aquatic environments that support fish and other species consumed by humans: they set water quality standards to determine how much contamination will be permitted to be released now and in the future; they set cleanup standards to determine to what level surface waters and sediments must be cleaned up once they are already contaminated. They also use exposure data to estimate risk in order to determine whether to issue fish consumption advisories. When EPA and other agencies use risk assessment to set environmental standards, they start from a level of risk that has been deemed "acceptable" or a threshold level of exposure that is believed not to result in adverse health effects. They then consider the toxicity of the contaminant in question (e.g., dioxin) and the various elements of humans' exposure to that contaminant (e.g., how much fish do people consume? for how many years do people live and consume fish at these rates? to what extent does the contaminant in question bioaccumulate in the fish tissue consumed?). Working from these inputs, agencies determine how much of the contaminant to allow to be discharged to or to remain in aquatic environments. Note that when agencies set standards in this way, they typically rely on values for each of the inputs that reflect the characteristics and practices of the general population. These values often do not reflect the characteristics and practices of affected communities and tribes, which often lead to greater exposures for these groups. This is problematic in that the resulting standards will not protect these more highly-exposed groups.

1. Evidence of Different Consumption Practices

While there is considerable evidence that different groups have different fish consumption practices, these differences have until recently been demonstrated chiefly by "anecdote" rather than by empirical study. Even today, there are many more instances in which practices that include high rates of fish consumption and/or consumption from seriously contaminated waters are evidenced by local knowledge, direct observation, or "anecdote" rather than by formal study. Thus, for example, as Yalonda Sindé, Executive Director of the Community Coalition for Environmental Justice, Seattle, reports:

> *We know there are people out there fishing on the Duwamish. People in the neighborhood see them out there.*[59]

The Duwamish waterway is highly contaminated and under advisory for a host of industrial chemicals; signs are posted warning against eating all bottom fish, all shellfish, and seaweed. Similarly, as Bowden Quinn of the Grand Cal Task Force reports:

> *Although we don't have any hard data, there is anecdotal evidence of people subsistence fishing on the Calumet River. People do fish and they likely eat the fish they catch . . . despite a "Class 5" restriction on the River, which means "Do Not Eat the Fish."*[60]

The Calumet Region is home to steel manufacturing facilities, petroleum refineries, chemical manufacturing facilities and a host of other heavy industries, and has been described as "one of the nation's most polluted areas."[61] And, Ora Rawls, Executive Director, Mississippi Rural Development Council, reports:

> *Fish consumption (volume) has been underestimated. As I shared with a DEQ (EPA) official, many individuals (African American) eat fish two to three times a week – in rural areas, as often as five times a week. Where I lived on the Coast (Gulport/Biloxi), four to five times a week. This volume is from personal fishing (streams, lakes, ponds), not from retail sales data that is used to capture consumption patterns.*[62]

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[59]Personal Interview with Yalonda Sindé, Executive Director, Community Coalition for Environmental Justice, Seattle, Washington (October 16, 2001).

[60]Telephone Interview with Bowden Quinn, Executive Director, Grand Cal Task Force (October 10, 2001); accord, Telephone Interview with Alex DaSilva, Remedial Action Coordinator, Indiana Department of Environmental Management (October 10, 2001).

[61]Bill Eyring, Center for Neighborhood Technology, *The Neighborhood Works,* "Industry's Polluted Legacy: The Calumet Region" 10 (October/November 1993).

[62]National Risk Communication Conference, Proceedings Document II-17-19 (2001).

Anecdotal evidence similarly describes people fishing on and consuming fish from Lake Erie and the Cuyahoga River in Cleveland;[63] from the Mississippi River in East St. Louis;[64] from the Columbia Slough in Portland, Oregon;[65] and from the Mississippi River between New Orleans and Baton Rouge.[66]

There are, however, several formal fish consumption studies that demonstrate that members of various communities of color, low-income communities, tribes, and other indigenous peoples consume far greater quantities of fish than do members of the general population. Further, these studies show that there are differences as well *among* these various communities, groups, or peoples. They also support the observation that the intersection of poverty and identity or group membership may be an important factor in accounting for differences in fish consumption practices. Table 1 presents a sampling of the fish consumption rates gathered by recent studies, selected to illustrate these characteristics of the data in the context of various subpopulations (e.g., Native American, Alaskan Native, Asian/Pacific Islander, African-American, southern, and urban subpopulations). Note that the values presented here are not directly comparable because of design and other differences among the studies. (For example, some studies include shellfish whereas others include only finfish; some studies provide *per capita* values – which include those who do not eat fish along with those who do – whereas other studies provide values for fish-consumers only.) These values are provided only to give some sense of the relatively higher consumption rates of communities of color, low-income communities, tribes, and other indigenous peoples compared to the general population (as well as some sense of the differences among and within these groups).[67]

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[63]Telephone Interview with Patrick C. West, Professor Emeritus of Natural Resources/Environmental Sociology, University of Michigan School of Natural Resources (October 23, 2001).

[64]Id.

[65]Videotape: The Water in Our Backyard (City of Portland, Bureau of Environmental Services).

[66]Telephone Interview with Mary Lee Orr, Louisiana Environmental Action Network (October 17, 2001).

[67]Some of these values, moreover, were generated for this purpose only and should *not* be cited or used without consulting the studies and their authors. In some cases, these numbers were generated in reliance on assumptions that may or may not be shared by the study authors (e.g., conversion methods for values originally given in g fish/kg bodyweight/day).

Table 1: Quantified Evidence of Fish Consumption

Study Authors (Date)	Sample Population	50th Percentile (g/day)	Mean (g/day)	90th Percentile (g/day)	95th Percentile (g/day)	Max. Value (g/day)*
Duncan (2000)	Suquamish Indian tribe	132.1	213.9	489.0	796.9	1453.6
Sechena (1999)	Ten Asian & Pacific Islander groups, King Co., WA	89	117.2	242	---	733.46
Chiang (1998)	Laotian Groups (Mien, Lao, Khmu, Thadum), West Contra Costa Co., CA	9.1	18.3	42.5	85.1	182.3
Toy, et al. (1995)	Squaxin Island and Tulalip tribes	35.6 - 48.7	60.6 - 82.9	159.7 - 221.7	205.1 - 280.5	391.4
West, et al. (1995)	Michigan fishers	---	14.7	---	---	---
	Low-income African Americans and off-reservation Native Americans	---	43.1	---	---	---
CRITFC (1994)	Nez Perce, Umatilla, Yakama, and Warm Springs tribes	29.0 - 32.0	58.7	97.2 - 130.0	170.0	972.0
Alabama DEM (1993)	Alabama Fishers	---	44.8	---	50.7	---
	Black anglers with income < $15,000	---	63	---	---	---
Dellenbarger, et al. (1993)	Houma, LA consumers	65	---	---	---	---
Nobmann, et al. (1992)	Alaskan Natives from 11 communities	---	109	---	---	---
Puffer, et al. (1982)	Los Angeles Harbor fishers	37	---	225	338.8	---

* Note: In some studies, these maximum values were treated as outliers and adjusted downward.

In addition to the studies presented here, several other studies provide further formal, quantified evidence of differences in fish consumption practices among communities of color, low-income communities, tribes, other indigenous peoples, and the general population.[68]

Significantly, the fish consumption rates presented in Table 1 are markedly higher, at virtually every point of comparison, than those relied upon by agencies to set water quality standards, to set cleanup standards for surface water and sediments, and to gauge baseline consumption to estimate health risks and the need for fish consumption advisories. As elaborated below, EPA until quite recently employed a fish consumption rate of 6.5 grams/day for all populations. EPA now employs a fish consumption rate of 17.5 grams/day for the general population and recreational fishers, and 142.4 grams/day for subsistence fishers.[69] These are 90th and 99th percentile values, respectively, from a study of the general population (fish consumers and non-consumers alike). That is to say, EPA targets protection at the 90th percentile of the general population (a point discussed further below). Compare these values with the 90th percentile of Asian and Pacific Islanders in King County, at 242 g/day or the 90th percentile of the Suquamish Indian tribe, at 489 g/day, or the 90th percentile of fishers in the Los Angles Harbor, at 225 g/day. Consider, too, that whereas those Asian and Pacific Islanders in King County consuming at the average (mean) rate may be adequately protected were the relevant environmental standards to reflect EPA's default for subsistence fishers (142.4 g/day), those consuming at the maximum rate – 733.46 g/day would be grossly underprotected. They would fare even worse were the relevant environmental standards to reflect EPA's default for the general population (17.5 g/day). Those consuming at the maximum rate for the Suquamish Tribe (1453.6 g/day), the Laotian communities in West Contra Costa County (182.3 g/day), the Squaxin Island and Tulalip tribes (391.4 g/day), and the four Columbia River tribes (972 g/day) would be similarly underprotected – and, as discussed below, consumption at these rates may reflect the very practices that these affected groups would want to see perpetuated and protected for cultural, traditional, religious, economic, and other reasons.

However, as this survey of the available data reveals, there are many communities, groups, or peoples for which empirical studies have not yet been conducted. In addition, there is still relatively little data about the intersection of factors such as ethnicity or group membership and income. And, for some groups, there is the matter of acute or peak consumption rates – very high rates of consumption for shorter periods, such as during ceremonies, religious and other holidays (e.g., Lent, during which Roman Catholics may consume 2 or more fish meals per week), or

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[68]Among these are studies of fish consumption in Santa Monica (CA); in the state of New York; on the Hudson River (NY); in Detroit (MI); in Lake Coeur d'Alene (ID); on Commencement Bay (WA); on the Savannah River (GA); in the state of Florida; on Lake Ontario; in American Samoa; on the Fox River (WI); among Wisconsin Chippewa Indians; among the Miccousukee Indian Tribes of South Florida; and among Native Americans living near Clear Lake, California. EPA canvassed these and other studies in preparing its AWQC Methodology. See, U.S. Environmental Protection Agency, Ambient Water Quality Criteria Derivation Methodology Human Health, Technical Support Document 89-103 (July 1998).

[69]It is not clear precisely which groups EPA means to include when it refers to "subsistence fishers."

harvest seasons (e.g. salmon runs, during which some Alaskan Natives consume 80-100 pounds of fish per month) – about which less may be known and for which, in any event, current risk assessment methods may fail to account. As Delores Garza, Alaska Native Science Commission, explains:

> *[W]e eat much more [fish, wildlife, and plants] than is listed [by EPA and other agencies], but we also eat it in a very short time period. That's when strawberries are fresh, when corn is fresh, when salmon run – you eat nothing but salmon. So you don't eat one steak per month or one filet per month. You eat salmon for breakfast, for lunch, and for dinner for a month, and then you go to your next resources and you eat that same amount of that resource.*[70]

Similarly, the Swinomish Indian Tribal Community, comments:

> *Not only should the EPA add multiple exposures and cumulative risks to health risk calculations done, but they should also publish and distribute methodology to Tribes who employ their own fish consumption rates, based on local data. Moreover, calculations and procedures to determine acute and chronic events ought to be explicitly described so that health risks can be determined from one high consumption event, for instance during a traditional ceremony, as well as over the long term.*[71]

In many cases, communities, groups, or tribes would be interested in conducting such studies, but lack the financial and/or technical resources to do so. Although anecdotal data may be plentiful, non-quantified data are difficult to incorporate into risk assessment as currently practiced; moreover, environmental agencies are unlikely to accept data that have not been quantified according to accepted norms (e.g., for statistical analysis, peer review, etc.). These are research needs that should be addressed. This point is discussed further in Part H, below.

2. EPA's Revised Fish Consumption Rates

Until recently, EPA used a standard or "default" assumption for the fish consumption rate (FCR) that would be factored into estimates of health risk: 6.5 grams/day.[72] This is about one 8-ounce fish serving *per month* – an amount that is outdated and inaccurate even for the general population. And, this amount grossly underestimates the consumption rates for many communities of color, low-income communities, tribes, and other indigenous peoples.

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[70]Delores Garza, Alaska Native Science Commission, *Testimony to National Environmental Justice Advisory Council* Vol III-89-90 (Annual Meeting Transcript) (Dec. 4, 2001).

[71]Swinomish Indian Tribal Community, *Comments on the National Environmental Justice Advisory Council's Draft Fish Consumption Report* (Feb. 5, 2002).

[72]Consent Decree Water Criteria, "Guidelines and Methodology Used in the Preparation of Health Effect Assessment" 45 Fed. Reg. 79,347, App. C (1980).

Recognizing this, EPA revised its default assumption in the fall of 2000, as part of an updated Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health ("AWQC Methodology").[73] Although in many cases federal and state water quality criteria currently in effect reflect the old 6.5 grams/day default, EPA now recommends the following default FCRs:

General population	17.5 grams/day
Recreational fishers	17.5 grams/day
Subsistence fishers	142.4 grams/day

EPA will use the 17.5 grams/day value when it derives or revises national criteria pursuant to CWA 304(a).[74] EPA will also consider these values when it reviews water quality standards set by states and authorized tribes,[75] as part of a four-part preference hierarchy:

(1) Use local data;
(2) Use data reflecting similar geography/population groups;
(3) Use data from national surveys; and
(4) Use EPA's default intake rates.

EPA "strongly emphasizes that States and authorized Tribes should consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s)."[76]

EPA's default value of 17.5 grams/day for the general population and for recreational fishers reflects the 90th percentile value of 17.53 grams/day for freshwater and estuarine ingestion by adults, taken from the USDA's CSFII Survey for the years 1994 to 1996. EPA's default value of 142.4 grams/day for subsistence fishers reflects the 99th percentile value of 142.41 grams/day for freshwater and estuarine ingestion by adults, taken from the USDA's CSFII Survey for the years 1994 to 1996. EPA states that it "believes that the assumption of 142.4 grams/day is within

[73]U.S. Environmental Protection Agency, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (October 2000) ["AWQC Methodology"].

[74]Under CWA 304(a), the EPA is to develop "criteria" – scientific information and guidance for use by the states and authorized tribes and the EPA itself in establishing water quality standards pursuant to CWA 303(c). Under CWA 303(c), states and authorized tribes have primary responsibility for establishing water quality standards. EPA is charged with reviewing these standards. EPA may promulgate superceding federal standards if a state's or tribe's standards are not consistent with the CWA and its implementing regulations, or if the EPA determines that national standards are necessary. In either event, EPA relies on the criteria it developed under CWA 304(a) as it undertakes review or promulgates standards itself.

[75]See id.

[76]AWQC Methodology at 4-25.

the range of *average* consumption estimates by subsistence fishers based on the studies reviewed."[77]

For states or tribes exercising any of the first three preferences, EPA remarks: "States and authorized Tribes may use either high-end values (such as the 90th or 95th percentile values) or average values for an identified population they plan to protect (e.g., subsistence fishers, sport fishers of the general population). EPA generally recommends that arithmetic mean values should be the lowest value considered by States or Tribes when choosing intake rates for use in criteria derivation. When considering geometric mean (median) values from fish consumption studies, States and authorized Tribes need to ensure that the distribution is based on survey respondents who reported consuming fish because surveys based on both consumers and nonconsumers can often result in median values of zero. If a State or Tribe chooses values (whether central tendency or high-end values) from studies that particularly target high-end consumers, these values should be compared to high-end fish intake rates for the general population to make sure that the high-end consumers within the general population would be protected by the chosen intake rates."[78]

Several aspects of the CSFII data and EPA's AWQC Methodology are worth discussing. First, while EPA's new default values represent a vast improvement over the old 6.5 g/day default, the new default values are problematic in that they aim to protect the general population at the 90th percentile, but to protect subsistence fishers only at a level somewhere "in the range of *average* estimates." This choice provides disparate levels of protection to the general population, on the one hand, and subsistence subpopulations, on the other. Taking this view, it is unclear why EPA's default values do not set protection for subsistence subpopulations at the 90th percentile – as they do for the general population – rather than at the average. Moreover, from the perspective of some groups or tribes, it is the very highest consumers that warrant particular attention and protection, because it is these individuals who are consuming at levels and in accordance with practices that are most consonant with the group's or tribe's traditional, cultural, religious or spiritual beliefs. Taking this view, it may be appropriate in some cases for states, tribes, and the EPA to use values that target protection at the 95th or 99th percentile, or even at the maximum value, for particular subsistence subpopulations.

Second, to EPA's credit, the AWQC Methodology's four-part hierarchy recommends using local data as a first choice, data reflecting similar geography/population groups as a second choice, and relying on EPA's default values only as a fourth and last choice. That having been said, the reality is that many states still rely on EPA's default values because they (and the affected communities and tribes within their borders) simply don't have any local data on which to

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[77] AWQC Methodology at 4-27; but compare Catherine A. O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 Stanford Environmental Law Journal 3, 59 (2000) (noting that EPA appears to offer conflicting accounts of what it means to be a "subsistence" fisher and that "EPA nowhere makes clear precisely who it views to be included in this grouping or to which studies it refers for the 'range of averages.'")

[78] AWQC Methodology at 4-26.

rely – often due to a lack of resources.[79] If using local data is to be a meaningful first choice, more resources need to be devoted to gathering this data, a point taken up at greater length below.

Third, EPA notes that the default values and the four-part preference hierarchy assume data reflecting consumption of freshwater and estuarine species only. For states or tribes exercising any of the first three preferences, EPA recommends that consumption of marine species be treated as an "other source of exposure." The effect of choosing to exclude marine species is to decrease the resulting default fish consumption rates (and, ultimately, to render any standard based on these defaults or recommendations less protective). Of note, too, EPA deemed salmon to be marine, although they are anadromous, spending a portion of their lifecycles in freshwater and/or estuarine environments. EPA estimates that the effect of this exclusion is to decrease the resulting default FCRs by approximately 13%.[80]

Fourth, the EPA's default values are based on *per capita* consumption rates from the general population – that is, "fish consumption" rates that include fish consumers and fish nonconsumers alike. The CSFII study on which the EPA's defaults are based for its Draft AWQC Methodology surveyed 11,912 individuals annually for 3-day periods.[81] Of the 11,912 participants, only 3,972 actually ate fish during the three days surveyed.[82] These were the fish consumers; their fish consumption rates were recorded. The 7,940 participants who didn't eat fish during the three-day period were the fish nonconsumers; their fish consumption rates were entered as "0." The CSFII study then generated two sets of figures: a set considering only the fish consumers and a set considering both the fish consumers and the fish nonconsumers. EPA chose to base its default values on the latter, *per capita* figures. Importantly, the effect of this choice is again to decrease the resulting default FCRs – with so many "zero" values factored in, the point estimates are decreased at every point of comparison. So, for example, whereas the mean value for fish consumers is 106.39 g/day, the mean value once fish nonconsumers are also included sinks to 18.01 g/day; similarly, whereas the 99th percentile value for fish consumers is

[79]Telephone Interviews with Denis Borum, Environmental Scientist, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency (Nov. 23, 1999 and March 15, 2002).

[80]Draft AWQC Methodology at 43,804.

[81]1 & 2 U.S. Department of Agriculture, Continuing Survey of Food Intake by Individuals (1998) [hereinafter 1 CSFII Study and 2 CSFII Study]. Note the caveat that the Draft AWQC Methodology references the CSFII study data for 3-day periods for the years 1989, 1990, and 1991, whereas the Final AWQC Methodology references the CSFII data for the years 1994, 1995, and 1996. The numbers in the paragraph are taken from the *Draft* AWQC Methodology, and the 1989-1991 data, which were available to the Fish Consumption Workgroup. While the numbers may be slightly different for the 1994-1996 data (on which EPA based its final AWQC Methodology, the phenomenon described here applies generally to the choice between *per capita* rates versus rates that include fish consumers only and is likely borne out by the 1994-1996 data as well.

[82]1 CSFII Study at IV-8 and IV-16. See caveat, id.

399.26 g/day, the 99th percentile value drops to 142.96 g/day.[83] It is unclear why EPA, in setting out to fashion water quality criteria that are protective of the health of humans who are exposed to contaminants through the fish ingestion route, chooses to consider the fish consumption practices of those who do not eat fish at all. People who don't eat fish aren't in any danger of being exposed via this route. And people who do eat a lot of fish will be underprotected by diluted FCRs influenced by so many "zero" values. This choice is akin to including non-smokers in a study of the direct (not indirect) exposure to nicotine, or setting occupational safety standards to protect non-workers from on-the-job hazards.

Finally, the CSFII participants were selected from the forty-eight contiguous states only. The authors of the CSFII study note that the exclusion of Alaska and Hawai'i may result in depressed fish consumption values given that Alaska and Hawai'i "could potentially contain" a larger percentage of subsistence and other higher-consuming groups than the forty-eight contiguous states. Given the available data regarding fish consumption practices in Alaska and Hawai'i, this is almost certainly the case. Moreover, as affected groups in Alaska and Hawai'i have emphasized, this exclusion is inappropriate not only as a matter of science, but also as a matter of justice.[84]

Taken together, these choices mean that EPA's default values are less protective of higher-consuming and subsistence subpopulations. Given that these subpopulations are in the main comprised of particular communities of color, low-income communities, tribes, or other indigenous peoples, these choices are deeply troubling. Even in those cases where a state or a tribe undertakes any of the first three options in the four-part hierarchy, they must demonstrate "consistency with the principles" of the guidance provided by EPA in order to satisfy EPA review under CWA 303(c). Thus, all of the choices EPA has made in setting its own default values in effect become recommendations for the states or tribes to do the same (or face having to justify departures).

3. Fish Consumption Rates Reflected in Current Water Quality Criteria and Standards[85]

As noted above, EPA has recently revised its default assumption for the fish consumption rate to capture more accurately current national consumption patterns. States and authorized tribes, moreover, have always been free, subject to EPA approval, to depart upward from EPA's

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[83]2 CSFII Study at IV- 9 (table A-4) and IV-17 (table B-4). Note that these values are for "all fish;" recall that EPA's default values are based not on all fish, but only on freshwater and estuarine fish. See caveat, id.

[84]See, e.g., Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[85]See discussion of water quality criteria under CWA 304(a) and 303(c), at note 74. Note that the term "water quality criteria," as used in CWA 303(c), is part of the definition of a "water quality standard," which is comprised of (1) designated uses of a water quality segment, together with (2) water quality criteria necessary to support those uses. The term "water quality criteria" or "criteria" is also used to refer to the scientific information and guidance to states and tribes provided by the EPA pursuant to CWA 304(a). It is to the former usage that this section of this Report refers.

default numbers to reflect their higher-consuming populations. And under EPA's revised AWQC Methodology, states and tribes are now expressly encouraged to do so. Nonetheless, the question remains to what extent do the water quality standards *currently in effect* (whether developed by EPA, various states or tribes) reflect fish consumption rates higher than the old 6.5 grams/day default?

Although a handful of states have developed their own default fish consumption rates for use in developing water quality criteria and standards (e.g., WA, NY, MN, others), by and large, states have relied on EPA's default of 6.5 grams/day. Note that EPA, for its part, has never disapproved state water quality criteria or standards developed using the 6.5 grams/day value on the basis that this FCR did not adequately reflect higher-consuming or subsistence fishers affected by that state's standards.[86] As a result, a significant number of the state-issued water quality criteria and standards currently in effect rely on the 6.5 grams/day value.[87]

When EPA develops national water quality criteria or when it steps in to develop water quality criteria for states or tribes,[88] it looks to its own default values. Because EPA's revisions have only been in place since fall of 2000, it is perhaps not surprising that many of the criteria currently in effect still reflect EPA's old default value of 6.5 grams/day.[89]

Taken together, a significant portion of water quality criteria and standards currently in effect still rely on the 6.5 grams/day value. As has been noted, this value grossly underestimates consumption by many communities of color, low-income communities, tribes, and other indigenous peoples, and is thus no longer scientifically defensible.

C. EXPOSURE: ASSUMPTIONS ABOUT SPECIES, PARTS, PREPARATION

As noted above, the fish, aquatic plant, and wildlife consumption and use practices of communities of color, low-income communities, tribes, and other indigenous peoples differ from those of the general population. These differences in practices refer not only to the quantities of fish, plants and wildlife consumed, but also to the species consumed; the fish, animal or plant parts used; and the preparation methods employed. The studies upon which EPA and other agencies base their risk assessment and risk management decisions, however, typically make assumptions about species consumed, parts used, and preparation methods employed that reflect the practices of the general population but do not depict fully or accurately the practices of affected communities and tribes. For example, agencies typically assume that people eat or prefer certain

[86]Rich Healy, U.S. Environmental Protection Agency, Office of Water (Fish Consumption Workgroup Conference Call, June 26, 2001).

[87]Telephone Interview, Dennis Borum, Environmental Scientist, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency (March 15, 2002).

[88]The only example here is the case of the Confederated Tries of the Colville Reservation.

[89]Telephone Interview, Dennis Borum, Environmental Scientist, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency (March 15, 2002).

species, and that they refrain from eating a host of others, including "unusual" species such as sea urchin, sea cucumbers or bottom-feeding fish. Agencies typically assume that people eat only the fillet of finfish, and that they do not eat the fat, head, skin, bones, eggs, or internal organs. Agencies typically assume that people dispose of the drippings or cooking fluid. One result is that agencies set water quality standards and issue consumption advisories that are founded on an inaccurate picture of affected communities' and tribes' exposure. In most cases, the resulting standards will therefore not be sufficiently protective of members of these groups, whose different practices often expose them to additional sources of contaminants beyond those considered by the agencies. For example, lead accumulates in the bones, and most PCBs and most other persistent and bioaccumulative toxins accumulate in tissue with high lipid content, such as fat or eggs. Also, consumption advisories may include irrelevant or inappropriate information or recommendations, a point taken up in Chapter Three.

There is considerable evidence that different groups have different practices with respect to species consumed, parts used, and preparation methods employed. Much of this evidence is contained in local knowledge, direct observation, or "anecdote," rather than in formal studies, although there is a growing body of empirical work that confirms what affected communities and tribes know to be the case. For example, an African-American fisher on the Detroit River explains:

> *I keep sheephead and carp [which are bottom-feeding fish] because I have a large family to feed.*[90]

According to a study by the Squamish Tribe:

> *Children still teethe on dried clams . . .* [91]

According to a study recounting subsistence consumption practices in the Chignik Lake area, Alaska:

> *In exchange for the "red" salmon, Chignik Lake [people] received shellfish such as chitons (bidarkies), sea urchins (uduks), and butter clams from Perryville and Ivanof Bay people, resources Chignik Lake people have to travel far to get.*[92]

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[90]Patrick C. West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low Income Afro-Americans from the Detroit River* 5 (forthcoming).

[91]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound* 9 (2001).

[92]Lisa Hitchinson-Scarbrough and James A. Fall, *An Overview of Subsistence Salmon and Other Subsistence Fisheries of the Chignik Management Area, Alaska Peninsula, Southwest Alaska* (1996) available at www.nativeknowledge.org/db/files/tp230.htm.

According to a study of fishers on the Lower Fox River in the Green Bay, Wisconsin area:

> *Of those who reported eating the fish, Caucasian anglers reported that they like to eat the walleye . . . Most Asian [Hmong and Laotian] anglers reported that they prefer to eat the White Bass. White Bass is on the list of "Do Not Eat" fish in the fish advisory.*[93]

According to a study of the subsistence hooligan fishery on the Chilkat and Chilkoot Rivers in Alaska:

> *Historically, hooligan oil was used primarily for eating with other foods, but also for preserving certain berries, roots, herbs, and salmon eggs. It was commonly mixed with fresh berries. It was also consumed at feasts.*
>
> *In 1990 and 1991, processors dipped crackers, raw vegetables, dry fish, or meat into the fresh oil while it was still cooking in the vats. Pieces of hooligan meat were scooped up and eaten from cooking vats. One processing group served fresh hooligan oil accompanied by an array of other wild or fresh foods including smoked seal, smoked salmon, and raw fruits and vegetables. Throughout the year, the oil generally was eaten as a condiment with foods. It was added to boiled fish and meat, and spread or dipped with a variety of foods. Herring eggs, other fish eggs, boiled fish, and black seaweed were often eaten with hooligan oil. It was used for frying red sea ribbons in early summer. Year-old oil was whipped and mixed with cranberries, or cranberries and coho or sockeye salmon eggs. The aged oil was preferred, as it tended to whip more easily than freshly rendered oil.*[94]

Velma Veloria, Washington State Representative, observes:

> *Culturally, in the Filipino community, we eat the fin that many cut off, along with the belly fat. We love the fat. We fry it up to make soup.*[95]

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[93] Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[94] Martha F. Betts, *The Subsistence Hooligan Fishery of the Chilkat and Chilkoot Rivers* (1994) available at www.nativeknowledge.org/db/files/tp213.htm.

[95] Velma Veloria, FCW Conference Call (Oct. 23, 2001).

According to a study of the Greenpoint/Williamsburg ("G/W") community in the Borough of Brooklyn in New York City:

> *[Hispanics and Caribbean Americans] consume considerable quantities of fresh shellfish, including parts of the fish not typically consumed (e.g., the highly contaminated hepatopancreas of blue crabs).*[96]

According to a study of lead contamination in the Spokane River from the Idaho state line to the Seven Mile Bridge:

> *Russians and other immigrants said they use the whole fish, including bones and internal organs, in fish stews. The lead concentrates in bone and brains, the fish study showed.*[97]

According to a study recounting consumption practices in Bristol Bay, Alaska:

> *A variety of parts of the salmon were used for human consumption by Naknek River residents during the study period. Some parts, such as fillets, are used from every fish. Other parts, such as milt, were used on an occasional basis. . . .*
>
> *[Fillets] were frozen, salted, canned, smoked, dried, or eaten fresh. Heads, particular for those kings or large sockeyes, were used by many households. Fish head chowder was the most common method of preparation. Among those persons who used fish heads, it was ranked a favorite part of the fish, particularly of the king salmon.*
>
> *Eggs were frequently used, either as bait or eaten. If eaten, eggs were boiled or prepared as caviar. Fried milt was also used as food. . . . Milt can be frozen, but most reported using it fresh. The backbone was used two ways, either when a whole fish was canned or as 'gumchuk.' Gumchuk is the local term for a backbone that is hung until the outside layer of meat is dry, while the inside portion remains moist. It is then stored in a freezer. The dried backbone piece is boiled for eating. The backbone itself is not eaten, but sucked to extract the marrow and juices. The second method of preserving the backbone was canning. This method of processing disintegrates the backbone which is then eaten along with the meat.*
>
> *Other salmon parts were used on a less frequent basis by local Naknek River residents. Some households fixed salmon tails. These were either dried or smoked, or more*

[96] Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 2-21 (1999).

[97] Karen Dorn Steele, *Agencies Warn of Lead in River's Fish Advisory; Targets Fish Consumption of Contaminated Fish Caught in Stretch of Spokane River*, The Spokesman Review A1 (Jun. 21, 2000).

frequently, salted, soaked out, and boiled. Tips were mainly salted and then boiled. The stomachs were cleaned and boiled by a few households. Livers and hearts were fried.[98]

According to a study by the Suquamish Tribe:

> *Nectar resulting from shellfish preparation methods was commonly used. Sixty-four percent of respondents reported drinking the nectar and 24% reported using it in cooking, in contrast to 19% who reported that they "threw it out."*[99]

Finally, as noted above, according to a recent survey of first- and second-generation Asian and Pacific Islanders in King County, Washington – including members of Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese ethnic groups:

> *[Asian and Pacific Islanders] consume a wide variety of seafod species, the most frequently consumed being shellfish. These seafood, depending on their feeding and habitat characteristics, and the tissue parts consumed pose varying chemical contaminant risks to APIs. For example, certain fat soluble chemicals, e.g., PCBs, are concentrated in the fat layer between the meat and the skin, potentially exposing such consumer to higher contaminant levels than whose who simply eat the fillet. Eating the fillet with skin is clearly a common practice in the API community. . . . Overall, skin was consumed with the fillet 55% of the time. . . .*
>
> *API community members appear to eat shellfish parts that are thought to contain higher concentrations of chemical contamination, e.g., clam stomachs or the hepatopancreas of crabs. Bivalve shellfish were consumed whole by 24% (geoduck) to 89% (mussels) of respondents depending on the species. The "butter" as well as the meat of crabs were consumed 43% of the time . . .Finally, cooking water, both for finfish and shellfish are commonly use in cooking or directly consumed.*[100]

Yet, the studies upon which EPA and other agencies base their risk assessment and risk management decisions often make assumptions about species consumed, parts used, and preparation methods employed that do not reflect these practices. Consider the following description of a study of Los Angeles Harbor fishers by Puffer, et al.:

> From January to December of 1980, 1059 interviews with sportfishers were conducted in several fishing areas of the Los Angeles Harbor area. No fisher was sampled more than once. Data was collected on the following: amount of fish caught on the day of the interview, the primary use of the fish (whether it was eaten by the fisher's family, given

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[98] Judith M. Morris, *The Use of Fish and Wildlife Resources by Residents of the Bristol Bay Borough, Alaska* (1985) available at www.nativeknowledge.org/db/files/tp123.htm.

[99] The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound* 51 (2001).

[100] Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999)

away, thrown back, etc.), frequency of fishing, and other variables. Based on this data *and assuming that only an edible portion (1/4 to ½) of the caught fish would be eaten*, median and 90th percentile consumption rates of 37 grams per day and 225 grams per day were determined.[101]

If the fishers studied were members of a group that viewed the "edible portion" of the fish to include more parts or a greater portion of the fish than assumed by the study authors, this consumption would not have been registered and the resulting consumption rates would be lower than the actual consumption rates of those studied. Although there is no way to know for exactly how many of the fishers studied this would be the case; however, given that a significant number of the fishers studied were what the authors characterized as "Orientals/Samoans," it would at least be true for some. Importantly, as noted above, it is also often the case that the different parts consumed by communities of color, low-income communities, tribes, and other indigenous peoples are the very parts that accumulate the toxins. For both of these reasons, these groups' exposure is often underestimated by agencies relying on conventional studies and methods.[102]

Of note is that the CSFII study on which the EPA bases its default fish consumption rates similarly relies on a variety of assumptions that tend to reflect the consumption practices of the general population. The CSFII study asks participants to categorize and quantify their food intake according to a list of approximately 6,600 different food codes, of which 460 relate to fish and shellfish.[103] The participants' responses are then matched with standard recipes contained in the U.S. Department of Agriculture recipe file, in order to adjust the responses to reflect the quantity of fish contained in the particular dish, assuming standard quantities and preparation methods.

The differences noted here have implications for EPA's risk assessment and risk communication decisions. When agencies set water quality standards that are founded on an inaccurate picture of affected communities' and tribes' exposure, the standards will not be sufficiently protective of members of these groups. Although the examples above provide a sense of the growing body of evidence of differences in consumption practices as between the general population and communities of color, low-income communities, tribes, and other indigenous peoples, there is still a need for systematic study for many of these groups. Further, there is no place in EPA's current risk assessment methods to account for these different practices and the higher level of exposure they entail. The fact that often extraordinary levels of exposure – e.g., exposure to the large amounts of contaminants accumulated in the hepatopancreas of crab – are

[101]U.S. Environmental Protection Agency, Office of Water, *Ambient Water Quality Criteria Derivation Methodology Human Health: Technical Support Document* 96 (1998) (emphasis added).

[102]Note that the extent to which exposure is likely to be underestimated depends in part on whether bioconcentration or bioaccumulation factors are determine using whole fish or merely "edible portions" of fish.

[103]1 U.S. Department of Agriculture, *Continuing Survey of Food Intake by Individuals* II-1-4 (1998).

simply unaccounted for by EPA and other agencies when they set environmental standards is extremely troubling to affected communities whose health is thereby relatively underprotected.

Finally, when agencies issue consumption advisories founded on a misunderstanding of affected communities' baseline practices, they may include irrelevant or inappropriate information or recommendations. This issue will be discussed at greater length in Chapter Three.

D. EXPOSURE: CONSUMPTION PRACTICES IN CONTEXT

The contamination of fish, aquatic plants, and wildlife is especially troubling to many communities of color, low-income communities, tribes, and other indigenous peoples because these groups consume and use these resources in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American." Thus, it is not only that there are differences in the quantities of fish consumed or in the species, parts, and preparation methods used, but also that there differences – sometimes profound differences – in the place that these practices occupy in the lives of these people and groups. This is abundantly demonstrated by both testimonial and social scientific evidence. These practices are, in an important sense, *indispensable* to many of these communities and tribes. These differences need to be understood (as best as is possible, given that there may be difficult issues of cross-cultural translation) and accommodated in risk assessment, risk management, and risk communication approaches.

In order to gain a full sense of the circumstances of exposure for many communities of color, low-income communities, tribes, and other indigenous peoples, it is necessary to understand the cultural context in which exposure occurs. A handful of recent community- or tribally-conducted studies have demonstrated the importance of context for understanding exposure. (The necessity of community and tribal involvement in these and other studies is taken up below, in Section H.) For example, the recent consumption study conducted by the Suquamish Tribe commences with an account of "Cultural Patterns and Practices Affecting Suquamish Seafood Consumption," and notes the importance of *"[t]he stories that are woven into the statistics presented in this report."*[104]

It is not only a matter of reconsidering approaches to research, but also a matter of reevaluating approaches to risk assessment and risk management. Tradeoffs or cost-benefit analyses that may be appropriate in other contexts may thus be inappropriate where those affected engage in fishing and fish consumption for the interrelated cultural, traditional, religious, historical, and economic reasons that characterize many affected groups' practices. Additionally, such tradeoffs may run afoul of legal obligations to particular groups, e.g., civil rights-based protections or trust- and treaty- based protections.

Importantly, this discussion has implications for agencies' choices among various risk management tools. In some cases, for some affected groups, it will simply not be appropriate to

[104]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region* 5-9 (2000).

ask members to avoid risks by reducing their consumption, by switching to alternative species or fishing locations, by avoiding certain fish parts, or by adopting different preparation methods. Some or all of these practices may be prescribed for cultural, traditional, religious, historical, and/or economic reasons. This issue will be discussed again in Chapter Three, but it should be recognized that its implications are broader.

E. MULTIPLE EXPOSURES AND CUMULATIVE RISKS

Agencies currently employ risk assessment methods that evaluate the risks of environmental contamination as if humans were exposed to only a single contaminant at a time, by a single route of exposure. Humans, however, are often exposed to multiple contaminants at a time or in succession, and often via more than one route of exposure. These contaminants may have synergistic (or antagonistic) effects in combination, yet very little is known about these effects and agencies do not take them into account.

It is the case, moreover, that members of communities of color, low-income communities, tribes, and other indigenous peoples are more likely to be exposed to multiple contaminants via multiple routes and pathways than are members of the general population. As Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, and Barbara Harper, Fourteen Confederated Tribes and Bands of the Yakama Nation, observe:

> *The issue of multiple contaminants is significant, and it is the norm, at least in the Columbia River system, for over 100 contaminants to be identified in fish tissues. While only a few might be at concentrations that trigger an action in any given fish, the combined risk for one fish or for the many species which comprise the native diet can be quite high. If these chemicals are in the fish, they are also in the water and/or sediment, so other routes of exposure are important. The toxicity of a mixture of dozens of carcinogens plus dozens of noncarcinogens . . . needs to be examined.*[105]

Similarly, communities along the Mississippi River Corridor between New Orleans and Baton Rouge, whose members are largely African American and/or low-income, are exposed to an unconscionable level and mix of contaminants, via several routes and pathways.[106] These multiple affronts include exposure to a host of toxic air pollutants (emitted at levels *several times* the levels elsewhere in the United States);[107] to mercury and numerous other contaminants in the fish, oysters and crayfish that are often staple foods;[108] and to vinyl chloride and other contaminants in

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[105]Barbara Harper and Stuart Harris, *Tribal Technical Issues in Risk Reduction Through Fish Advisories*, Proceedings of the American Fisheries Society, Forum on Contaminants in Fish 17,19 (1999).

[106]Charles Lee, ed., United Church of Christ Commission for Racial Justice, *From Plantations to Plants: Report of the Emergency National Commission on Environmental and Economic Justice in St. James Parish, Louisiana* (1998).

[107]Id.

[108]Telephone Interview, Barry Kohl, Department of Geology, Tulane University (Oct. 17, 2001); Louisiana Department of Environmental Quality and Louisiana Department of Health and Hospitals,

drinking water.[109] And northern Ojibwa tribes are exposed to mercury via multiple resource pathways, given its uptake by fish and its presence in and on wild rice.

EPA and other agencies have begun to look at how to address multiple exposures and cumulative risk. For example, and to its credit, EPA's Office of Policy has recently conducted a cumulative exposure project to begin to assess the total exposure of more than 100 contaminants across multiple pathways; one component of this project is a community-specific study in the Greenpoint/Williamsburg community in Brooklyn, NY, designed to assess exposures to a variety of contaminants via fish consumption, water ingestion, air inhalation, and lead exposure.[110] This urban community is one of the poorest in New York City; it is comprised of substantial African American, Hispanic (including Caribbean American), Polish, Italian, and Hasidic subpopulations.[111] It is well recognized, however, that many of the issues of multiple exposures and cumulative risks remain unaddressed for the bulk of risk assessments currently being conducted.

F. SUSCEPTIBILITY AND CO-RISK FACTORS

Even if it were the case that all individuals' exposure circumstances were the same – that they came in contact with the same environmental contaminants, by the same routes, at the same frequency, for the same duration – they might not suffer the same adverse health effects as a result of this contact due to differences in their susceptibilities and differences in the extent to which their life circumstances allowed them to be prepared for and recover from the insult of an environmental contaminant, i.e. in their "co-risk" factors.

One might be more or less susceptible to a given level or "dose" of an environmental contaminant depending on one's life stage (e.g., children or the elderly may be more susceptible); one's prior exposure to the same or other contaminants (e.g. those who have become sensitized through prior exposures and now have more severe responses); one's genetic makeup (e.g., genetic susceptibilities that occur in a small but significant percentage of the population); or one's existing conditions or diseases (e.g., asthmatics). Although very little is known about the coincidence of some of these factors – genetics, for example – and whether one is a person of

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Human Health Protection Through Fish Consumption and Swimming Advisories in Louisiana available at www.deq.state.la.us/surveillance/mercury/fishadvi.htm (listing advisories statewide, many of wide apply to the waters of the Mississippi River Corridor).

[109] See, e.g., Chris Frink, *State Knew Well was Contaminated*, The Advocate Online available at www.theadvocate.com/news/story.asp?storyid=20619; Telephone Interview, Mary Lee Orr, Louisiana Environmental Action Network (October 17, 2001).

[110] Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 1-1- 1-5 (1999).

[111] Id. at 1-2.

color, a low-income person, or a Native American, it is fair to say that there is a significant correlation for others – prior exposures, or access to adequate health care, for example.[112]

One may also be more or less able to prepare for and recover from exposure to given level or "dose" of an environmental contaminant depending on the various resources an individual, community, group, or tribe can call upon and depending on other aspects of one's life circumstances. Thus, one may be more or less able to withstand and recover from a toxic insult depending on one's income, the quality of one's baseline diet, whether one is employed, whether one has access to adequate health care, whether one has adequate insurance, and whether one's community or tribe can assist to provide coping systems.

Current risk assessment, risk management and risk communication methods do not account adequately for susceptibilities and co-risk factors that affect individuals' responses to the environmental contaminants with which they come in contact. This is especially troubling to the extent that current risk estimates are made assuming the life circumstances of the general population or the affluent and fail thereby to account for the particular susceptibilities and co-risk factors that tend to be clustered in or characterize various communities of color, low-income communities, tribes, and other indigenous peoples. To take but a single co-risk factor by way of example, consider that of the respondents surveyed in a recent study of Asian and Pacific Islander communities in King County, Washington, 90% of Samoans, 62% of Vietnamese, 60% of Mien, 50% of Cambodians and 45% of Laotians live under the federal poverty line.[113] Among American Indians and Alaskan Natives, one in three lives below the federal poverty line.[114] Here again, more data need to be gathered about the particular susceptibilities and co-risk factors relevant to communities of color, low-income communities, and tribes. And here, too, EPA's and other agencies' risk assessment, management and communication methods need to be able to incorporate and address differences in susceptibilities and co-risk factors.

G. SUPPRESSION EFFECTS AND THEIR IMPLICATIONS

A "suppression effect" occurs when a fish consumption rate (FCR) for a given population, group, or tribe reflects a current level of consumption that is artificially diminished from an appropriate baseline level of consumption for that population, group, or tribe. The more robust baseline level of consumption is suppressed, inasmuch as it does not get captured by the FCR.[115]

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[112]See e.g., Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 University of Illinois Law Review 103.

[113]Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999).

[114]See Chapter 4 for a more complete discussion of the susceptibilities and co-risk factors of American Indians and Alaskan Natives.

[115]This effect was recognized and named in an early survey of Michigan sport anglers, and cited by the study's authors as a basis for adjusting the observed FCR upward. Patrick West, et al., *Michigan Sports Anglers Fish Consumption Survey: Supplement I, Non-Response Bias and Consumption Suppression Effect Adjustments* (School of Natural Resources, University of Michigan, Ann Arbor; Natural Resource Sociology Research Lab, Technical Report No. 2 (1989).

There are two circumstances in which suppression effects have implications for an environmental justice policy that seeks to sustain healthy aquatic ecosystems and to protect the health and safety of people consuming fish, shellfish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes. In the first, a suppression effect may arise when an aquatic environment and the fish it supports have become contaminated to the point that humans refrain from consuming fish caught from particular waters. Were the fish not contaminated, these people would consume fish at more robust baseline levels. In the second, a suppression effect may arise when fish upon which humans rely are no longer available in historical quantities (and kinds), such that humans are unable to catch and consume as much fish as they had or would. Such depleted fisheries may result from a variety of affronts, including an aquatic environment that is contaminated, altered (due, among other things, to the presence of dams), overdrawn, and/or overfished. Were the fish not depleted, these people would consume fish at more robust baseline levels.

The implications for environmental justice policy will depend in part upon which of these two scenarios accounts for the suppression effect observed. They will also depend upon how the more robust "baseline" level is defined – an exercise that itself raises important environmental justice issues. This question of an appropriate "baseline" will in turn be related to the particular group affected. In many cases, for example, a tribe will be able to cite a historical "point of reference" that would describe an appropriate baseline in terms of environmental quality, geographic delineation, and treaty rights.[116] In each case, there would be important questions of history, culture, and aspiration that would need to be considered in determining an appropriate baseline; that is to say, an appropriate baseline might mean examination into what people *had* consumed as well as aspiration for what people *would* consume were there "fair access for all to a full range of resources,"[117] or were the conditions fulfilled for full exercise of treaty- and trust-protected rights and purposes.

When environmental agencies employ a FCR that does not capture fully the consumption that is suppressed – under either scenario in which suppression effects occur – they set in motion a sort of downward spiral whereby the resulting environmental standards permit further and further contamination or depletion of the fish and so diminished health and safety of people consuming fish, shellfish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes. These effects play out somewhat differently in each of the two scenarios, as elaborated below.

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[116]Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of Yakama Nation (C3G Conference Call, August 3, 2001). For the Tribes and Bands of the Yakama Nation, for example, this point of reference would be 1855. Id.

[117]Principles of Environmental Justice, Proceedings of the First National People of Color Environmental Leadership Summit (1991).

1. Contamination

Health and environmental agencies have increasingly responded to contaminated aquatic environments by issuing fish consumption advisories warning humans to limit or stop their consumption of fish from polluted waters.[118] In many cases, individuals have responded to these advisories and/or to a greater general awareness of the dangers of consuming contaminated fish by eating less fish.[119] The extent to which individuals respond to fish consumption advisories by reducing their consumption varies.[120] In some cases, this is due to the fact that advisories are more effectively communicated to some affected populations than others. Among other things, advisories may not be communicated in culturally or language-appropriate ways. In other cases, this is due to the fact that, for cultural, traditional, spiritual, economic, and/or other reasons, the individuals to whom the advisories are addressed do not respond by reducing their consumption.

When environmental agencies set or approve water quality standards that are meant to be protective of human health, agencies look to gauge humans' exposure by how much fish they are consuming, i.e. their fish consumption rate. Agencies estimate or measure this FCR, and on this basis determine how much pollution can remain in or be discharged to the relevant waters and sediments and still result in what have been deemed "acceptable" levels of contamination and risk to human health. Notably, the FCRs on which agencies rely are meant to represent *current* rates of fish consumption, rates that may reflect a suppression effect as outline above.

When environmental agencies set or approve water quality standards that rely on a picture of exposure that takes people to be eating smaller quantities of fish, agencies will permit relatively greater quantities of pollutants to remain in or be discharged to the waters and sediments. That is to say, agencies will set less protective standards. The downward spiral thus begins, as these aquatic environments and the fish they support will be permitted to become increasingly contaminated, and some individuals in turn might be expected to respond by reducing their fish consumption even further. The downward spiral would continue, as agencies would then register this even lower rate of consumption, set new standards assuming that little or no human exposure to contaminants occurs via fish consumption, and permit even greater quantities of pollutants in aquatic ecosystems.

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[118]U.S. Environmental Protection Agency, Office of Water, Update: National Listing of Fish and Wildlife Advisories 2 (April 2001), available at www.epa.gov/ost/fish.

[119] See, e.g., Telephone interview with Shawn Martin, Clean Water Manager, St. Regis Mohawk Tribe Environment Division (July 12, 2001).

[120]Studies suggest varying degrees of both (1) awareness of fish consumption advisories by members of the public and (2) "compliance" with fish consumption advisories through changed fish consumption practices even when members of the public are aware of fish consumption advisories. See e.g., John Tilden et. al, Health Advisories for Consumers of Great Lakes Sport-Fish: Is the Message Being Received?, 105 Environmental Health Perspective 1360 (Dec. 1997); Hugh F. MacDonald and Kevin J. Boyle, Effect of a Statewide Sport Fish Consumption Advisory on Open-Water Fishing in Maine, 17 Journal of Fisheries Management 687 (1997).

2. Depletion

Many species of fish upon which people have traditionally relied are no longer readily available, due to habitat degradation and diminishment, ecosystem alteration, overfishing, and other causes. In the Pacific Northwest, for example, compromised aquatic ecosystems mean that fish are no longer available for tribal members to take, as they are entitled to do in exercise of their treaty rights. These numerous affronts have resulted in 24 salmon and steelhead runs being listed as endangered or threatened under the Endangered Species Act, and other fisheries being depleted. With fewer fish available to be taken, many tribal members have been prevented from consuming fish at the level that they would have were they able to exercise their treaty rights to the fullest extent.[121]

Again, when environmental agencies set or approve water quality standards that rely on a picture of exposure that takes people to be eating smaller quantities of fish, agencies will permit relatively greater quantities of pollutants to remain in or be discharged to the waters and sediments. Thus, tribal members are not only left with fewer fish to take and consume, but those that remain will be permitted to become increasingly contaminated. If fish stocks continue to decline, a variation on the downward spiral described above can be expected, with lower FCRs resulting from the fact that there are simply fewer fish to be consumed. Again, agencies would then register this even lower rate of consumption, set new standards assuming that little or no human exposure to contaminants occurs via fish consumption, and permit even greater quantities of pollutants in aquatic ecosystems.

It should be noted, too, that contamination is related to depletion. To take but one example, among the contaminants that have contributed to the decline and listing of salmon populations in the Pacific Northwest are numerous pesticides. Recent studies have shown that pesticides disrupt the ability of salmon to develop properly and to home to their natal streams; these harmful effects are in addition to their toxic effects on humans and other animals that consume fish.[122]

3. Evidence of Suppression Effects

There is limited evidence regarding the existence and extent of suppression effects. This is likely due in part to the fact that this term for the phenomenon hasn't been widely used – indeed, although diminished fish consumption due to contamination and/or depletion has been observed in numerous contexts, it is believed that this Report is the first document to bring these observations together under a single umbrella term. Nonetheless, there is a growing body of evidence of suppression effects due to contamination and/or to depletion. Among other sources of data are recent studies conducted to evaluate the effectiveness of fish consumption advisories for

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[121] Telephone Interview with Kelly Toy, Shellfish Biologist, Tulalip Tribes (November 9, 1999).

[122] See, e.g., Oregon Pesticide Action Network, *Diminishing Returns: Salmon Decline and Pesticides* (1999).

contaminated waters. To the extent that such studies find that people have "complied" with advisories by eliminating or lowering their consumption of fish, they provide evidence of a suppression effect – an artificially diminished level of consumption relative to a more robust baseline level. Too, community-based or tribally-conducted fish consumption studies often document broadly the subject group's fish consumption practices. Often, these studies include information about historic consumption and explore reasons for altered and diminished consumption practices.

Some of the available evidence documents suppression effects due to contamination. For example, as noted above, West, et al. recognized and named this effect in an early survey of Michigan sport anglers.[123] In a recent study of Lake Ontario anglers, Connelly, et al. cite recently altered health advisories that resulted in less Lake Ontario fishing as the reason that only 43% of anglers indicated that they had fished Lake Ontario in 1992.[124] A recent study of the Laotian communities in the San Francisco Bay area reports that 19.7% of survey respondents indicated that they had changed their fish consumption habits over the past five years, with 68.9% of these indicating that they eat less fish now.[125] Among the reasons cited for eating less fish: bay fish are "unsafe to eat."[126] Ken Jock, Director, Akwesasne Environment Program, provides an account of the effects of PCB contamination in the St. Lawrence River on the Mohawks at Akwesasne:

> *This all used to be a fishing village. That's all gone now. There's only one family that still fishes. . . . Our traditional lifestyle has been completely disrupted, and we have been forced to make choices to protect our future generations. . . . Many of the families used to eat 20-25 fish meals a month. It's now said that the traditional Mohawk diet is spaghetti.*[127]

Other available evidence documents suppression effects due to depletion or due to depletion *and* contamination. For example, as noted above, in the Pacific Northwest compromised aquatic ecosystems and depleted salmon and other fisheries mean that fish are no longer available for tribal members to take, as they are entitled to do in exercise of their treaty rights. According to Kelly Toy, Shellfish Biologist, Tulalip Tribes, with fewer fish available to be taken, many tribal members have been prevented from consuming fish at the level that they would

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[123] Patrick West, et al., *Michigan Sports Anglers Fish Consumption Survey: Supplement I, Non-Response Bias and Consumption Suppression Effect Adjustments* (School of Natural Resources, University of Michigan, Ann Arbor; Natural Resource Sociology Research Lab, Technical Report No. 2 (1989).

[124] U.S. Environmental Protection Agency, Office of Water, *Ambient Water Quality Criteria Derivation Methodology Human Health: Technical Support Document* 97 (1998).

[125] Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra County, California* 18 (1998). Note that 31% of those who indicated that their consumption practices had changed indicated that they eat more fish now.

[126] Id.

[127] Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* 17 (1999) (quoting Ken Jock, Director, Akwesasne Environment Program).

have were they able to exercise their treaty rights to the fullest extent.[128] Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of the Yakama Nation, confirms similarly depleted fisheries, diminished opportunities for catching and consuming fish, and compromised treaty rights.[129] A recent study of the Suquamish Tribe reports that approximately 2/3 of respondents (67%) indicated that their consumption patterns had changed over time, with 68% of these indicating that they ate less seafood (57%) or ate a different mix of species (11%) than twenty years ago.[130] "Most explanations for changes in consumption related to changes in family composition which affected harvesting patterns, accessibility/availability of finfish and shellfish, and restricted harvesting opportunities due to 'red tides' and increased pollution."[131] As one respondent elaborated:

> *We used to eat lingcod, sole, rockfish, flounder, and I caught Grunters for my grandfather. All of my brothers used to fish; now, only one of us can because the fish are diminishing in number . . . The water is not clean. Septics are malfunctioning . . . There's pollution from the Navy, and the filling at Keyport had a big effect . . . Beaches are dug out . . . We need to reseed and enhance our beaches in order to have the number of clams we need and are used to . . . We eat more geoduck now, because more are available to us, but we used to dry oysters and clams; they're good for teething . . .*[132]

Similarly, Hawaii's Thousand Friends relates:

> *Many shellfish and limu (seaweed) staples of Native Hawaiian diets are becoming harder to find or have disappeared due to pollution and/or destruction of habitat. Thus Native Hawaiians are unable to continue eating (healthy) foods traditional to their culture and lifestyle.*[133]

There is, however, a need to understand more fully the extent and causes of suppression effects. Among other things, the evidence presented here shows that people's responses to contamination and depletion are complex and varied. Further exploration of these effects would be useful. In particular, where consumption by communities of color, low-income communities, tribes, and other indigenous peoples seems relatively low, research is needed to ascertain whether a suppression effect is at work.

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[128]Telephone Interview with Kelly Toy, Shellfish Biologist, Tulalip Tribes (November 9, 1999).

[129]Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of the Yakama Nation (Conference Call, Aug. 3, 2001).

[130]The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound* 2 (2001). Note that 31% of those who indicated that their consumption practices had changed indicated that they eat more fish now.

[131]Id.

[132]Id. at 68 (ellipses in original).

[133] Hawaii's Thousand Friends (Written Comments, March 11, 2002).

4. Implications

To the extent that people are prevented from consuming fish as they had or would due to contamination or depletion of the fish and aquatic ecosystems that support the fish, there are important implications for EPA's and other agencies' risk assessment, risk management, and risk communication approaches. As noted above, when environmental agencies set or approve water quality standards that rely on a picture of exposure that takes people to be eating smaller quantities of fish, agencies will permit relatively greater quantities of pollutants to remain in or be discharged to the waters and sediments. That is to say, agencies will set less protective standards. The downward spiral thus begins, as these aquatic environments and the fish they support will be permitted to become increasingly contaminated, and some individuals in turn might be expected to respond by reducing their fish consumption even further. Or some individuals in turn might find that there are fewer fish to be caught (and those that remain to be increasingly contaminated) or there are fewer places open for shellfish harvesting. In either case, studies would reflect even lower FCRs, and agencies would then set new standards assuming that little or no human exposure to contaminants occurs via fish consumption, and permit even greater quantities of pollutants in aquatic ecosystems.

In order to avoid this downward spiral, EPA should identify appropriate "baselines" that reflect the more robust levels of consumption and employ these baselines in setting and approving water quality criteria. There is, of course, the difficult question of what the appropriate baseline should be, and the answer will likely differ according to the circumstances surrounding and the group affected by the observed suppression effect. For example, as noted above, a tribe will often be able to cite a historical "point of reference" that would describe an appropriate baseline in terms of environmental quality, geographic delineation, and treaty rights.[134] In each case, there would be important questions of history, culture, and aspiration that would need to be considered in determining an appropriate baseline. An appropriate baseline might mean examination into what people *had* consumed as well as aspiration for what people *would* consume were there "fair access for all to a full range of resources,"[135] or were the conditions fulfilled for full exercise of treaty- and trust-protected rights and purposes. It is recognized that the resulting baseline would surely require EPA to depart from the then-current estimates of actual fish consumption by the relevant group. In so doing, EPA would need to shift its emphasis from a descriptive assessment to a normative assessment. This shift is not without precedent, however, and, importantly, would seem to be necessary in some cases to avoid the downward spiral noted here.

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[134]Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of Yakama Nation (C3G Conference Call, August 3, 2001). For the Tribes and Bands of the Yakama Nation, for example, this point of reference would be 1855. Id.

[135]Principles of Environmental Justice, Proceedings of the First National People of Color Environmental Leadership Summit (1991) available at http://www.sccs.swarthmore.edu/org/speec/ejdef.html.

H. RESEARCH METHODS AND ISSUES

This part highlights two issues respecting EPA's current research methods and priorities: the importance of facilitating community-based or tribally-conducted research, and the need for research that seeks not only to describe affected groups' exposure but also to connect exposure to the sources of contaminants in aquatic environments.

1. Community-Based and Tribally-Conducted Research

It will often be crucial to the relevance, accuracy and acceptability of research in these areas that the affected community, group or tribe be central to the process throughout. In the case of consumption studies, for example, affected groups need to be involved from the earliest stages (e.g., project conception, group/subgroup identification, survey design) through implementation (e.g., survey administration, data interpretation) to utilization (e.g., community outreach regarding results, risk assessment, management and communication incorporating results). This is not only a matter of community access or tribal consultation, but importantly, a matter of scientific defensibility. There are currently sizeable gaps in the data and methods that are being used by EPA and other agencies to assess, manage, and communicate risk, and it is often the case that these gaps can only be filled by community- and tribally-based research. *Communities and tribes have expertise that is simply not going to be able to be replicated by non-member researchers.* This point is well supported by the large literature on "participatory research." Consider the following two examples of the importance of affected group involvement:

> <u>Asian and Pacific Islanders in King County, Washington.</u>[136] A study of the Asian and Pacific Islander communities (including members of Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Mien, Samoan, and Vietnamese communities) in Seattle and King County, Washington was conducted by the Refugee Federation Service Center (the largest social aid organization for recent immigrants and refugees in King County) and the University of Washington. The study was funded by an Environmental Justice Community/University Partnership Grant through EPA Region 10. The community played a pivotal role in the study, from its initiation through the final report. A Community Steering Committee, comprised of members representing each of the ten affected ethnic groups, conducted the planning, design and development of the survey. They worked together with and received input from a Technical Committee (comprised of statisticians, toxicologists, epidemiologists, and other technical advisors) and an Advisory Committee (comprised of representatives from agencies, industry, and the medical profession). As the study authors note: "During the study period, the researchers had frequent interactions with the community because the researchers viewed the study as 'by the API community,' instead of 'for the API community.' This interaction and cooperation helped the study team in its understanding of community concerns and therefore gained the support of the community, which was vital for the completion of this

[136]Ruth Sechena, et al., *Asian and Pacific Islander Seafood Consumption Study* (1999).

study involving ten ethnic groups with diverse cultural backgrounds."[137] Among other things, the Community Steering Committee was instrumental to several aspects of the study design. It explained that the use of creel, mail, or telephone surveys would be culturally inappropriate, indicating that API community members would be unlikely to participate at all in a survey conducted by these methods; instead, a face-to-face questionnaire method was selected. It identified the seafood species and parts most often consumed by community members, and explained the usual preparation methods – elements crucial to questionnaire design. It also suggested interviewers that would have the requisite cultural knowledge and fluency in both English and the various native languages of the study participants. Thus, for these and other reasons, this study likely produced more accurate data by (1) avoiding the non-response bias that likely plagues other studies attempting to gauge API consumption practices; (2) including quantities consumed where the species or part consumed might have been excluded altogether from other, more generalized studies (e.g., clam stomachs or the hepatopancreas of crabs); (3) identifying consumption and preparation practices that differ from the general population and so bear on risk assessment, risk management and risk communication decisions (e.g., consuming the "butter" as well as the meat of crabs). There are also other important advantages of a community-based study, including community education and empowerment. These issues will be taken up in Chapter Three.

The Suquamish Tribe.[138] A study of Suquamish tribal members (adults and children) living on and near the Port Madison Indian Reservation was conducted upon approval by the Suquamish Tribal Council. The study was conducted by the Suquamish Tribe and funded by the Agency for Toxic Substances and Disease Registry through a grant to the Washington State Department of Health . The stated purpose of the study was to determine seafood consumption rates, patterns, and habits of members of the tribe and, secondarily, to identify "cultural practices and attributes which affect consumption rates, patterns, and habits of members of the Suquamish Tribe."[139] A Project Support Team was established, comprised of two members of the Suquamish Tribal Council, the Director of Human Services, and the Self Governance Director, all of whom are enrolled Suquamish tribal members. The study manager from the Suquamish Tribe Fisheries Department worked together with individuals from the Washington Department of Health. Suquamish Elders were consulted concerning fish and shellfish important to tribal members for commercial, subsistence, and ceremonial purposes.[140] Additionally, transcripts of the Suquamish Tribe Oral History Project of 1982, anthropological and archeological literature were consulted to document cultural practices.[141] Tribal members were integral to the study design, survey administration, and data interpretation. The study was

137 Id.

138 The Suquamish Tribe, *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region* (2000).

139 Id. at 1.

140 Id.

141 Id. at 3.

designed to determine consumption rates by individual type of finfish and shellfish – information of interest to the tribe and unavailable through other relevant fish consumption studies. Consumption data were gathered using a survey questionnaire and face-to-face interviews; these interviews were conducted by tribal members. These interviewers set up and conducted meetings with survey participants "in accordance with cultural norms."[142] The personal knowledge of those conducting the study enabled them to interpret the resulting data in a manner that ensured accuracy. For example, the data revealed some large fish consumption rates, which might be designated as "outliers" according to strictly numerical criteria. Because this designation often carries with it an assumption of error, reported consumption rates for outliers are often adjusted downward. In this case, however, "the study staff were familiar with a number of the individuals with large consumption rates and maintained that the reported rates were likely to reflect real consumption. Thus, no adjustment for potential outliers has been carried out."[143] Thus, for these and other reasons, this study likely produced more relevant, contextualized, and accurate information. Tribally-managed studies are also a manifestation of tribal self-governance and, in the case of the Washington treaty tribes, of their status as co-managers of the fish, shellfish and aquatic resources. Issues unique to tribes will be taken up at greater length in Chapter Four.

Other community-based or tribally-conducted studies have demonstrated similar advantages in terms of relevancy, accuracy, acceptability and appropriateness to the affected group. The community-based study team for the consumption survey of Laotian communities in West Contra County, for example, was able to identify and take advantage of important community festivals as a means of reaching survey participants;[144] to appreciate the existence and relevance of subgroups within the larger Laotian community;[145] and to interpret data in light of cultural, historical, social, economic and other relevant factors.[146] In the case of tribes, members have often lived their entire lives – and their families and ancestors have lived for generations – in the same place, about which they therefore have vast amounts of knowledge. In addition, many tribes today have developed extensive environment and resources management departments.

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[142] Id. at 18-19.

[143] Id. at 23. The study authors note that, in the end, this inclusion had little influence on the reported percentiles, with all but one (the 95th percentile for "all finfish") being unaffected. Id. at 70-71.

[144] Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 6 (1998) (describing outreach conducted at the Laotian New Year's Festival, "one of the most well-attended community events in Richmond").

[145] Id. at 7-10 and 35-36 (discussing representation of the various ethnic groups within the Laotian community, including Mien (Christian), Mien (non-Christian), Lao, Khmu, Thaidum, Lue, Hmong, Lahu, and a Mien group from a different village in Laos than the Mien who are members of the first two groups).

[146] Id. at 36 (discussing likelihood that many respondents who fish in San Francisco Bay indicated that they did not, for fear that the survey was linked to law enforcement about fishing from the Bay, fear of losing disability benefits if they said they went fishing, or concern about "'losing the power to feed their family traditionally cooked meals'" and noting that the survey results therefore likely understated the extent of fishing in the Bay by community members).

Tribes and their members will thus be uniquely positioned to identify ecological changes,[147] suggests subjects for inquiry, and design and implement useful experiments, surveys and studies.

To the extent that research is conducted by and for communities and tribes, it can serve the additional important function of capacity building or, as Moses Squeochs, Fourteen Confederated Tribes and Bands of the Yakama Nation, perhaps more appropriately terms it, "capacity augmentation."[148] This goal is important and an issue of environmental justice in and of itself, for both communities and tribes. And, to the extent that communities and tribes see that their concerns are shaping the research to be conducted, that the information gathered will be relevant from their perspective, and that their members stand to enhance their skills, knowledge and capacity in the process – as opposed to merely providing information that enables others to enhance *their* skills, knowledge and capacity – participation and trust are likely to be increased, and accuracy thereby enhanced.[149]

Indeed, those affected are likely to have a unique and heightened interest in gathering relevant and accurate data. Given that they depend on the resource in question, they have an interest in determining precisely the nature and extent of the contamination, in producing a full and accurate picture of their exposure, and in addressing any resulting problems through risk management and risk communication.[150] It may be the case as well that affected communities and tribes are less likely than other governmental entities to be subject to the competing claims of multiple stakeholders – enabling them, among other things, to devote their full time and attention to the particular problem.

Funding is crucial to the ability of affected communities and tribes to be involved in research. Although community and tribal members have considerable expertise to offer, they

[147]See, e.g., Gerald Nicholia, Tanana, Interior Regional Meeting, Alaska Traditional Knowledge and Native Foods Database, available at www.nativeknowledge.org/db/concerns.asp ("But one thing I see is changes in the animals we live off of. The mining has affected us; mercury levels in our fish. I don't know what is in our moose. Few muskrats in our area. I don't know what happened to the whitefish in our area. It's hard to pinpoint. . . . But I know that there are a lot of changes in the Tanana area.").

[148] Moses Squeochs, *Testimony to National Environmental Justice Advisory Council* Vol III-97 (Annual Meeting Transcript) (Dec. 4, 2001) (observing "[I]n reference to a tribe, [I do not use the term capacity building,] but more so capacity augmentation. The capacity of the people that I'm from has been there for thousands of years. It's been along the Duwamish River for thousands of years. It's been in watersheds scattered across the country for thousands of years.")

[149]See, e.g., id. at 37 (noting that the survey planning team made connections with the Laotian Organizing Project's ongoing capacity building efforts regarding community health and safety, which motivated many community members to participate in the survey and explaining: "The planning team was originally hesitate about the perception commonly held by community members of outsiders taking information from the community without community people seeing the benefits of research. Linking the survey to a community based organization helped counter this perception.").

[150]Consider, e.g., the work of the Shoalwater Tribe to monitor shellfish in the Willapa Bay, described at greater length in Chapter 4. Electronic-mail Interview, Gary Burns, Environmental Programs Director, Shoalwater Bay Indian Tribe (Oct. 3, 2001).

often have minimal or no funding to support their work. *To a person*, community members, tribal members, inter-tribal organization staff, and state and local agency representatives who work with affected groups stressed the importance of adequate funding. Diana Lee, a research scientist with the California Department of Health Services who has worked extensively with communities as part of the Palos Verdes Fish Contamination Outreach and Education Project and other studies in the San Francisco Bay area, is emphatic:

> *I cannot underscore enough the need to provide funding to affected communities so that they can participate fully in every aspect of the research process, from needs assessment to dissemination of the results. Funding, moreover, needs to be provided on an on-going, rather than one-time, basis.*[151]

EPA, in particular, has to date helped fund several studies and projects that have contributed enormously to the advancement of research relevant to affected communities and tribes. The EPA has helped fund such important work as the fish consumption study of and by Asian and Pacific Islanders in King County, Washington; the fish consumption study of and by the four tribes who are members of the Columbia River Inter-Tribal Fish Commission; and the community-specific cumulative risk assessment for the Greenpoint/Williamsburg community in Brooklyn, New York. In addition, the EPA, together with the ATSDR, has recently announced relevant grant initiatives, including two programs: *Lifestyle and Cultural Practices of Tribal Populations and Risks from Toxic Substances in the Environment*[152] and *Superfund Minority Institutions Program: Hazardous Substance Research*.[153] Affected communities and tribes have commended EPA's past efforts to this end, and welcome EPA's new initiatives. However, those affected have noted that the need for funding to enable communities and tribes fully to be involved in research and decisions affecting risk assessment, management, and communication far outstrips the funding that has been so far made available.

2. Research Connecting Exposure to the Sources of Contamination

It is particularly important from the perspective of affected groups that research seeking to describe exposures more accurately be undertaken *as but one component of* research that presents

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[151] Telephone Interview, Diana Lee, Research Scientist, California Department of Health Services (Oct. 26, 2001).

[152] U.S. Environmental Protection Agency, Office of Research and Development, *Lifestyle and Cultural Practices of Tribal Populations and Risks from Toxic Substances in the Environment* available at http://es.epa.gov/ncer/fra/02trib_risk.html (noting, importantly, that "It is expected that Tribal members and representatives will play a leading role in the planning, conduct, analysis, translation and dissemination of the research.").

[153] U.S. Environmental Protection Agency, Office of Research and Development, *Superfund Minority Institutions Program: Hazardous Substance Research* available at http://es/epa.gov/ncer/rfa/02minhazinst.html (listing as eligible program grant recipients "Minority institutions, including Historically Black Colleges and Universities (HBCUs), Hispanic Serving Institutions (HSIs), and Native American Tribal Colleges (TC) in the U.S.").

a fuller picture and seeks to connect affected groups' exposures to the sources of the contamination that gives rise to these exposures. As noted above, given their dependence on aquatic resources, communities of color, low-income communities, tribes, and other indigenous peoples have an acute interest in determining the nature, extent, and sources of such contamination, in producing a complete and accurate picture of their exposure, and in seeing that the contamination is addressed. Thus, while further research regarding various groups' exposure is important, it should not be undertaken at the expense of research that aims to identify the sources of the contamination and to understand that mechanisms by which substances that have been or are being emitted or discharged from these sources make their way to contact with humans (and other non-human components of aquatic ecosystems). Nor should research on exposure be undertaken in isolation of renewed efforts to *reduce* the resulting risks, a point echoed repeatedly by affected groups[154] and emphasized throughout this Report. As the Swinomish Indian Tribal Community stresses:

> *We urge [explicitly that EPA undertake and] support[] efforts to establish undeniable connections between contaminants found in harvested fish and shellfish and the sources of those contaminants. . . . [We believe that pinpointing the source of the pollution and mitigating it at the source will be the only successful strategy in accomplishing risk reduction.*[155]

I. REFINING AND REEVALUATING CURRENT RISK-BASED APPROACHES

Although quantitative risk assessment has increasingly, since the 1970s, been employed by environmental agencies to set health-based environmental standards, its use remains controversial.[156] Commentators have pointed out several serious concerns with quantitative risk assessment as currently practiced.[157] For example, they have taken issue with risk assessment's priorities and assumptions; they have noted that the considerable uncertainty and variability that characterizes health and environmental decisions means that risk assessment is a highly subjective process, requiring value judgments at numerous steps along the way;[158] and they have criticized the ways in which the use of risk assessment perpetuates and exacerbates the disproportionate

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[154]See, e.g., Shawna Larson, Project Coordinator, Indigenous Environmental Network and Alaska Community Action on Toxics, Panelist, "Right to Toxic-Free Traditional Foods in Our Environment," Alaska Forum on the Environment (Feb. 4-8, 2002).

[155]Swinomish Indian Tribal Community, *Comments on the National Environmental Justice Advisory Council's Draft Fish Consumption Report* (Feb. 5, 2002).

[156]See, e.g., Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 Harvard Environmental Law Review 409 (1995).

[157]See, e.g., Catherine A. O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 Stanford Environmental Law Journal 3, 19-37 (2000).

[158]See, e.g., National Research Council, *Science and Judgment in Risk Assessment* (1994); O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 Stanford Environmental Law Journal at 27-30.

burdens visited on communities of color, low-income communities, tribes, and other indigenous peoples.[159]

While quantitative risk assessment is not without attributes to recommend it, the continued presence of the concerns sketched above – and the observation that these concerns are often amplified when those who bear the risk are environmental justice communities – means that it would be inappropriate to embrace unexamined risk assessment as currently practiced. Reevaluation of the method, moreover, is particularly appropriate at this juncture in light of recent work elaborating risk assessment's limitations from the particular perspectives of various communities of color, low-income communities, tribes, and other indigenous peoples; in light of refinements developed by researchers in response to some of the limitations noted above; in light of alternatives envisioned by those whose objections are more fundamental in nature; and, more generally, in light of the lessons afforded by several decades of experience with what is, after all, a method of relatively recent origin in the environmental regulatory context. Reevaluation may also be useful given that the method is costly and time-consuming: "a single risk assessment on a single chemical might take up to five years and cost upwards of $5 million."[160]

This part identifies two categories of efforts that merit involvement by EPA and other health and environmental agencies: (1) efforts to refine current risk assessment methods; and (2) efforts to reevaluate risk assessment and employ alternative approaches, especially approaches that focus on prevention and precaution. This part does not aim to provide a complete account of the various efforts that might be undertaken in each category; rather, it discusses a few important examples and counsels further exploration by EPA and others, together with affected groups.

1. Refining Risk Assessment

As currently practiced, quantitative risk assessment focuses in the main on a finite set of adverse effects to human physical health, narrowly defined. From the perspectives of many of those affected, this understanding of the problem captures only part of what is at stake in decisions affecting the environment. Among other things, it fails to grasp the interrelated physical, psychological, social, and cultural nature of the harms that are visited on some groups when environments are contaminated. These concerns are to some extent outlined above, in Section A. The discussion here is meant to highlight current work suggesting refinements to risk assessment that may go some or all of the way to addressing these concerns, and to suggest that EPA look to these efforts and support similar work. Thus, to the extent that EPA continues to

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[159]See, e.g., Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 University of Illinois Law Review 103; Daniel C. Wigley & Kristin Schrader-Frechette, *Environmental Racism and Biased Methods of Risk Assessment*, 7 Risk: Health, Safety & Environment 55 (1996); O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 Stanford Environmental Law Journal 3.

[160]*Protecting Public Health and the Environment: Implementing the Precautionary Principle,* "Introduction: To Foresee and Forestall" 1, 4 (Carolyn Raffensperger and Joel Tickner, eds. 1999). Note that "[t]his excludes the cost of the harm that may be caused by the activity under study." Id.

employ risk assessment as a tool for making environmental decisions, it should at least consider the following and other refinements.

It is possible to refine current risk assessment practices by expanding the risk assessment framework so that, from the outset, it includes social, cultural, and economic risks as well as physical and ecological risks. Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, and Barbara Harper, International Institute for Indigenous Resource Management, for example, have developed just such a framework for assessing and characterizing risks to tribal health and cultures.[161] This model not only takes a broader view of the components of risk assessment, incorporating all of the elements of an "overall eco-cultural system," including "human health (using appropriate exposure scenarios), ecological health, and socio-cultural/socio-economic health," but it does so in a way that is holistic in that it recognizes the interrelations among these components.[162] It employs the concept of "the natural-cultural resource dependency web based on cultural ecosystemic stories."[163] Among other things, it offers a risk assessment model that is more scientifically defensible in that it more completely and accurately captures the nature and extent of the risks than do conventional models.[164] A related point is that "risk" may be defined quite differently by different affected groups. It may be comprised of different components, or be differently understood. Therefore, it is important that the affected group itself be involved in determining the contours of "risk," i.e. describing what is at stake – as well as involved in the subsequent step of determining what levels of risk are acceptable, in which contexts, and under which circumstances.[165]

It is also possible to refine current risk assessment practices by selectively employing the method. Thus, for example, risk assessment may be inappropriate where the contaminants to be regulated are persistent, bioaccumulative, and/or highly toxic or where the contaminants have particularly troubling effects (including not only human physical health, narrowly defined, but also human health and well-being along multiple dimensions including psychological, social, and cultural health; and including ecological health). The Columbia River Inter-Tribal Fish Commission offers just this perspective:

> *CRITFC maintains that risk assessments have no useful purpose for making regulatory decisions for persistent, bioaccumulative toxics, known carcinogens, "probable human*

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[161]Stuart G. Harris & Barbara L. Harper, *Using Eco-cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures*, 2 Environmental Science & Pollut. Res. 91 (Special Issue, 2000).

[162]Id. at 92.

[163]Id.

[164]Id. Note, too, that the model suggested by Harris and Harper does not inherently contain any more uncertainty than conventional risk assessment models.

[165]Note that the answer may in some cases be that only "zero increased risk" is judged acceptable by those who must bear the risk.

carcinogens," and substances known to cause reproductive, developmental or neurological effects.[166]

Finally, it is possible to refine current risk assessment practices by incorporating, to a far greater extent, the precautionary principle (this principle is discussed below). Some commentators have begun to explore how this might be accomplished.[167]

2. Alternatives to Risk-Based Approaches

Quantitative risk assessment and related analytic approaches reflect one subjective set of priorities and assumptions for environmental policy. When agencies choose these tools, they choose to privilege certain values, at the expense of others. As commentators have recognized, these methods do not – and cannot – provide the neutral, bias-free bases for environmental decisions that some proponents have suggested. As currently practiced, for example, risk assessment assumes that some amount of risk from contamination is "acceptable," and that so long as this amount is not exceeded, there is no reason or relationship that would call upon humans to prevent or limit contamination. It excludes all experience or understanding that is not readily quantified, and accepts only certain kinds of knowledge as valid. It lends a false sense of precision and accuracy to decisions about enormously uncertain and highly variable events, and operates within a regulatory framework that, for the most part, places the burden of resolving uncertainties on risk-bearers rather than risk-producers. Many people of color, low-income people, tribes, and other indigenous people do not share some or all of these assumptions, and so have questioned methods based on these premises. As Moses Squeochs, Fourteen Confederated Tribes and Bands of the Yakama Nation, explains:

> *When I first began this work and I first learned about risk assessment, I took issue with it immediately and I still have issues with it today. That's been over 10 years now, and I have continually taken a position that risk assessment – or conventional risk assessment – is based on an American experience, not an indigenous American experience. So there is a disparity there that needs to be recognized and it needs to be addressed.*[168]

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[166]Columbia River Inter-Tribal Fish Commission, *Comments to Administrator Browner on the Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* 3 (1999).

[167]See, e.g., Nicholas A. Ashford, *Protecting Public Health and the Environment: Implementing the Precautionary Principle* "A Conceptual Framework for the Use of the Precautionary Principle in Law"198 (Carolyn Raffensperger and Joel Tickner, eds. 1999); see also, Stuart G. Harris & Barbara L. Harper, *Using Eco-cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures*, 2 Environmental Science & Pollut. Res. 91, 92 (Special Issue, 2000) (noting that "[t]he Precautionary Principle is not the antithesis of risk-based decisionmaking, but complements it by allowing decisions to be made in the face of uncertainty that is inherent in all predictive and variable situations.")

[168]Moses Squeochs, Fourteen Confederated Tribes and Bands of the Yakama Nation, *Testimony to National Environmental Justice Advisory Council* Vol III-101 (Annual Meeting Transcript) (Dec. 4, 2001).

Affected groups and others have also worked to envision alternative approaches. Important among these is an approach guided by the *precautionary principle*. As Tom Goldtooth, Executive Director, Indigenous Environmental Network, observes:

> *[W]e are engaged in a clash of two competing paradigms. One is an aging model based upon quantitative risk assessment, assimilative capacities, and acceptable discharges for individual compounds, which has dominated chemical and environmental policy . . . The other is an emerging paradigm based upon prevention, precaution, and clean production processes; and this is what we've been calling precautionary action, or [the] precautionary principle.*[169]

In broad terms, the precautionary principle focuses on *preventing* environmental contamination in the first place. It views prevention as preferable to other approaches as a matter of efficiency, justice, and ethics. That is, prevention avoids the enormous monetary costs of having to cleanup contamination after it has been permitted (and, given the propensity of many pollutants to migrate, mingle and otherwise pose more severe – and more costly – problems once they are released into the environment, prevention will very often be cheaper than "cure" in this context)[170] and of having to care for the sick whose illnesses have resulted from exposure to contaminants. Prevention addresses the problem of irreversible and very long term effects, e.g., once someone has cancer, this cannot be reversed, only treated; once a species is extinct, it is gone forever; once the fishery on which the St. Regis Mohawk tribe relies is devastated, generations will come and go without being able to fish. These concerns simply cannot be addressed by after-the-fact cleanup or health care. Prevention also helps to alleviate the extraordinary burden from contamination that is currently borne by communities of color, low-income communities, tribes and other indigenous peoples. Finally, prevention does not discriminate against those whose spiritual or cultural traditions include an ethic of reciprocity.

Beyond this broad focus on prevention, what would be entailed by the precautionary principle has been more specifically elaborated. Although the precautionary principle has been defined somewhat differently in the various instruments and statements invoking it, at the heart of these definitions are several core concepts:

> a. A judgment that something of great value is at stake (usually accompanied by a recognition that what is of value includes not only human but non-human components of ecosystems, and includes not only the well-being of present generations but of future generations);
> b. An acknowledgment that the threat to what is of value is potentially serious and/or irreversible; and

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[169]Tom Goldtooth, Executive Director, Indigenous Environmental Network, *Comments to the National Environmental Justice Advisory Council*, "Public Comment" Vol III-28 (Annual Meeting Transcript) (Dec. 4, 2001).

[170]*Protecting Public Health and the Environment: Implementing the Precautionary Principle,* "Introduction: To Foresee and Forestall" 1, 4 (Carolyn Raffensperger and Joel Tickner, eds. 1999).

c. A recognition, therefore, that action to prevent or reduce this threat is appropriate, and that uncertainty as to the existence or magnitude of the threat should not constitute a sufficient reason for refraining from action.

These concepts, in turn, have been taken to suggest further precepts, such as a shift in the burden of proof – such that those who propose to introduce or continue to produce toxic substances are required to demonstrate the non-existence of a threat; a preference for less toxic alternatives – such that laws and policies that facilitate the search for less toxic substitutes are called for; and a "proportionality of response" – such that the appropriateness of actions taken to prevent or reduce the threat from contamination depends in part upon the seriousness or irreversibility of the threat relative to the costs of the action. Although these precepts, in particular, may not be present in every conception of the precautionary principle, the outline above gives some sense of the perspectives that underlie the principle.

The precautionary principle is a component of numerous international agreements, including several to which the United States is party.[171] Perhaps most prominent among these is Section 15 of the Rio Declaration of the United Nations Conference on Environment and Development, signed in 1992 by the United States and a host of other nation-states.[172] Not only is the precautionary approach a part of United States law as a result of its international commitments, but this approach is included in domestic law, in environmental statutes and elsewhere. Thus, for example, commentators have noted that the precautionary approach is embodied in aspects of the National Environmental Protection Act (NEPA), the Clean Water Act (CWA), the Toxic Substances Control Act (ToSCA), and the Pollution Prevention Act (PPA), among other federal, state, and tribal statutes.[173] And the U.S. President's Council on Sustainable Development, a multi-stakeholder presidential board, recently issued a statement invoking the precautionary approach.[174]

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[171] For a list of these treaties and agreements, see Appendix B, in *Protecting Public Health and the Environment: Implementing the Precautionary Principle* 356 (Carolyn Raffensperger and Joel Tickner, eds. 1999).

[172] Section 15 provides: "In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Rio Declaration on Environmental and Development, June 14, 1992, 31 International Legal Materials 874.

[173] See, e.g., *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, "Introduction: To Foresee and Forestall" 1, 4-7 (Carolyn Raffensperger and Joel Tickner, eds. 1999).

[174] Principle number 12 provides: "We believe: even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable." President's Council on Sustainable Development, *Sustainable America: A New Consensus* (1996) (cited in *Protecting Public Health and the Environment: Implementing the Precautionary Principle,* "Appendix B" 356 (Carolyn Raffensperger and Joel Tickner, eds. 1999)).

Much work remains to be done to explore and specify the contours of the precautionary principle in various contexts; to identify and make use of opportunities for precautionary approaches within the existing legal structure in the United States; and to consider and advocate appropriate changes to existing laws. There is, nonetheless, a significant and growing body of recent work on which to build. For example, recent work by Carl F. Cranor contributes to efforts along each of these fronts.[175] First, he has sought to clarify and specify several aspects of the principle. He has suggested the clarification, among others, that whereas the lack of scientific certainty may not constitute a *sufficient* reason for refraining from action, it may nonetheless count *among* the reasons for choosing among actions or for refraining from action. Second, he has identified opportunities within existing environmental laws for EPA and other agencies to revisit interpretations that discourage precaution in favor of interpretations that incorporate precaution. He has pointed out that agencies may have latitude under statutes such as TOSCA to require manufacturers to make a greater pre-market showing of safety than is currently required before introducing substances (a) that are chemically similar to those known to be highly toxic or (b) that have certain characteristics, such as a tendency to persist, to bioaccumulate, or to be mutagenic. He has also argued that agencies may have the ability under various statutes to reinterpret the burdens and standards of proof that operate to permit such persistent, bioaccumulative, highly toxic substances to continue to be manufactured or produced as byproducts. Third, he has noted instances in which changes to existing laws might be warranted in order to implement the precautionary principle, and suggested models (e.g., particular aspects of the Swedish approach) for such changes. Other commentators, too, have contributed to the efforts to elaborate the precautionary principle. And an array of local efforts – ranging from community-led efforts to eliminate consumers' contributions to contamination to small businesses' undertakings to reduce their use of toxic inputs and as a result lower their costs – have devised creative ways to implement precaution in practice. EPA should draw on this body of work and support efforts further to develop it.

[175]Carl F. Cranor, *Protecting Public Health and the Environment: Implementing the Precautionary Principle, "*Asymmetric Information, the Precautionary Principle, and Burdens of Proof" 74 (Carolyn Raffensperger and Joel Tickner, eds. 1999).

CHAPTER II: USING EXISTING LEGAL AUTHORITIES

How might EPA's authority under federal environmental and other laws be implemented more effectively to sustain healthy aquatic ecosystem*s* and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?

RISK REDUCTION STRATEGIES AND PROBLEM POLLUTANTS

This chapter focuses on *risk reduction* strategies – that is, strategies by which agencies look to risk-producers to cleanup, limit, and prevent environmental contamination. In the case of contamination in aquatic ecosystems, these strategies have been developed under a variety of legal authorities, the Clean Water Act prominent among them. In addition to the authority provided by the Clean Water Act, this chapter considers how the authority of other relevant sources of law might be invoked more effectively to sustain healthy ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife. This chapter begins by providing background on the contaminants of greatest concern to affected communities of color, low-income communities, tribes, and other indigenous peoples. Part A considers how EPA might better prevent and reduce contamination in the first place, focusing primarily on efforts under the Clean Water Act and secondarily on efforts under other legal authorities. Part B discusses how EPA might better cleanup and restore those aquatic ecosystems that are already contaminated, again focusing primarily on efforts under the Clean Water Act and secondarily on efforts under other legal authorities.

Access to water of sufficient quality and quantity is vital to tribal, state, and local governments, as well as to environmentalists, developers, industry, and the public including minority and low-income communities. Unquestionably, degradation of water quality threatens not only the viability of aquatic ecosystems, but also human health; subsistence, traditional, cultural, and spiritual practices; economies; sustainability of tribal homelands as contemplated by federal Indian treaties and other laws;[176] and ultimately all life itself. As Rachel Carson noted in her landmark book *Silent Spring:*

> *Water must also be thought of in terms of the chains of life it supports--from the small-as-dust green cells of the drifting plant plankton, though the minute water fleas to the fishes that strain plankton from the water and are in turn eaten by other fishes or by birds, mink, racoons--in an endless cyclic transfer of materials from life to life. We know that the necessary minerals in the water are so passed from link to link of the food chains. Can we suppose that poisons we introduce into water will not also enter into these cycles of nature?*[177]

Quite simply, poisoning the aquatic food chain ultimately poisons the Earth's entire food web.

The pollutants enumerated below are believed to result in harm to aquatic ecosystems and to pose the greatest risks to the health of people consuming or using fish, aquatic plants and wildlife for traditional, cultural and religious purposes. These pollutants have been identified by federal, tribal, state, and territorial governments as well as by affected groups and independent researchers. While numerous contaminants are potentially a basis for concern,[178] available data indicate that the following contaminants are currently the source of greatest concern.

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[176]Often, pursuant to explicit treaties, tribes bargained with the with federal government for the terms of vast land cessions and the retention of certain other lands for Indian use and occupation. Through express treaty terms or by virtue of retained aboriginal title, tribes reserved every incident of ownership not expressly relinquished to the federal government or abrogated by Congress. United States v. Winans, 198 U.S. 371, 381 (1905). These reserved rights include a recognized right to water sufficient to fulfill the purposes of the reservation. Winters v. United States, 207 U.S. 564, 577 (1908). Among other things, reserved rights have been understood to include water to maintain a permanent homeland, to preserve, produce, or sustain food and other reservation resources, and to maintain the tribe's way of life. See, e.g. Winters v. United States, 143 F. 740, 742 (1906); Colville Confederated Tribes v. Walton, 647 F.2d 42, 49 (1981 9th Cir.), *cert. denied*, 454 U.S. 1092 (1981); Felix S. Cohen, *Handbook of Federal Indian Law* 588-89 (1982 ed.). Frequently, treaties expressly retained a tribe's right to hunt, fish, and gather both on a reservation and off-reservation in all usual and accustomed places. United States v. Winans, 198 U.S. 371, 381 (1905); United States v. Adair, 723 F.2d 1394, 1410, 1417-18 (9th Cir. 1983), *cert. denied*, Oregon v. United States, 467 U.S. 1252 (1984).

[177]Rachel Carson, *Silent Spring* at 46 *(1962).*

[178]There are more than 70,000 chemicals currently in use; yet for the vast majority of these, comprehensive data about human and environmental health effects is sorely lacking. Of these chemicals, those that are highly toxic, that persist in the environment for relatively long periods, and that bioaccumulate are likely to be of particular concern here. The Washington State Department of Ecology, for example, has identified 64 highly toxic, persistent and bioaccumulative contaminants to be screened and prioritized (of these, nine have been slated for immediate action) as part of its initiative to address persistent, bioaccumlative toxins. See Washington State Department of Ecology, *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* (No. 00-03-054) (Dec. 2000) available at http://www.ecy.wa.gov/pubs/0003054.pdf.

Five contaminants – mercury, PCBs, dioxins, DDT, and chlordane – are responsible for the majority of fish and wildlife consumption advisories issued by federal, tribal, state, or territorial governments.[179] These five contaminants are often also among the contaminants of greatest concern according to those affected. For example, David Ludder, of the Legal Environmental Assistance Foundation in Tallahassee reports that affected communities in Florida, Alabama, and Georgia are concerned in the main with these five contaminants and toxaphene.[180] Similarly, the Asian Pacific Environmental Network cites evidence of the presence of these five chemicals and dieldrin at levels of concern for those consuming fish from San Francisco Bay, particularly members of the Laotian community in West Contra Costa County.[181] In addition to these five contaminants, there are approximately 40 different chemicals or chemical groups that give rise to at least one fish and wildlife consumption advisory.[182]

While the existence of a consumption advisory provides one useful gauge as to which contaminants are the basis for concern, there are limitations to this measure. Importantly, the absence of a consumption advisory does not necessarily mean the absence of contamination. In some cases, the necessary assessments of fish and wildlife tissues have not yet been undertaken, often for lack of resources.[183] In other cases, states or tribes might decline to issue fish consumption advisories for a variety of reasons, including economic, health and cultural

[179]According to the EPA Office of Water, most advisories are triggered by one or more of five primary contaminants: mercury, PCBs, dioxins, DDT, and chlordane. See U.S. Environmental Protection Agency, Office of Water, *Update: National Listing of Fish and Wildlife Advisories* 5 (April 2001) available at www.epa.gov/ost/fish.

[180]Telephone Interview with David Ludder, Legal Environmental Assistance Foundation, Tallahassee, Florida (Aug. 22, 2001). Ludder noted, however, that this concern was premised primarily on the existence of fish consumption advisories and so indicated that this was a preliminary list.

[181]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community of West Contra Costa County, California* App. 1 (1998) (citing San Francisco Bay Regional Water Quality Control Board, Office of Health Hazard Assessment, *Chemical Contamination in Fish from San Francisco Bay: Study Results* (1995)).

[182] These include Arsenic, Cadmium, Chlorinated Benzene, Chlorinated Pesticides, Chromium, Copper, Creosote, Dichloroethane, Gasoline, Hexachlorobutadiene, Industrial & Municipal Discharge, Kepone, Lead, Lindane, Metals, Organo-metallics, PAHs, PBBs, Pentachlorobenzene, Pentachloroethylene, Photomirex, Phthalate Esters, Selenium, Tetrachlorobenzene, Tetrachloroethane, Tetrachloroethylene, Tributyltin, Trichloroethane, Trichloromethane, Vinyl Chloride, VOCs, Zinc.

[183]The trend to date has been for advisories to increase as assessments are completed. Thus, EPA notes that the number of advisories in 2000 represents a 7% increase over the number reported in 1999 and a 124% increase over the number reported in 1993 and observes that "[t]he increase in advisories issued by the states [territories and tribes] generally reflects an increase in the number of assessments of chemical contaminants in fish and wildlife tissues." U.S. Environmental Protection Agency, Office of Water, *Update: National Listing of Fish and Wildlife Advisories* 2 (April 2001) available at www.epa.gov/ost/fish. The need for additional funding to address a shortfall in resources for tissue and environmental assessments is particularly acute for many tribes.

reasons.[184] The Fond du Lac Environmental Program, for example, is in the process of issuing "tribal consumption guidelines."[185] Contrary to "advisories," these guidelines do not warn *against* consumption of fish or wildlife; rather, they provide guidelines for healthy consumption, consistent with tribal traditions and practices.[186] In addition, fish and wildlife advisories generally arise from one exposure scenario (consuming contaminated fish or wildlife), and so do not account for other routes or sources of exposure to those consuming or using fish, aquatic plants and wildlife for traditional, cultural and religious purposes. (e.g., consuming contaminated aquatic plants; consuming or otherwise being exposed to contaminated waters, etc.). And, fish and wildlife advisories focus on the problem of the contamination of fish and wildlife, and leave unaddressed the problem of the availability of fish, aquatic plants, and wildlife for consumption and use.

Thus, in addition to the five contaminants that have given rise to the bulk of fish and wildlife consumption advisories, there are other contaminants of concern. Chief among these are contaminants that are highly toxic, bioaccumulative, and persistent. The Convention on Persistent Organic Pollutants (POPs) initially targets twelve POPs of concern: in addition to PCBs, dioxins, DDT and chlordane, the Convention identifies aldrin, dieldrin, endrin, helptachlor, hexachlorobenzene, mirex, toxaphene, and furans as being of primary concern.[187] The EPA has also identified these same twelve contaminants as part of its Persistent Bioaccumulative Toxin

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[184]See, generally, Stuart Harris, *Impacts of Fish Contamination on Native American Culture* (talk delivered to the Annual National Forum on Contaminants in Fish, May 9, 2001) Neither Wyoming nor Alaska have issued fish or wildlife consumption advisories. Briefing by Rich Healy, U.S. Environmental Protection Agency, Office of Water to Fish Consumption Workgroup (Jun. 26, 2001). But see the recently issued *Statement from the Alaska Division of Public Health*, expressly denouncing the applicability of the general mercury advisories in Alaska and recommending "unrestricted consumption of fish from Alaskan waters" for all, given their independent review of mercury levels in Alaska fish, the known health benefits of fish consumption, and the fact that "the subsistence lifestyle and diet are of great importance to the self-determination, cultural, spiritual, social, and overall health and well being of Alaska Natives." *Mercury and National Fish Advisories Statement* from Alaska Division of Public Health: Recommendations for Fish Consumption in Alaska (Bulletin no. 6) (Jun. 15, 2001) (endorsed by the Alaska Department of Environmental Conservation, Alaska Department of Health and Social Services, Alaska Native Health Board; Alaska Native Science Commission; Alaska Native Tribal Health Consortium; Aleutian/Pribilof Islands Association, Inc.; Institute for Circumpolar Health Studies; University of Alaska Anchorage; North Slope Borough; University of Alaska Fairbanks; and Yukpm Kuskokwim Health Corporation) available at www.epi.hss.state.ak.us/bulletins/docs/b2001_06.htm

[185]Telephone Interview with Nancy Costa, Fond du Lac Environmental Program (Jul. 31, 2001).

[186]Id. Costa explains that the Fond du Lac Environmental Program is careful *not* to use the word "advisory," because "the last thing we want to do is discourage tribal and band members from eating their native diet, given the serious health effects that we've seen of getting away from a native diet." Id.; see also, Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Fish Safely* (Fall 2000).

[187]Convention on Persistent Organic Pollutants (POPs). The United States is a signatory to this Convention, although it awaits the advice and consent of the Senate available at http://www.unece.org/env/lrtap/protocol/98pop.htm.

(PBT) Initiative. Each of these POPs or PBTs is also the source of at least one fish or wildlife consumption advisory.[188]

A variety of pesticides[189] have emerged as particular sources of concern for various affected communities, groups and tribes. The Shoalwater Bay Indian Reservation is concerned with the health of tribal members and the flourishing of the shellfish resource in Willapa Bay, on which members of the tribe depend for commercial, subsistence, and ceremonial uses. Although tribal studies are only recently underway (such that there is no evidence at this time that these pesticides are in fact harming shellfisheries), potential sources of contamination include pesticides such as diazinon, lorsban, and guthion, all of which are used by nearby commercial cranberry bog farmers; carbaryl and glyphosate, applied to the oyster beds and tideflats; and various organochlorine herbicides, sprayed in surrounding and upland areas by the U.S. Forest Service as it seeks to kill "nuisance" species, typically after clear-cut logging.[190] The Louisiana Environmental Action Network is concerned with the high levels of pesticides (among other contaminants), particularly atrazine and cyanazine, that a recent study revealed to be present in the Mississippi River between New Orleans and Baton Rouge: "As would be expected, the pesticides appeared in early spring and persisted throughout the summer, coinciding with the southern and midwestern growing seasons."[191] The study focused on the Mississippi River as a source of drinking water, noting that "[p]esticides presented the largest health hazard, where maximum levels were found to be 60 to 360 times the EPA's Maximum Contamination Level (MCL) for drinking water."[192] Various community and fishing groups have identified 48 pesticides commonly used in the Pacific Northwest that have been determined by either EPA or the United States Geological Survey (USGS) to threaten salmon and salmon habitat.[193]

Lead is a source of concern for those consuming fish from the Spokane River from the Idaho state line to the Seven Mile Bridge in Washington, given recent studies revealing elevated

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[188]See U.S. Environmental Protection Agency, Office of Water, *National Fish and Wildlife Contamination Program.* available at www.epa.gov/ost/fish.

[189]The term "pesticides", as used throughout this report, is meant to encompass all pesticides, including rodenticides, insecticides, herbicides, and fungicides, unless the context indicates a different usage.

[190]E-mail Correspondence with Gary Burns, Environmental Programs Director, Shoalwater Bay Indian Tribe (Oct. 3, 2001); E-mail Correspondence with Chetana Acharya, Community Outreach and Education Program Manager, NIEHS Center for Ecogenetics and Environmental Health, University of Washington (Oct. 2, 2001); Paul Shukovsky, *Tribe Sounds Alarm Over Fetal Deaths: 13 Pregnancies in 2 years; 1 Baby Survives*, Seattle Post-Intelligencer (Feb. 22, 1999).

[191]Louisiana Environmental Action Network, *Final Report on the Riverkeeper Project* (1998) available at www.leanweb.org/rivkeep.html.

[192]Id.

[193]"Groups Uncover Government Documents Showing Pesticides Can Harm Salmon," (May 7, 2001) available at www.pesticide.org/MSJnewsrelease.html (joint press release by Washington Toxics Coalition; Northwest Coalition for Alternatives to Pesticides; Pacific Coast Federation of Fishermen's Associations; Institute for Fisheries Resources; and Earthjustice Legal Defense Fund in course of litigation against EPA for Endangered Species Act violations).

lead levels (along with elevated levels of other metals), particularly for children (given that lead causes adverse developmental effects) and for those, such as Russian immigrants, who consume the whole fish (given that lead concentrates in the bones and brains of fish).[194] Lead is also a source of concern for the Coeur d'Alene Tribe, given its presence (along with cadmium) in and on water potatoes, a staple of the Coeur d'Alene diet.[195]

Fecal coliform, marine biotoxins (e.g., saxitoxin and domoic acid released by algal blooms), and various other bacterial and viral contaminants are sources of concern for those communities, groups and tribes that rely on shellfish for commercial, subsistence, and/or ceremonial purposes. Thus, these contaminants are a source of concern for tribal resource managers in the Puget Sound and coastal regions of Washington,[196] among them the Shoalwater Tribe,[197] the Suquamish Tribe,[198] the Lower Elwha Klallam Tribe,[199] and the Tulalip Tribes.[200] These contaminants are a source of concern for various communities of color and low-income communities in Southern California.[201] And they are a source of concern for Alaskan Natives. For example, at a southeast regional meeting called to discuss Alaskan Natives' concerns with contaminants in native foods, Dangel Helen, Douglas, observes:

> *There is in North Douglas a development not served by a sewer line. A lot of the mud flats are contaminated. The shellfish aren't good to eat.*[202]

Finally, these and several additional pollutants are of particular concern to one or more affected groups or tribes. For example, the Fond du Lac Environmental Program is concerned with contamination from metals, given the negative effects of several metals (aluminum, cadmium, copper, lead, and zinc, in addition to mercury) on the growth of wild rice.[203] The Tulalip Tribes

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[194] Karen Dorn Steele, *Agencies Warn of Lead in River's Fish; Advisory Targets Consumption of Contaminated Fish Caught in Stretch of Spokane River* A1 The Spokesman Review (Jun. 21, 2000).

[195] Telephone Interview with Marc Stifelman, Environmental Protection Agency (Region X)(Oct. 30, 2001).

[196] See, generally, Northwest Indian Fisheries Commission, *Tribal Shellfish Management* available at www.nwifc.wa.gov/ctnrm/2001_shellfish.htm.

[197] E-mail Correspondence with Gary Burns, Environmental Programs Director, Shoalwater Bay Indian Tribe (Oct. 3, 2001); E-mail Correspondence with Chetana Acharya, Community Outreach and Education Program Manager, NIEHS Center for Ecogenetics and Environmental Health, University of Washington (Oct. 2, 2001).

[198] Telephone Interview with Jay Zischke, Marine Fish Program Manager, Suquamish Tribe Fisheries Department (Oct. 17, 2001).

[199] Telephone Interview with Russ Busch, Attorney, Legal Counsel for the Lower Elwha Klallam Tribe. (Oct. 4, 2001).

[200] Terry Williams, Commissioner, Tulalip Tribes, Fisheries and Natural Resources (C3G Conference Call, Jul. 20, 2001).

[201] Telephone Interview with Marianne Yamaguchi, Santa Monica Bay Restoration Project.

[202] Alaska Traditional Knowledge and Native Foods Database, *Native Concerns*. Available at www.nativeknowledge.org/db/concerns/asp.

[203] Telephone Interview with Larry Schwarzkopf, Fond du Lac Resources Program (Jul. 12, 2001).

are concerned with sediment and silt loadings, given their contribution to degradation of salmon habitat and, ultimately, to the depletion of the salmon fishery.[204] The various communities that fish the Devil's Swamp, Devil's Swamp Lake, Bayou Baton Rouge, and Capitol Lake in East Baton Rouge Parish face contamination from lead and arsenic, in addition to hexachlorobenzene, hexachloro-1,3-butadiene, PCBs and mercury.[205] The Fourteen Confederated Tribes of the Yakama Indian Nation and the Confederated Tribes of the Umatilla Indian Reservation are concerned with a host of contaminants in the Columbia River, which is "heavily laden with heavy metals from mining, agricultural chemicals from intensive orchards and vineyards, radionuclides from Hanford, runoff from dairy farms, and PCBs from a variety of sources."[206] As Chief Johnny Jackson elaborates:

> *I'm from the Columbia River. I've lived there all my life. I was born and raised there. I'm a fisherman. My family have all been fishermen . . . Many of my people today are dying of cancer as well as diabetes . . . and we talk about cleaning up the area and cleaning up the water and the air, but nobody talks about what is happening up at Hanford and what's happening to the soil and the water at Hanford, and what it's doing to our river. . . We're fishing people. Fishing is our life and fish is our food, but we don't know what they're swimming through when they are going back up that river. I think it's a great injustice until somebody does something about it and cleans that river up and stops pollution at Hanford.*[207]

In addition, there is concern that the health of aquatic ecosystems is being compromised by temperature changes; changes in pH and dissolved oxygen content; introduction of exotic species; dams, diversions, and other alterations; and numerous other affronts.

The discussion below elaborates the health effects and sources of mercury, PCBs, dioxins, DDT, chlordane, and, to a lesser extent, the remaining POPs/PBTs, and other contaminants of concern.

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[204] Terry Williams, Commissioner, Tulalip Tribes, Fisheries and Natural Resources (C3G Conference Call, Jul. 20, 2001).

[205] See Louisiana Department of Health and Hospitals, under cooperative agreement with The Agency for Toxic Substance and Disease Registry, *Public Health Assessment: Petro-Processors of Louisiana Incorporate Baton Rouge, East Baton Rouge Parish, Louisiana* (Jan. 16, 1996). Available at atsdr1.atsdr.cdc.gov/HAC/PHA/petro/pet_toc.htm.

[206] Barbara Harper and Stuart Harris, *Proceedings of the American Fisheries Society: Forum on Contaminants in Fish*, "Tribal Technical Issues in Risk Reduction Through Fish Advisories" 17 (1999).

[207] Chief Johnny Jackson, *Comment to the National Environmental Justice Advisory Council* Vol III-4-6 (Annual meeting transcript) (Dec. 4, 2001).

Mercury

Background

Mercury is responsible, at least in part, for nearly 79% of all fish and shellfish advisories issued in the United States; as of December, 2000, it was the basis for 2,242 advisories issued by 41 states, territories or tribes.[208] Thirteen states have issued statewide advisories for mercury in the freshwater lakes and/or rivers within their boundaries; another nine states have issued statewide mercury advisories for their coastal marine waters.[209] Mercury is also responsible for the first ever issuance of a national fish consumption advisory: in January, 2001, the EPA (together with ATSDR) and the FDA each independently issued advisories cautioning various populations against consuming fish due to mercury contamination.[210]

Mercury has been identified as a major pollutant of concern by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) and the Fond du Lac Environmental Program, given its deleterious effects on both fish and wild rice.[211] Mercury has been identified as a pollutant of concern by the St. Regis Mohawk Tribe Environment Division (although of less significance than PCBs).[212] Hawaii's Thousand Friends observes that mercury has been identified as the major contaminant in fish eaten in Hawai'i.[213] Mercury has been identified as a major concern by the Grand Cal Task Force, given its significant contribution to the contamination of the Grand Calumet River and the Indian Harbor Ship Canal, where "virtually all fish tested in Indiana show levels of mercury and all streams are considered impaired."[214] Mercury has been identified as a source of significant concern in Louisiana, particularly in the heavily contaminated parishes along the Mississippi River between New Orleans and Baton Rouge by the Louisiana Environmental

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[208]See U.S. Environmental Protection Agency, Office of Water, *Mercury Update: Impact on Fish Advisories* 4 (June 2001) available at www.epa.gov/ost/fish/chemfacts.html. [hereinafter "EPA. Mercury Fact Sheet"]

[209]Id.

[210]U.S. Environmental Protection Agency advisories are available at www.epa.gov/ost/fish. U.S. Food and Drug Administration advisories are available at www.cfsan.fda.gov/~dms/admehg.html. Briefing by Rich Healy, U.S. Environmental Protection Agency, Office of Water to Fish Consumption Workgroup (Jun. 26, 2001).

[211]Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Fish Safely* (Fall 2000) available at www.glifwc.org. Telephone Interview with Larry Schwarzkopf, Fond du Lac Resources Program (Jul. 12, 2001).

[212]Telephone Interview with Shawn Martin, Clean Water Manager, St. Regis Mohawk Tribe Environment Division (Jul. 12, 2001).

[213]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[214]Telephone Interview with Bowden Quinn, Executive Director, Grand Cal Task Force (Oct. 10, 2001); Grand Calumet Task Force, *Mercury and the Grand Calumet River* available at www.igc.apc.org/gctf/newsletter002.htm..

Action Network and by Dr. Barry Kohl, Department of Geology, Tulane University.[215] Mercury is a source of concern for the Passamaquoddy tribe, who rely on both saltwater and freshwater fish, given that all lakes in the state of Maine are under a state-issued fish advisory for mercury.[216] At an interior regional meeting called to discuss Alaskan Natives' concerns with contaminants in native foods, Orville Huntington, Huslia, observes:

> *Around home, I think it's an accumulation. All those poisons dumped in the river are in the fish and they accumulate in your body. . . . The pike around Hog River I won't eat anymore because there's too much mercury in there.*[217]

Health Effects[218]

Methylmercury is rapidly and nearly completely absorbed by humans from the gastrointestinal tract. It readily crosses the placental and blood/brain barriers. The National Research Council (NRC) of the National Academy of Sciences observes: "[Methylmercury (MeHg)] is highly toxic. Exposure to MeHg can result in adverse effects in several organ systems throughout the life span of humans and animals. There are extensive data on the effects of MeHg on the development of the brain (neurodevelopmental effects) in humans and animals. . . . Effects [at high doses] included mental retardation, cerebral palsy, deafness, blindness, and dysarthria in individuals exposed in utero and sensory and motor impairment in exposed adults. Chronic, low-dose prenatal MeHg exposure from maternal consumption of fish has been associated with more subtle end points of neurotoxicity in children. Those end points include poor performance on neurobehavioral tests, particularly on tests of attention, fine-motor function, language, visual-spatial abilities (e.g., drawing), and verbal memory."[219] There is also evidence of adverse effects on developing and adult cardiovascular systems in both humans and animals.[220] Some studies have demonstrated an association between methylmercury and cancer, but, according to the NRC, these studies are inconclusive.[221] EPA concurs and does not regulate methylmercury as a carcinogen.

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[215]Telephone Interview with Marylee Orr, Louisiana Environmental Action Network (Oct. 17, 2001); Telephone Interview with Dr. Barry Kohl, Department of Geology, Tulane University (Oct. 17, 2001).

[216]See Paul Kuehnert, *Health Status and Needs Assessment of Native Americans in Maine: Final Report* (Jan. 15, 2000) available at www.state.me.us/dhs/boh/files/nar/nar.htm.. U.S. Environmental Protection Agency fish advisories available at www.epa.gov/ost/fish.

[217]Alaska Traditional Knowledge and Native Foods Database, *Native Concerns* available at www.nativeknowledge.org/db/concerns.asp.

[218]Unless otherwise noted, health effects information is taken from the EPA Mercury Fact Sheet.

[219]National Research Council, National Academy of Sciences, *Toxicological Effects of Methymercury* 4 (2000).

[220]Id.

[221]Id.

Sources of Mercury in the Environment[222]

Overview: Nearly 80% of the mercury contamination in surface waters comes from mercury emissions to the air. Mercury contamination also comes from direct discharges to the water, from releases to soils, and from naturally occurring mercury in the environment.

Mercury exists in the environment as elemental mercury (metallic mercury), and in inorganic and organic mercury compounds (primarily methylmercury).

Air: Mercury is released to the air by solid waste incineration and fossil fuel combustion, especially coal-fired power plants (in combination, these sources account for approximately 87% of mercury emissions in the United States); mining and smelting operations; industrial operations involving the use of mercury such as chlor-alkali production facilities; cement production; medical waste incineration (accounts for approximately 10% of mercury emissions in the United States),[223] and non-industrial combustion (e.g., wildfires and open burning).

Water/Sediments: Mercury is released to surface waters from naturally occurring mercury in rocks and from industrial processes, including pulp and paper mills, leather tanning, electroplating, and chemical manufacturing, and from some wastewater treatment facilities. Mercury emissions to the air are an important indirect source of mercury in surface waters: mercury is deposited from rain and other processes to water surfaces and to soils. Sediments contaminated with mercury also contribute mercury to surface waters upon being disturbed (e.g., by flooding or dredging).

Soils: Mercury is released to soils through the direct application of fertilizers, fungicides, and sludge or "recycled" industrial waste containing mercury to soils and crops. Mercury is also released to soils when solid waste, including batteries and thermometers, and municipal incinerator ash is disposed in landfills.

Notes

Unlike many other contaminants that are the source of fish consumption advisories, mercury does not accumulate primarily in the fatty tissue of fish but in the muscle (i.e., the portion of fish that comprises a fillet). Thus, skinning and trimming the fish do not reduce the amount of mercury in a fillet, nor is mercury removed by cooking processes.[224]

[222]Unless otherwise noted, sources information is taken from the EPA Mercury Fact Sheet.

[223]U.S. Environmental Protection Agency, *Mercury Study Report to Congress*, "Vol. 1: Executive Summary" (No. EPA-452/R-97-003) (December 1997) available at www.epa.gov/oar/mercury.html.

[224]U.S. Environmental Protection Agency Mercury Fact Sheet; Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Fish Safely* (Fall 2000) available at www.glifwc.org.

PCBs[225]

Background

PCBs are responsible, at least in part, for nearly 27% of all fish and shellfish advisories issued in the United States; as of December, 1998, PCBs were the basis for 679 advisories issued by 37 states, territories or tribes.[226] Three states have issued statewide advisories for PCBs in the freshwater lakes and/or rivers within their boundaries; another six states have issued statewide PCBs advisories for their coastal marine waters.[227]

PCBs have been identified as a major pollutant of concern by the St. Regis Mohawk Tribe Environment Division.[228] PCBs have been cited by the Village of Savoonga and other Alaska Native villages as "[posing] special problems for Alaska Tribes who live near PCB contaminated former U.S. military sites."[229] PCBs have been identified by the Arbor Hill Environmental Justice Corporation as impacting the health of inner city communities, many of whose members subsistence fish along the Hudson River in upstate New York.[230] PCBs have been cited as a source of significant "community concern" given the number of anglers fishing along the contaminated Lower Fox River in the Green Bay area of Wisconsin (including Caucasians, Hmong, Laotian, Native American, and African-American anglers).[231] PCBs have been identified as among the issues of concern in Alabama by Project AWAKE, given that recent fish tissue monitoring by the Alabama Department of Environmental Management has revealed levels of PCBS exceeding FDA guidelines in striped bass from upper Lay Reservoir and channel catfish from upper Neely Henry Reservoir.[232]

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[225]"PCBs" is a shorthand for a group of 209 individual cogeners – members of a group of structurally similar chemicals with different configurations. PCBs generally occur as a complex mixture of some assortment of these cogeners.

[226]U.S. Environmental Protection Agency, Office of Water, *Polychlorinated Biphenyls (PCBs) Update: Impact on Fish Advisories* 3-4 (September 1999) available at www.epa.gov/ost/fish/chemfacts.html. [hereinafter EPA PCBs Fact Sheet]

[227]Id.

[228]Telephone Interview with Shawn Martin, Clean Water Manager, St. Regis Mohawk Tribe Environment Division (Jul. 12, 2001).

[229]See, e.g., Native Village of Savoonga, Resolution # 00-10.

[230] *"Fishing for Justice – May 13, 2000 Island Creek Park on the Hudson River"* available at www.ejcr.cau.edu/fishingforjust.htm (citing Arbor Hill Environmental Justice Corporation President Aaron Mair's call for increased awareness of the issue and for "GE to do the right thing and clean up the PCB's they dumped into the River").

[231]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[232]Facsimile Communication, Daisy Carter, Project AWAKE (Oct. 25, 2001); Alabama Department of Environmental Management, *ADEM Announces Results of Fiscal Year 2001 Fish Tissue Monitoring Effort* (Apr. 25, 2001) available at www.adem.state.al.us/EduInfo/PressReleases/4fish01.htm..

Health Effects[233]

PCBs have been classified by EPA as "probable human carcinogens." Studies have suggested that PCBs may play a role in inducing breast cancer. Studies have linked PCBs to increased risk of several other cancers as well, including: liver, biliary tract, gall bladder, gastrointestinal tract, pancreas, melanoma, and non-Hodgkin's lymphoma. PCBs may also cause non-carcinogenic effects, including reproductive effects and developmental effects (primarily to the nervous system). PCBs tend to accumulate in the human body in the liver, adipose tissue (fat), skin, and breast milk; PCBs have also been found in plasma, follicular fluid, and sperm fluid. Fetuses may be exposed to PCBs in utero, and babies may be exposed to PCBs during breastfeeding. According to EPA, "[s]ome human studies have suggested that PCB exposure may cause adverse effects in children and developing fetuses while other studies have not shown effects. Reported effects include lower IQ scores, low birth weight, and lower behavior assessment scores."[234]

Sources of PCBs in the Environment[235]

Overview: The manufacture of PCBs was banned in the United States in 1979. However, items containing PCBs that were still in service at the time of the ban were "grandfathered" in and not required to be removed from use; some remain in use today. For example, electrical transformers containing PCBs are still in use and have a life expectancy of 30 years. The major source of PCBs in the environment is from past releases that have not been cleaned up; most PCBs are contained in sediments and are released from sediments over long periods of time to the waters, air, and soil.

There are no naturally occurring sources of PCBs; all PCBs in the environment are therefore of human origin.

Air: PCBs from past releases to soils and surface waters evaporate or volatilize to the air over long periods of time. From the air, they are redeposited back to the land and to surface waters.

Water/Sediments: Most PCBs from past releases are contained in sediments. PCBs are extremely persistent in the environment: they have half-lives in sediments ranging from months to years; they have very low solubility in water and low volatility. Because of these characteristics, PCBs continue to be released from sediments to surface waters over long periods of time. PCBs may also be mobilized to surface waters if they are disturbed (e.g. flooding, dredging). In addition to evaporation or revolatization, PCBs may be transferred from surface waters by adsorption to sediments.

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233 Unless otherwise noted, health effects information is taken from EPA PCBs Fact Sheet.
234 EPA PCBs Fact Sheet at 5.
235 Unless noted, sources information is taken from EPA PCBs Fact Sheet.

Soils: PCBs from past releases may also be contained in soils. PCBs have long half-lives in soils and are released over long periods by evaporation or volatilization to air, and are in turn redeposited to soils and surface waters.

Dioxins[236]

Background

Dioxins/furans are responsible, at least in part, for approximately 2% of all fish and shellfish advisories issued in the United States; as of December, 1998, dioxins/furans were the basis for 59 advisories issued by 19 states, territories or tribes.[237] Three states, Maine, New Jersey, and New York, have issued statewide dioxins/furans advisories for their coastal marine waters.[238] Dioxins are the source of advisories on all of the Great Lakes.[239] Dioxins are also the source of advisories for the Potomac River and numerous National Estuary Program and National Estuarine Research Reserve System sites, including Casco Bay (ME), Wells (ME), Long Island Sound, Peconic Bay (NY), the Hudson River, New York/New Jersey Harbor, Barnegat Bay (NJ), Jacques Cousteau-Great Bay and Mullica River (NJ), Delware Estuary, Albemarle-Pamlico Sounds (NC), Galveston Bay (TX), Puget Sound (WA), and the Columbia River.[240]

Dioxins are a major source of concern for the Penobscot Indian Nation.[241] Although recent changes in rules affecting pulp and paper mills in Maine that use chlorine in their bleaching process (requiring a switch from the use of elemental chlorine to chlorine dioxide) may be reducing dioxin levels in the Penobscot River and sediments, the use of chlorine dioxide still leads to discharges that result in small amounts of dioxins in the water, and historical discharges, among

[236]"Dioxins" is a shorthand for a group of synthetic organic chemicals, comprised of 210 structurally related chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs). This group of compounds ranges in toxicity, with 2,3,7,8-TCDD being the most toxic.

[237]U.S. Environmental Protection Agency, Office of Water, *Polychlorinated Dibenzo-p-dioxins and Related Compounds Update: Impact of Fish Advisories* 3 (Sept. 1999). Available at www.epa.gov/ost/fish/chemfacts.html. [hereinafter EPA Dioxins Fact Sheet]

[238]Id.; U.S. Environmental Protection Agency, *Update: National Listing of Fish and Wildlife Advisories* 3-5 (2001) available at www.epa.gov/ost.

[239]Id.

[240]Id.

[241]Dawn Gagnon, *Spiritual Keepers of the Penobscot*, Bangor Daily News (Oct. 6, 1995); Andrew Kekacs, *Penobscots Oppose Mill Permit; Any Discharge of Dioxin in River Detrimental, Tribal Member Says*, Bangor Daily News (Mar. 4, 1997); Mary Anne Lagasse, *Indians, People's Alliance Take Fish Advisories to Task; King Critics Say Dioxin Problem Downplayed*, Bangor Daily News (Apr. 2, 1997); Dieter Bradbury, *Contamination in Fish Weakens Cultural Link for Maine Tribe: Catching and Eating Fish is a Tradition No Longer Passed on to Many Penobscot Children*, Portland Press Herald (Sept. 30, 1997).

other sources, still likely contribute to the presence of dioxins in the sediments.[242] Given dioxins' persistence in the environment, its propensity to bioaccumulate (concentrations of dioxins in aquatic organisms may be hundreds to thousands of times higher than the concentrations found in surrounding waters or sediments), and its extreme toxicity even small amounts of discharge are reason for the Penobscot Nation Department of Natural Resources to be concerned.[243]

Health Effects[244]

Studies suggest a wide variety of adverse effects from dioxin, although there is still debate about the extent of these effects in humans. Among these are adverse effects on hepatic, gastrointestinal, hematological, dermal, endocrine, immunological, neurological, reproductive, and developmental systems. A recent report concluded more than a decade of study on dioxin's cancer-causing potential, identifying TCDD as a "human carcinogen" and the "mixture of dioxins to which people are exposed" as a "likely human carcinogen."[245] Even very small amounts of dioxins may be toxic to humans.

Sources of Dioxins in the Environment[246]

Overview: Dioxins in the environment are primarily the unintended by-products of industrial and other processes that use or burn chlorine. The major source of dioxins in the environment is incineration. Other sources of dioxins include direct discharges to water from industrial processes, resuspension of contaminated sediments, and releases from soils.

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[242]As a result of recent regulations, EPA projects considerable reductions in *discharges* of dioxins to waters; however, there is little or no data characterizing the *levels* of dioxins in the waters and sediments, resulting from historic discharges and the cycling of dioxins through the environment. See, generally, U.S. Environmental Protection Agency, *Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* (Draft, 2000)[hereinafter "Draft Dioxin Reassessment"]; U.S. Environmental Protection Agency, Office of Research and Development, *Information Sheet 4, Dioxin: Summary of Major EPA Control Efforts* (June 12, 2000); Telephone Interview with Dwain Winters, U.S. Environmental Protection Agency (March 29, 2002). See, also, Andrew Kekacs, *Penobscots Oppose Mill Permit; Any Discharge of Dioxin in River Detrimental, Tribal Member Says*, Bangor Daily News (Mar. 4, 1997); Mary Anne Lagasse, *Indians, People's Alliance Take Fish Advisories to Task; King Critics Say Dioxin Problem Downplayed*, Bangor Daily News (Apr. 2, 1997).

[243]See, generally, Draft Dioxin Reassessment; accord, Dawn Gagnon, *Spiritual Keepers of the Penobscot*, Bangor Daily News (Oct. 6, 1995) (quoting Director John Banks: "Dioxin is suspected of being the most toxic compound that the EPA has ever evaluated.").

[244]Unless otherwise noted, health effects information is taken from EPA Dioxins Fact Sheet.

[245]National Institute of Health, *Ninth Report on Carcinogens*. The National Institute of Health is a part of the U.S. Department of Health and Human Services. Available at ehis.niehs.nih.gov/roc/ninth/rahc/tcddsticker.pdf. Dioxin was listed as "Known to be a Human Carcinogen in the January 2001 addendum to the Ninth Report on Carcinogens." Id. See, also, Draft Dioxin Reassessment.

[246]Unless otherwise noted, sources information is taken from EPA Dioxins Fact Sheet.

Air: Most dioxins are introduced into the environment as emissions to the air. Incineration is a major source of dioxins (including incineration of municipal solid waste, medical waste, sewage sludge, and hazardous waste), although the relative contribution of incineration is projected to decline over the next several years, as regulations require reductions.[247] Dioxins are also emitted from backyard burning, metal smelting, cement kilns, land-applied sewage sludge, residential and industrial wood burning, coal-fired utilities, diesel trucks, and pulp and paper mills.[248] Dioxins released into the air may be suspended for a long time and travel great distances before being deposited to soils and surface waters.

Water/Sediments: Dioxins are discharged directly to surface waters from pulp and paper mills that use chlorine compounds in bleaching processes.[249] Dioxins are also discharged to waters from the industrial production of chlorinated organic chemicals, such as chlorinated phenols. Most dioxins are contained in sediments, where they persist for long periods because of half-lives ranging from months to years. Particles resuspended from sediments to surface waters are an important source of dioxin in surface waters.

Soils: Dioxins enter the soils when industrial wastes and municipal sludge contaminated with dioxins are applied as fertilizer to crops or grazing lands. Dioxins that have been emitted to the air are also deposited to soils. Dioxins in the soils may in turn be released into surface waters through run-off or leaching.

Chlordane[250]

Background

Chlordane is responsible for advisories on Lake Superior, Lake Michigan, and Lake Huron.[251] It is the source of advisories for several National Estuary Program and National Estuarine Research Reserve System sites, including the Potomac, Black and Anacostia Rivers (all of which connect to Chesapeake Bay).[252] The Baltimore Harbor is under advisory for chlordane, as is the New York/New Jersey Harbor, Barnegat Bay (NJ), Jacques Cousteau-Great Bay and

[247]U.S. Environmental Protection Agency, *Inventory of Sources of Dioxin in the United States* (1998; updated 2000)(Draft); accord, Chlorine Chemistry Council (untitled and undated fact sheet)

[248]Id.

[249]Id.

[250]"Chlordane" is a manufactured mixture of more than 26 compounds. Chlordane is used here to refer to chlordane and to the multiple breakdown products of chlordane, which themselves are persistent and bioaccumulative.

[251]U.S. Environmental Protection Agency, *Update: National Listing of Fish and Wildlife Advisories* 3-5 (2001) available at www.epa.gov/ost.

[252]Id.

Mullica River (NJ), and Delaware Estuary.[253] Chlordane is the source of a statewide advisory for lakes and rivers in New York[254].

According to a recent study of the Greenpoint/Williamsburg community in the Borough of Brooklyn in New York City, fish are a major source of chlordane exposure for African-Americans and Hasidic Jews, and shellfish are a major source of chlordane exposure for Hispanics/Caribbean Americans.[255]

Health Effects

Chlordane is associated with cancer in some but not all studies; it is classified by EPA as a probable human carcinogen.[256] Chlordane also has adverse effects on the central nervous system, the digestive system, and the liver at higher doses. Chlordane metabolites may reside in human breast milk, and may be passed on to infants through breastfeeding.

Sources of Chlordane in the Environment

Overview: The manufacture and use of chlordane has been banned in the United States since 1988. It was once used as an agricultural pesticide (on crops including corn and citrus), and on home lawns and gardens. One of chlordane's most common uses was for treatment of termites. Once chlordane is released into the environment, it may evaporate or it may bind itself to soil particles (particularly in the upper layers of soil) or to sediments in water. The breakdown of chlordane once it is bound to soil particles or sediment is very slow. According to the National Resources Defense Council, "[s]o persistent is the residue, that a recent study showed that detectable levels of chlordane are still present in some food grown in the United States, even though it has been decades since chlordane was used in agriculture."[257]

Air: Chlordane from past applications to agricultural soils, soils near houses treated for termite control, or soils near waste sites and landfills may be present in the air in small amounts.

Water/Sediments: Chlordane from past releases is contained in surface waters and especially in sediments. It is highly persistent, and may be present in sediments for years.

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[253]Id.

[254]Id.

[255]Industrial Economics, Inc., *Community-Specific Cumulative Exposure Assessment for Greenpoint/Williamsburg New York* 2-19 (1999).

[256]Washington State Department of Ecology, *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* 44 (No. 00-03-054) (Dec. 2000) available at http://www.ecy.wa.gov/pubs/0003054.pdf.

[257]Natural Resources Defense Council, *Healthy Milk, Healthy Baby: Chemical Pollution in Mother's Milk; Chemicals: Chlordane* available at www.nrdc.org/breastmilk/chem1.asp.

Soils: Chlordane from past releases is also contained in soils, where it is highly persistent. Chlordane has been found in some cases to be present in soil up to 20 years after application.[258]

DDT[259]

Background

DDT is the source of a statewide advisory for lakes and rivers in New York, as well as advisories in California, Texas, and Maine.[260] The total number of advisories for DDT increased from 40 in 1999 to 44 in 2000.[261]

DDT is a contaminant of concern for the Fourteen Confederated Tribes of the Yakama Nation, given that the Yakama River, which forms a reservation boundary and is a tributary to the Columbia River, is contaminated with DDT and currently under a state-issued advisory.[262]

Health Effects

DDT, together with DDD and DDE, is classified by EPA as a probable human carcinogen. DDT may cause damage to the central nervous system at high doses, leading to tremors and seizures.[263]

Sources of DDT in the Environment

Overview: DDT was one of the most widely used pesticides in the United States from 1946 to 1972. Its use has been banned in the United States, except for "public health emergencies."[264]

Other Persistent Organic Pollutants (POPs)/Persistent Bioaccumulative Toxins (PBTs)

Several other contaminants are sources of concern because they are bioaccumulative and persistent. That is, these contaminants accumulate in aquatic organisms at concentrations many times higher than the concentrations present in surrounding waters. They also persist for long

[258] Id.

[259] "DDT' here refers not only to DDT, but also to its breakdown products, DDD and DDE.

[260] U.S. Environmental Protection Agency, *Update: National Listing of Fish and Wildlife Advisories* 3-5 (2001) available at www.epa.gov/ost.

[261] Id.

[262] Barbara Harper and Stuart Harris, *Proceedings of the American Fisheries Society: Forum on Contaminants in Fish*, "Tribal Technical Issues in Risk Reduction Through Fish Advisories" 17 (1999).

[263] Washington State Department of Ecology, *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* 44-45 (No. 00-03-054) (December 2000) available at http://www.ecy.wa.gov/pubs/0003054.pdf.

[264] Id.

periods of time in the environment, particularly in the sediments where bottom-dwelling aquatic species can accumulate them and pass them up the food chain to fish, other predatory species, and, ultimately, humans. The contaminants are also highly toxic. In addition to the five contaminants canvassed above, the Convention on Persistent Organic Pollutants and the EPA's Persistent Bioaccumulative Toxin Initiative each include among the POPs or PBTs of concern the following seven pesticides: Aldrin, Dieldrin, Endrin, Heptachlor, Hexachlorobenzene, Mirex, and Toxaphene;[265] and the industrial chemical Hexachlorobenzene. Note that this list is likely not exhaustive; these contaminants are merely those that have been identified as being of the very highest priority. Some groups have argued, for example, the lead belongs on this list, given that it is persistent, it builds up in bone tissue, it is toxic even in minute concentrations, and its effects on exposed children are particularly troubling.[266] In some cases, governments and agencies are in the process of studying whether additions are appropriate. The Washington State Department of Ecology, for example, has identified more than 60 additional candidates for screening and prioritization, based on initial evaluations demonstrating their persistence, propensity to bioaccumulate and toxicity.[267]

Exposure to these POPs or PBTs has been linked to a wide range of toxic effects in fish, wildlife, and humans, including cancer, adverse developmental effects and adverse effects on the nervous, reproductive, immune and endocrine systems.[268] POPs or PBTs are contaminants of concern for many affected communities, groups and tribes.[269] The Indigenous Environmental Network, for example, explains some of their concerns:

> *Indigenous Peoples have special cultural and spiritual relationships to traditional foods that create increased consumption patterns compared to non-Indigenous populations.*

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[265]See U.S. Environmental Protection Agency, Office of Water, *Toxaphene Update: Impact on Fish Advisories* (September 1999) available at www.epa.gov/ost/fish/chemfacts.html.

[266]Washington Toxics Coalition, *Comments on Ecology's Draft Strategy Addressing Persistent Pollutants* available at www.watoxics.org/uaPBTcomments.htm.

[267]Washington State Department of Ecology, *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* 60-61 (No. 00-03-054) (December 2000) available at http://www.ecy.wa.gov/pubs/0003054.pdf.

[268]Id. at 5.

[269]Numerous tribes and indigenous peoples' organizations passed resolutions to this effect during the negotiating process for the International Treaty on Persistent Organic Pollutants, urging the "elimination, phase-out, or reduction wit the aim to eliminate toxic substances that are persistent and bioaccumulate in the environment and in the bodies of American Indian/Alaska Native populations." See, e.g., The National Congress of American Indians, *Resolution # PSC-99-054*; Great Lakes Indian Fish & Wildlife Commission, *Resolution No. 8-16-89-01*; Alaska Inter-tribal Council, *Resolution 99-27*; Qawalangin Tribe of Unalaska, *Resolution # 00-05*; Tanana Chiefs Conference, Inc., *Resolution No. 2000-38*; Traditional Council of Togiak, *Resolution 00-30*; Native Village of Wales, *Resolution 00-09*; Algaaciq Tribal Government, *Resolution 00-19*; Native Village of Fort Yukon, *Resolution No. 00-21*; Native Village of Elim, *Resolution 00-11*; Chickaloon Village Traditional Council, *Resolution # 000801-01*; Bill Moore's Slough Elder's Council, *Resolution # 2000-09*; Chenega I.R.A. Council, *Resolution # 00-26*; Native Village of Savoonga, *Resolution # 00-10.*

Unfortunately, the main way POPs enter our bodies is through food. POPs have been found in eagles, cormorants, ducks, geese, caribou, reindeer, raccoons, rabbits, quail, deer, moose, bison, turtles, crocodiles, sheep, cows, polar bears, seals, whales, and fish. . . . Advisories prohibiting or discouraging the consumption of traditional foods affect Indigenous Peoples' right to practice our cultural and spiritual ways.[270]

Similarly, Faith Gemmill, Arctic Village, Alaska, explains:

I speak before you today as a young Gwichin woman with an infant daughter and with a deep commitment to ensuring her future and the continuation of the Indigenous way of life. . . . One cannot separate the health of the environment from the health of our peoples. . . . As Indigenous peoples we are greatly concerned when we realize evidence which suggests that women, infants, and children are very vulnerable to POPs. This threatens the very existence of our peoples and cultures. The multigenerational impacts threaten our hope of healthy, thriving, and productive future generations.[271]

A. PREVENTION AND REDUCTION

How might EPA better prevent contamination in the first place in order to protect the aquatic ecosystems and the health of people consuming or using fish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes?

Efforts to prevent or reduce contamination in the first place are vital to protecting the health of communities of color, low-income communities, tribes, and other indigenous peoples. These efforts are especially important given that members of these groups are among the most highly-exposed to environmental contaminants (as discussed in Chapter One) and given that for many of these groups, risk avoidance – eating less fish, using a different preparation method, fishing in a different location – is simply not a realistic or culturally appropriate option (as will be discussed in Chapter Three). Thus, these groups will disproportionately bear the burden of sources of ongoing contamination that are not adequately addressed. Prevention and reduction efforts will need to be directed at those contaminants of concern that are still being used or produced, including mercury, dioxins, and others.

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[270]Indigenous Environmental Network, *Drum Beat for Mother Earth: Persistent Organic Pollutants (POPs)* available at www.ienearth/org/pops_threat-p2.html.

[271]Faith Gemmill, Gwichin, Arctic Village, Alaska, Oral and Written Testimony at the Third Session of the United Nations Environment program Intergovernmental Negotiating Committee for and International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants (POPs) (Sept. 8, 1999).

1. Clean Water Act

Enacted in 1972, the Clean Water Act[272] (CWA) and its complex implementing regulations and guidelines focus on protecting public natural resources and welfare and improving water quality through the control of discharges of pollutants into national waters. The statutory objective of the CWA is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[273] As stated in the CWA, national goals provide that: (1) the discharge of pollution into navigable waters be eliminated by 1985; (2) an interim goal of water quality that provides for the protection and propagation of fish, shellfish, and wildlife and for recreation be achieved by July 1, 1983; (3) the discharge of toxic pollutants in toxic amounts be prohibited; (4) federal financial assistance be provided to construct publicly owned waste treatment works; (5) areawide waste treatment management planning processes be developed to assure adequate control of pollution sources in each state; (6) major research and demonstration efforts be undertaken to eliminate the discharge of pollutants into national waters; and (7) programs to control point and nonpoint discharges be developed expeditiously to meet the goals of the CWA.[274] Water quality standards are key to implementing the framework of the CWA and are necessary for regulatory and enforcement actions to protect water quality where existing controls like technology-based limitations may be insufficient to maintain or restore water quality.

Generally, the CWA requires that the U.S. Environmental Protection Agency (EPA) set standards for various sources of pollution, to enforce those standards through permitting systems, and, where a state so requests to delegate primary enforcement authority to that state. As originally enacted, the CWA, as well as many other federal environmental laws, did not mention tribes or Indian reservations or provide for direct participation by tribal governments. Because the jurisdictional rules applicable to Indian country left EPA unable to pursue its usual practice of delegating primary enforcement responsibility to states, EPA was forced to develop special rules and practices concerning environmental regulation on Indian reservations and the role to be played by tribal governments. In November 1984, EPA issued the EPA Policy for the Administration of Environmental Programs on Indian Reservations (Indian Policy) to address tribal participation and the unique circumstances presented by Indian country.[275] Each EPA Administrator, including most recently Administrator Christine Todd Whitman, has reaffirmed the principles enumerated in the Indian Policy.[276] In 1987, Congress amended the CWA to allow federally-recognized tribes to be treated as states for certain purposes under the Act. As of

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[272] 33 U.S.C. §§ 1251-1387.

[273] 33 U.S.C. § 1251(a).

[274] 33 U.S.C. § 1251(a).

[275] U.S. Environmental Protection Agency, *Policy for the Administration of Environmental Programs on Indian Reservations* (Nov. 8, 1984).

[276] On July 11, 2001, Administrator Whitman issued a Memorandum on EPA Indian Policy to all EPA Employees recognizing the right of tribes as sovereign governments to self-determination and acknowledging the federal government's trust responsibility owed to tribes. The Administrator also reaffirmed EPA's commitment to the long-established Indian Policy and "in building a stronger partnership with tribal governments to protect the human health and environment of Indian communities."

December 2000, only eighteen tribes (of the approximately 565 total federally recognized tribes) have received treatment as a state status and adopted standards for purposes of the water quality standards effective under the CWA, and EPA has promulgated standards for one additional tribe.[277] As a result, a large gap exists in water quality standards coverage in Indian country. For example, tribal lands lacking approved water quality standards constitute an area approximating the size of all of New England plus New Jersey and as many reservation residents as the populations of Wyoming, Alaska, and Vermont combined.[278] Where tribes have not yet received treatment as a state status and assumed responsibility for CWA on their reservations and lands, EPA is responsible for implementing and enforcing the CWA within Indian country pursuant to the CWA and the federal trust responsibility owed to tribes.[279] Toward that end, EPA recently has been considering a proposal to develop core federal water quality standards for certain waters in Indian country that do not have water quality standards under the CWA.[280] The Core Standards currently call for a four-part hierarchy for selecting a fish consumption rate for use in setting water quality standards in Indian country. This hierarchy sets up a preference for using "the results of any existing fish consumption surveys of local Indian country watersheds to establish fish intake provisions that are representative of the populations being addressed."[281] While this preference for local data is appropriate, the reality, as discussed in Chapter 1, is that many tribes have not gathered this data – often for lack of resources. In the absence of such data, the proposed Core Standards would look to EPA's default fish consumption rates, and perhaps to a rate as low as 17.5 grams/day.[282] As noted in Chapter 1, this number grossly underestimates consumption for many tribes.

As discussed in Chapter One, EPA has recently updated its default values for fish consumption rates, as part of its revisions to the Ambient Water Quality Criteria Methodology for the Protection of Human Health, pursuant to CWA 304(a). The EPA has indicated that the revised values will likely guide water quality standard-setting and policy for years to come (the former values were in place for roughly 20 years). This may be problematic from the perspective of affected groups whose members consume fish at the highest levels, and whose practices are therefore not adequately accounted for or protected by even the revised AWQC Methodology. Moreover, as noted in Chapter One, to the extent that the revised AWQC Methodology

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[277] *EPA Fact Sheet: Water Quality Standards for Indian Country* (April 2001) (available online at http://www.epa.gov/ost/standards/tribal/tribalfact.html). Note, we need the Office of Water or the AIEO to verify this figure officially at the time of the report.

[278] Id.

[279] The courts have long recognized that the United States has a trust relationship with Indian tribes. See, e.g. Worcester v. Georgia, 31 U.S. 515 (1832); Cherokee Nation v. Georgia, 30 U.S. 1 (1831).

[280] On January 19, 2001, EPA's Administrator signed the proposed Federal Water Quality Standards for Indian Country and Other Provisions Regarding Federal Water Quality Standards, which were withdrawn from the Federal Register on January 20, 2001 to allow regulatory review by the Administrator. 66 Fed. Reg. 7701 (Jan. 24, 2001).

[281] U.S. Environmental Protection Agency, Office of Water, *Federal Water quality Standards for Indian Country and Other Provisions Regarding Federal Water Quality Standards* (unofficial prepublication copy, Jan.19, 2001) available at www.epa.gov/ost/standards/tribal/ .

[282] Id. at 17.

recommends that states and tribes prefer local data, EPA will need to provide funding to enable this preference to exist as a meaningful option. And, to the extent that EPA's revised AWQC Methodology proposes that "acceptable" risk for the general population be defined as an incremental cancer risk of 1 in 100,000 to 1 in 1,000,000, but deems a greater level of risk "acceptable" for "more highly exposed subgroups," including subsistence fishers, i.e., up to 1 in 10,000, this is a troubling potential source of environmental injustice.[283] EPA should decline to exercise this option to provide lower levels of protection to communities of color, low-income communities, tribes, and other indigenous peoples as it sets and approves water quality standards. Additionally, as a general matter, EPA needs to take into account the differences in fish consumption rates, practices, and context, as outlined in Chapter One, as it undertakes triennial reviews of state and tribal water quality standards under CWA 303(c)(1).

Additionally, the CWA provides some authority for addressing non-point sources of water pollution (including through TMDLs). Given that non-point sources are major contributors of numerous contaminants of concern, this authority should be interpreted broadly to enable EPA to prevent and reduce contamination from these sources. Non-point sources, moreover, are of particular concern to some affected groups. In Hawai'i, for example, there is a need for further studies on the effect of non-point sources on fish and other aquatic resources on which Native Hawaiians and other communities of color in Hawai'i depend, and for more extensive efforts to prevent and reduce pollution from these sources. As explained by Hawaii's Thousand Friends:

> *When it rains, Hawaii's short watersheds create immediate impacts to coastal areas from non-point source pollution. Studies so far have concentrated on impacts to estuaries, receiving ocean waters and coral, but not on impacts to fish and cru stations.*

Commentators have noted, moreover, the inefficiencies and unfairness, from the perspective of point sources, of failing to recognize and address as well the considerable relative contributions of non-point sources.

Neither the CWA nor its regulations alone will accomplish the objective and goals of the CWA. EPA, and authorized state and tribal governments, simply must ensure strict and widespread compliance with the CWA. Without such enforcement, polluters have absolutely no incentive to comply with the CWA as "noncompliance results in economic benefits (the free use of public waterways for waste disposal), while compliance exacts a financial cost (the construction and operation of expensive pollution removal facilities)."[284]

Water quantity is also of serious concern given, among other things, its recognized connections to and implications for water quality and integrity. For example, congressional goals and policies under the Clean Water Act direct federal agencies to "co-operate with State and local agencies to develop comprehensive solutions to prevent, reduce and eliminate pollution in concert

[283] Draft AWQC Methodology at 43,762.

[284] John Cronin and Robert F. Kennedy, Jr., *The Riverkeepers* 178 (1997).

with programs for managing water resources."[285] And the U.S. Supreme Court has recognized the connection between water quantity and quality, upholding a state's imposition of minimum instream flows as part of a Section 401 determination.[286] Wetlands, which provide essential wildlife habitats, are also recognized as an integral and natural way of removing pollutants from water bodies, and the Clean Water Act's Section 404 permitting program as well as EPA's "no net loss" strategy for wetlands preserves both the quality and quantity of these waters. Additionally, reduction in water quality affects surface flows and may increase the concentration of pollutants and other chemicals.[287]

2. Other Authorities

The Clean Air Act (CAA) is an important source of authority for addressing contamination of aquatic environments that results in part from the deposition of toxic contaminants emitted into the air. For example, it is estimated that air emissions account for some 80% of mercury contamination in water. Most dioxins released into the environment also come from emissions to air; as noted above, dioxins emitted into the air may be suspended for a long time and travel great distances before being deposited to surface waters. Among other things, the CAA Section 112 addresses certain "hazardous air pollutants;" the 1990 amendments to the CAA direct EPA to develop rules for categories of sources that emit these hazardous air pollutants, and to do so over the next ten years. EPA has promulgated many of these rules, although there are some source categories for which EPA is still in the process of rule development. Because mercury compounds and dioxin are among the hazardous air pollutants regulated under CAA Section 112, this provides an important basis for preventing and reducing these contaminants. Moreover, EPA has several upcoming opportunities under Section 112 (e.g., upcoming rule for coal-fired power plants, the single largest source of mercury emissions nationwide; upcoming rule for chlor-alkali plants, a significant source of mercury, particularly in some locales, such as Louisiana;[288] upcoming rule for industrial boilers, another important source of mercury) to address these concerns as it develops these rules. In addition, whether under CAA authority and/or other authorities, the EPA needs to attend to sources of toxic air pollutants that are currently un- or under-regulated (e.g., dioxin emissions from backyard burning). The relative contribution to dioxin emissions from these sources has increased as industrial and other sources of dioxins have been required to control their emissions; as such, addressing these un- and under-regulated sources will be a challenge for the near future.[289] Again, commentators have noted that where this

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[285]33 U.S.C. § 1251(g).

[286]PUD No. 1 v. Washington Dep't of Ecology, 511 U.S. 700 (1994).

[287]See, e.g., United States v. Gila Valley Irrigation Dist., 920 F. Supp. 1444 (D. Ariz. 1996) (finding that upstream water uses reduced surface flows and increased saline levels in water reaching an Indian reservation to the extent that traditional agricultural activities were impaired and recognizing that the tribe was entitled to surface water of adequate quantity as well as quality).

[288]Telephone Interview with Dr. Barry Kohl, Department of Geology, Tulane University (Oct. 17, 2001).

[289]U.S. Environmental Protection Agency, *Inventory of Sources of Dioxin in the United States* (1998; updated 2000)(Draft); accord, Chlorine Chemistry Council (untitled and undated fact sheet).

is the case, issues of inefficiency and unfairness, from the perspective of regulated sources, mean that agencies should also look to un- and under-regulated sources for reductions. And while some community groups have recently taken it upon themselves to get community members to reduce backyard burning,[290] EPA should not rely on ad hoc, voluntary efforts but should work to coordinate, facilitate, and, where appropriate, require reduction from these and other un- and under-regulated sources.

The CAA also provides authority to address other air-related sources of contaminated waters. For example, the CAA regulates oxides of nitrogen (NOx) through a variety of provisions. NOx causes acidification and euthrophication (a process in which an overabundance of nutrients causes some algae to multiply exponentially causing oxygen depletion that limits the ability of some species to thrive and survive), a potential problem for shellfisheries and other aquatic resources. Among these, the New Source Review program, which decides controls for NOx on new or modified facilities on a case-by-case basis, is under review pursuant to the National Energy Policy. In addition, implementation of the new Ozone National Ambient Air Quality Standard (NAAQS) may affect NOx emissions as NOx is an important ozone precursor.

Other statutory and regulatory authorities similarly provide authority useful for preventing and reducing contamination of fish and aquatic environments. Several statutes and regulations pertaining to hazardous waste may provide authority to address more thoroughly the use of "recycled" wastes from various industrial processes as fertilizer – which is then applied to crops, grazing lands, and gardens, and may contribute to run-off of dioxins, lead, mercury, cadmium, and other contaminants of concern to surface waters and contamination of groundwater, including drinking water. Although current regulations address this practice, they contain a loophole exempting steel mill waste and may still permit unacceptable levels of these contaminants in fertilizer.

The Federal Insecticide, Fungicide, and Rodenticide Control Act (FIFRA) may provide authority to address the fact that "[w]ell over a billion pounds of pesticides are applied annually in the United States, at least 50 million pounds in the Great Lakes Watershed alone."[291] Also authority under FIFRA is limited, there may well be opportunities for EPA to use the available tools more aggressively, e.g., prominent advisories on pesticide labels, prohibitions on use within a specified distances from wells (well set-backs), prohibitions on use in designated geographic areas, and restricting pesticides' use to certified applicators.[292]

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[290]Shawna Larson, Project Coordinator, Indigenous Environmental Network and Alaska Community Action on Toxics, Panelist, "Food, Toxic Chemicals & Health: An Environmental Justice Forum," Anchorage, AK (Feb. 6, 2002).

[291]U.S. General Accounting Office, *Issues Concerning Pesticides Used in the Great Lakes Watershed* (1993).

[292]Zygmunt J. B. Plater, et al., *Environmental Law and Policy: Nature, Law, and Society* 728 (2d ed. 1998).

The Pollution Prevention Act (PPA), enacted in 1990, might similarly be mined for tools that EPA might employ more aggressively to prevent pollution from entering aquatic environments in the first place.

Finally, a variety of sources of authority and EPA offices have been gathered in EPA's recent Contaminated Sediment Management Strategy. Given that in terms of volume, some 10% of the sediments underlying the nation's waters are contaminated , that 96 of the watersheds tested indicate contamination at levels of serious concern, and that the contaminants that most frequently contributed to this concern were mercury, PCBs, pesticides (especially DDT), and PAHs, addressing sediment contamination should indeed be a priority.[293]

B. CLEANUP AND RESTORATION

How might EPA enhance restoration efforts in order to rehabilitate aquatic ecosystems and thereby protect the health of people consuming or using fish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes?

Many aquatic environments remain degraded such that they require restoration in order to ensure the viability of the ecosystem; the health of people consuming or using fish, aquatic plants, and wildlife for subsistence, traditional, cultural, or religious purposes; the ability to support economies dependent on aquatic resources; and the sustainability of tribal homelands. Efforts to cleanup and restore contaminated aquatic environments are vital to protecting the health of communities of color, low-income communities, tribes, and other indigenous peoples. These efforts are especially important given that members of these groups are among the most highly-exposed to environmental contaminants (as discussed in Chapter One) and given that for many of these groups, risk avoidance – eating less fish, using a different preparation method, fishing in a different location – is simply not a realistic or culturally appropriate option (as will be discussed in Chapter Three). Thus, these groups will disproportionately bear the burden of existing contamination that is not adequately addressed. Moreover, because production (and, in many cases, use) in the United States has been banned for several of the contaminants of greatest concern – for example, PCBs, DDT, chlordane, and toxaphene – the presence of these contaminants in the environment can only be reduced through cleanup and restoration efforts.

"Restoration" has been taken by different people to mean different things.[294] Restoration has sometimes been defined somewhat narrowly, to the exclusion of the historical, cultural, legal, and social contexts within which restoration takes place. Thus, for example, the National Research Council has defined restoration of aquatic ecosystems as "the reestablishment of

[293]U.S. Environmental Protection Agency, Office of Science and Technology, *The Incidence and Severity of Sediment Contamination in Surface Waters of the United States, Volume 1: National Contaminant Survey* (1997).

[294]For several examples relevant to the restoration of aquatic environments, see U.S. Environmental Protection Agency, Office of Water, *River Corridor and Wetland Restoration*, "What is Restoration?" at www.epa.gov/owow/wetlands/restore/defs.html.

predisturbance aquatic functions and related physical, chemical and biological characteristics."[295] Others define restoration more broadly and suggest that the ends and means of restoration can only be contemplated *in context*, i.e. in light of the particular historical, cultural, legal, and social circumstances of a place. The Society for Ecological Restoration, for example, observes that restoration should attend to "regional and historical context," and must take into account the need to sustain cultural activities, especially the cultural practices of indigenous peoples.[296] Similarly, among the Principles of Environmental Justice articulated by the First National People of Color Environmental Leadership Summit, is that "[e]nvironmental justice affirms the need for urban and rural ecological policies to clean up and rebuild our cities and rural areas in balance with nature, honoring the cultural integrity of our communities and providing fair access for all to a full range of resources."[297]

In the case of restoration affecting tribal homelands (including tribal resources and culturally-important resources whether located on- or off-reservation), tribes and commentators have noted that the ends or "point of reference" for restorative efforts cannot be considered separately from the obligations that the United States has undertaken in treaties and as part of its trust responsibility.[298] Restoration here must attend to the purposes for which tribal lands and resources have been reserved under treaties and protected in furtherance of the federal trust responsibility.[299] As noted above, arguably the primary purpose of all reservations is the creation of a permanent tribal homeland where the tribe can maintain its traditional subsistence activities including the exercise of treaty rights to hunt, fish, and gather. Water of sufficient quality and quantity for this purpose is essential.[300] Thus, for example, in introducing their plan for restoring salmon and other anadromous fish in the Columbia River Basin, *Wy-Kan-Ush-Mi Wa-Kish-Wit*,

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[295]National Research Council, *Restoration of Aquatic Ecosystems* 18 (1992).

[296]See, generally, The Society for Ecological Restoration at www.ser.org.

[297]*Proceedings of the First National People of Color Environmental Leadership Summit*, "Principles of Environmental Justice" xiii (1991).

[298]Moses Squeochs, Director, Environmental Program, Fourteen Confederated Tribes and Bands of the Yakama Nation (Aug. 3, 2001 conference call).

[299]Jana Walker, Attorney, Law Offices of Jana L. Walker (Aug. 3, 2001 conference call); Mary Christina Wood, *Indian Land and the Promise of Native Sovereignty: The Trust Doctrine Revisited*, 1994 Utah Law Review 1471; Mary Christina Wood, *Fulfilling the Executive's Trust Responsibility Toward Native Nations on Environmental Issues: A Partial Critique of the Clinton administration's Promises and Performances*, 25 Environmental Law 733 (1995); Mary Christina Wood, *Protecting the Attributes of Native Sovereignty: A New Trust Paradigm for Federal Actions Affecting Tribal Lands and Resources*, 1995 Utah Law Review 109.

[300]See, e.g. Winters v. United States, 143 F. 740, 742 (1906); Colville Confederated Tribes v. Walton, 647 F.2d 42, 49 (9th Cir.1981), *cert. denied*, 454 U.S. 1092 (1981); Felix S. Cohen, *Handbook of Federal Indian Law*, 588-89 (1982 ed.); see also Mary Christina Wood *Indian Land and the Promise of Native Sovereignty: The Trust Doctrine Revisited*, 1994 Utah Law Review 1471; Mary Christina Wood, *Fulfilling the Executive's Trust Responsibility Toward Native Nations on Environmental Issues: A Partial Critique of the Clinton administration's Promises and Performances*, 25 Environmental Law 733 (1995); Mary Christina Wood, *Protecting the Attributes of Native Sovereignty: A New Trust Paradigm for Federal Actions Affecting Tribal Lands and Resources*, 1995 Utah Law Review 109.

the Columbia River treaty tribes explain that "[u]nlike other plans, this plan establishes a foundation for the United States and its citizens to honor their treaty and trust obligations to the four tribes. If implemented, it would at least begin to meet ceremonial, subsistence, and commercial needs of tribal members and to return fish to many of the tribes' usual and accustomed fishing places, as guaranteed in the 1855 treaties."[301] Restoration affecting tribal lands and resources, moreover, must attend to the related matters of cultural flourishing and tribal sovereignty.[302] As John LaVelle observes in the context of restoration plans for *Paha Sapa* or the Black Hills, those pursuing plans "must embrace the restoration of tribal sovereignty and cultural integrity as an indispensable remedial norm to be realized through the proposal's development and implementation."[303]

EPA's Watershed Ecology Team has set forth Principles for the Ecological Restoration of Aquatic Resources.[304] These "Guiding Principles" include (1) preserve and protect aquatic resources; (2) restore ecological integrity; (3) restore natural structure; (4) restore natural function; (5) work within the watershed and broader landscape context; (6) understand the natural potential of the watershed; (7) address ongoing causes of degradation; (8) develop clear, achievable, and measurable goals; (9) focus on feasibility; (10) use a reference site; (11) anticipate future changes; (12) involve the skills and insights of a multi-disciplinary team; (13) design for self-sustainability; (14) use passive restoration, when appropriate; (15) restore native species and avoid non-native species; (16) use natural fixes and bioengineering techniques, where possible; and (17) monitor and adopt where changes are necessary.

1. Clean Water Act

As noted above, the statutory objective of the CWA is "to *restore* and maintain the chemical, physical, and biological integrity of the Nation's waters."[305] In addition to the efforts discussed above in conjunction with prevention and reduction, EPA should read its authority under the CWA consonant with this stated objective and look creatively and aggressively for restoration opportunities.

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[301]Columbia River Inter-Tribal Fish Commission, 1 Wy-Kan-Ush-Mi Wa-Kish-Wit: Spirit of the Salmon, iv (1995).

[302]See, e.g., id. at v ("protect tribal sovereignty" among goals of restoration); *Chairman's Corner: The Exercise of Tribal Sovereignty Lies at the Heart of Healthy Ecosystems*. Fort Apache Scout 2 (May 24, 1996); see, generally, Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* (1999).

[303]John P. LaVelle, *Rescuing Paha Sapa: Achieving Environmental Justice by Restoring the Great Grasslands and Returning the Sacred Black Hills to the Great Sioux Nation*, 5 Great Plains Natural Resources Journal 40, 78 (Spr./Sum. 2001) (italics omitted).

[304]U.S. Environmental Protection Agency, *Principles for the Ecological Restoration of Aquatic Resources* (2000) available at www.epa.gov/owow/wetlands/restore/principles.html.

[305]33 U.S.C. § 1251(a).

2. Other Authorities

Clearly, the focus of CERCLA or "Superfund" is on cleanup and restoration of contaminated environments, including aquatic environments. Under CERCLA and its implementing regulations, once contaminated sites have been identified as potential priorities for cleanup action, EPA investigates the nature and extent of the threat posed by the contamination (the "remedial investigation" or "RI") and develops alternative approaches for responding to the contamination at that site (the "feasibility study" or "FS"). EPA uses a screening process to evaluate the alternatives identified during the RI/FS, which includes, among other criteria, whether the alternatives comply with all "applicable, relevant, and appropriate requirements," whether they achieve overall protection of human health and the environment, whether they reduce the toxicity, mobility or volume of the contamination through treatment, whether they are effective in the short-term as well as the long-term, whether they are implementable and how much they cost, and whether they are acceptable to the state and to the community. Note that these criteria provide EPA with considerable latitude to choose a more or a less protective alternative as the "remedy" for the contamination. EPA's work in this regard could be improved in several ways relevant to communities of color, low-income communities, tribes, and other indigenous peoples. First, EPA needs to set cleanup levels and determine appropriate remedies in light of the considerations discussed in Chapter 1. Specifically, when EPA sets cleanup levels for contaminated sediments and surfaces waters, it needs to take into account the different fish consumption rates, practices and contexts of affected groups and set levels sufficiently protective of these groups. EPA site managers need to consider matters of aggregate or multiple exposures and cumulative risks, and delineate sites, goal, and remedies accordingly. EPA needs to refrain from falling back on "institutional controls" (e.g., put a fence around the site and post "No Fishing" signs) and undertake aggressive cleanups where the sites are past or present locations for fishing and other activities that expose communities of color, low-income communities, tribes, and other indigenous peoples to contamination. Second, EPA needs to take seriously the requirement of "community acceptance" as it chooses among alternatives. In order to do so, it needs to ensure that participation by affected communities (and co-management by affected tribes) takes place from the outset and at every point in the decision-making process. To accomplish this, EPA should be ready to provide financial and technical support. These issues of affected group involvement are also taken up in Chapter One and Chapter Three. Finally, to the extent that the Natural Resource Damage provisions of CERCLA (or other statutes) are invoked, involved agencies should work with the community to ensure that efforts are undertaken with an eye toward making the community whole. Community involvement here, of course, will be critical; tribes may well be involved in their roles as Natural Resource Damage trustees. The discussion above regarding restoration is also relevant here.

Other statutory and regulatory authorities similarly provide authority useful for cleaning up and restoring contaminated aquatic environments. Among these, as discussed above in the context of prevention and reduction, a variety of sources of authority and EPA offices have been gathered in EPA's recent Contaminated Sediment Management Strategy.

CHAPTER III: FISH CONSUMPTION ADVISORIES

What role should fish consumption advisories play in efforts to protect more effectively the health and safety of people consuming or using fish, aquatic plants, and wildlife?

Whereas Chapter Two focused on issues surrounding *risk reduction* strategies, this chapter focuses on issues surrounding a *risk avoidance* strategy: fish and wildlife consumption advisories. Rather than looking, as risk reduction strategies do, to the risk-producers to cleanup, limit, and prevent environmental contamination, risk avoidance strategies look to *risk-bearers* – those who bear the risks of contamination – to change their lives and practices in order to avoid exposure to harmful contaminants. They do this by encouraging or requiring individuals to change the way they live, specifically, to alter or refrain from certain pursuits or practices that, once a place has been allowed to become contaminated, expose them to risk.

It is important to note that with risk avoidance strategies such as fish consumption advisories, the *responsibility* for addressing environmental contamination and its harmful human health effects is allocated to those who are made to bear the risks of contamination rather than to the sources of that contamination. Furthermore, because risk avoidance strategies place this responsibility on those who are exposed to environmental contaminants, they will necessarily impose a greater burden on communities of color, low-income communities, tribes, and other indigenous peoples. As has been amply demonstrated, it is members of these groups who are among the most exposed.

In light of these and other considerations, and in view of the reality of the harmful health effects of consuming fish from seriously contaminated environments, Part A of this chapter will take up the question: what role should fish consumption advisories play in efforts to protect more effectively the health and safety of people consuming or using fish, aquatic plants, and wildlife? *It is important to note that the answer to this question is likely to be different for different communities, groups, or tribes, and should be determined by or together with the affected group.*

Parts B, C and D will examine the related matter of fish consumption advisories' "effectiveness." The concept of "effectiveness" itself raises a host of issues, the first of which is definitional: what is meant by an "effective" advisory? Again, the answer to this question may be different for different agencies and for different communities, groups, or tribes. This question will be discussed in Part B. Part C will canvas the current state of research regarding how those to whom advisories are directed respond to this information, focusing on what is known about awareness and responses among communities of color, low-income communities, tribes, and other indigenous peoples. Part D will then explore ways in which to improve the effectiveness of risk communication and fish consumption advisories. Throughout, this chapter will seek to address the question: how can EPA better meet the needs of all people, including communities of color, low-income communities, tribes, and other indigenous peoples, as it works to address degradation of aquatic ecosystems and to protect the health and safety of people consuming or using fish, aquatic plants, and wildlife?

A. FISH CONSUMPTION ADVISORIES' ROLE

Risk avoidance strategies such as fish consumption advisories shift the responsibility for addressing environmental contamination's harmful health effects to risk-bearers, as opposed to allocating this responsibility to risk-producers. In the case of fish consumption advisories, this choice disproportionately burdens communities of color, low-income communities, tribes, and other indigenous peoples, given that these groups consume fish at higher rates and according to different practices than the general population, as discussed in Chapter One. When agencies employ fish consumption advisories, moreover, they assume that there are adequate substitutes in the lives of those to whom the advisories are directed for fishing and fish consumption. Although consumption advisories issued by federal or state agencies typically do not state as much explicitly, they rely implicitly on the assumption that there are ready substitutes for being able to fish at the same place, in the same manner, and for the same fish as one had traditionally or would today were the fish not contaminated. This assumption requires a judgment on the part of the agencies that such a substitution (1) is possible, and (2) will not occasion great loss.[306] This is a value judgment that is likely to reflect the understandings of the dominant society that fishing and fish consumption are expendable "habits," "activities," or "behaviors," for which, at the very least, substitutes can be readily obtained; and, that various groups' particular fishing and fish consumption practices can be altered without great anguish (or that this anguish and loss does not matter).[307]

However, this value judgment does not reflect the understandings of many of those who are affected – those who are being asked to change their lives and practices. First, it is often unrealistic as a practical matter to think that there are substitutes ready at hand for fishing, preparing fish, and eating fish in the manner currently practiced by affected individuals. This may be so for economic, geographic, historical, cultural, and/or other reasons. It is often difficult if not impossible to fish at a different bay, river, lake, or bayou – how would one get there if it is too far to walk, or if the bus doesn't go there, or if there isn't any money to put enough gas in the car? how would one learn what it takes to catch fish at a new place, and how would one put food on the table in the meantime? what if all of the waters nearby were also contaminated, as is likely to be the case when the sources of the contaminants are air emissions (e.g., mercury) or the entire area is heavily industrialized (e.g., the Mississippi River Corridor between New Orleans and Baton Rouge) or the entire area is plagued by pesticide runoff from farms? It is often difficult if not impossible to fish for different species or to fish for younger fish as some advisories suggest – what does one do for dinner when the only fish that are biting that day are old and the "wrong" species? It is often difficult if not impossible to stop eating fish altogether and to obtain nutrition benefits similar to fish from other sources – what if one cannot afford to pay for substitute sources of protein, such as beef, which is often more expensive? how does one account for the fact that fish are unequaled in regard to some nutrition benefits: for example, fish are an especially efficient source of protein inasmuch as fish are low in fat relative to other protein sources? Consider, for example, the obstacles and concerns identified by the following.

[306]Catherine A. O'Neill, *Risk Avoidance and Environmental Justice* (forthcoming).
[307]Id.

Raymond Moseley, a fisher along the Columbia Slough in Portland, Oregon, explains:

> *We have caught big fish down there, between them two posts. Plenty catfish in there. Ain't too many other places to fish – except way out of town.*[308]

A low-income, African American fisher along the Detroit River, explains:

> *Yes, income affects everything. A fishing license is expensive – or outrageous is more like it. You need money for everything. To fish is expensive and what happens when you are poor? . . . You even have to spend money on gas so that you can get to the water and if you can't get there then you can't get food.*[309]

According to an account of the response of Alaskan Natives on Nelson Island to an unusual year marked by reduced numbers of herring and a prevalence of fatty herring:

> *Several families did not fish for herring at all, resulting in the lowest overall household involvement in herring production in the years of survey. Instead, they diverted efforts to increase halibut, Pacific cod, and salmon harvests, filling drying racks and freezers with these welcome, but less preferred, alternatives. Local residents do not consider halibut and Pacific cod adequate, or even improved, substitutes for herring, as non-local people may, but these species certainly are preferred by Nelson Island families to non-local, imported foods. Herring is the traditional winter food for Nelson Island families. Changing subsistence fishing strategies often means purchasing new gear and more gasoline, adjusting processing and drying facilities, investing more time fishing for other species, and altering subsistence production roles in the family*[310]

Yin Ling Leung, Executive Director of Asians and Pacific Islanders for Reproductive Health, California, explains:

> *To our communities, being able to fish means being able to either put food on the table, or basically eat a much less nutritious meal. I think that's a non-choice.*[311]

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[308]Videotape: The Water in Our Backyard (City of Portland, Bureau of Environmental Services).

[309]Patrick C. West and Brunilda Vargus, *A Subsistence-Culture Model for High Toxic Fish Consumption by Low-Income Afro-Americans from the Detroit River* 15 (forthcoming).

[310]Mary C. Pete, *Subsistence Herring Fishing in the Nelson Island and Nunivak Island Districts* (1991) available at www.nativeknowledge.org/db/files/tp196.htm.

[311]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 1 (1998).

As Daisy Carter, Project AWAKE, Coatopa, Alabama, summarizes,

> *When it comes to people, their health and survival, EPA must become real. It is not about formality, but reality.*[312]

Second, even if those affected in some senses could as a practical matter alter their fishing and fish consumption practices, to be asked or required to do so might be *unthinkable* in the sense of occasioning profound loss or anguish. This may be so for traditional, cultural, religious, historical, and/or other reasons. For some communities or peoples, fish and fishing are a way of life, a way to be who they are. For these groups it is *necessary* to fish in traditional places, and to catch, prepare and eat fish in accordance with traditional ways. From their perspective, these are not expendable "habits," "activities," or "behaviors;" they are crucial for survival – of the individual, the community or people, and, in some cases, the entirety of the earth.

Barbara Harper, Fourteen Confederated Tribes and Bands of the Yakama Nation, and Stuart Harris, Confederated Tribes of the Umatilla Indian Reservation, explain:

> *There are many issues relating to the evaluation of tribal health risk and, even more importantly, the health of people as they exist within their eco-cultural communities. . . . We need to think not only about human people as receptors, but about the culture itself as a receptor. We should be very uncomfortable about having to write a fish advisory in the first place. . . Really, there is just a single cultural community that is comprised of human and fish peoples and their rules for behaving and mutually surviving. It has been explained that the fish community existed first, and accepted people as community members, but only if human people follow certain rules of participating in the ecology, including a nutritionally adequate level of respectful consumption (a sacrament), and protecting the fish members from contamination and habitat degradation in return for being protected from starvation. Writing a fish advisory to protect some community members from other members is very disquieting, and causes many consequences on its own.*[313]

Similarly, the Swinomish Indian Tribal Community explains:

> *In the Swinomish Tribal Community, fish and shellfish represent vital subsistence and commercial resources for the Tribe as well as an important point of cultural association for the Tribe's identity. Employed in cultural and religious ceremonies, incorporated into the common diet, and sold to support families on the Reservation, the current ecological status and fate of these species is of utmost interest to the Tribe. . . . [We believe that risk reduction exemplifies a much more effective answer to addressing the risk [from contamination] than does risk avoidance. . . . [O]ptions such as closing*

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[312]Daisy Carter, Project AWAKE (Written Comments to FCW, undated).

[313]Barbara Harper and Stuart Harris, *Proceedings of the American Fisheries Society: Contaminants in Fish,* "Tribal Technical Issues in Risk Reduction Through Fish Advisories"17 (1999).

harvesting sites, substituting with other sources of food, and posting "no fishing" signs are not viable considerations for reducing risk.[314]

And, as Hawaii's Thousand Friends emphasizes:

For the Native Hawaiian, the proposal of not eating fish because of contamination is unimaginable and unacceptable.[315]

Thus, it is often impossible to conceive of fishing at a different bay, river, lake, or stream – what if it belongs to someone else traditionally, historically and/or legally? This is an issue, in particular, for many tribes, especially the fishing tribes (e.g., of the Pacific Northwest or of the Great Lakes), whose rights to hunt, fish, and gather are tied to particular places and protected by treaties – these place-based rights are not transferable. Nor can many tribal fishers imagine going "somewhere else" to fish, even if they could. Margaret Palmer, a Yakama tribal fisher, elaborates:

I don't feel like it's within our rights, as the tribe that we are, to go to a different area and live off of something that maybe God has blessed them with. This is our blessing. This is the way we see it. This is where we should stay. I don't believe that I would leave the area. I believe I would stay where I'm at – by the water. It's our lineage.[316]

Moreover, the particularized skills and knowledge that tribal peoples have developed over centuries are place-specific and comprise a part of their intergenerational heritage, to be passed from generation to generation. It is often impossible to fish for, hunt for, or gather different species or to fish for younger fish as some advisories suggest – what if a particular species is bound up with one's cultural identity and with every aspect of who one is, as in the case of salmon and the Native peoples of the Pacific Northwest or in the case of wild rice and the Native peoples of Northern Minnesota?

Winona LaDuke, Mississippi Band of Anishinaabeg, explains:

It's mid-September in northern Minnesota. Somewhere on one of the many lakes Lennie Butcher and his wife Cleo are making wild rice. Mamoominikewag. *That is what they do.*

It's a misty morning on Big Chippewa Lake. The Anishinaabeg couple drag their canoe toward the water's edge. The woman boards in the front and sits on her haunches. The man pushes the canoe offshore and jumps in the boat behind her. As they pole toward the wild rice beds, they can feel the crisp dampness of September on their faces. The man rises to stand, his head visible just above the tall sticks of rice. The woman pulls the

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[314]Swinomish Indian Tribal Community, *Comments on the NEJAC Draft Fish Consumption Report* (Feb. 5, 2002).

[315]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[316]Videotape: My Strength is From the Fish (Columbia River Inter-Tribal Fish Commission 1994).

rice over her lap with a stick and gently raps it with another one. This is a thousand-year-old scene on Big Chippewa Lake. And there is a community that intends to carry it on for another thousand years.

There are many wild rice lakes on the White Earth reservation in northern Minnesota; my community, the Anishinaabeg, calls the rice Manoomin*, or a gift from the Creator. Every year, half our people harvest the wild rice, the fortunate ones generating a large chunk of their income from it. But wild rice is not just about money and food. It's about feeding the soul.*[317]

Or what if a particular preparation method is an important component of traditional, cultural, or ceremonial use?

A majority of respondents [to the Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California] (76.1%) said they always eat the skin of the fish. Some respondents also report regularly consuming the head and organs of the fish. Many chemicals are concentrated in the fat, which is just underneath the skin, and in the organs of the fish. Consumption of these parts of the fish exposes a person to higher amounts of chemical contaminants than consumption of only the fillet.

Cooking methods often determine which parts of the fish are eaten. The California Environmental Protection Agency (Cal EPA) health advisory recommends that people eat only fillet portions of fish, and bake, broil, steam or grill fish on a rack so that juices from the fat drip off during cooking. This survey shows that frying, baking, steaming, grilling, and making "fish pudding" are the most common ways of preparing fish in the Laotian community. According to the survey staff, the whole fish, including the head, skin, and organs, is frequently cooked when frying, baking, steaming and grilling fish. . . . "Fish pudding" or lap is also made out of the whole fish, and is oftentimes made from raw fish. When making lap, the organs of the fish are commonly removed, cooked separately, chopped up and then included in the mixture. According to the survey staff, striped bass is a popular fish for lap. Sauces and pastes made from whole and raw fish, shrimp or crab are also popular traditional Laotian condiments. The health advisory's recommendations for methods of cooking fish to lower one's risk of taking in harmful chemicals clearly are at odds with traditional ways of preparing fish and other seafoods.[318]

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[317]Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* 115 (1999).

[318]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 35 (1998).

According to a recent study of African American fishers on the Detroit River, frying is "a firmly rooted cultural tradition amongst African Americans" and is either the only method or the preferred method of preparing fish; as one fisher summarized:

> *It's cultural. Blacks fry. It's simple.*[319]

It is often simply impossible to stop eating fish altogether and to obtain nutrition benefits similar to fish from other sources. For some communities and peoples, there are simply no replacements that equal the nutritional and health benefits – in the broadest sense of these terms – of the fish, aquatic plants, and wildlife that they have traditionally consumed. Yvonne Smith and Laura Berg explain in *Wana Chinook Tymoo*, in a sidebar entitled "Declining Fish, Declining Health:"

> *The shortage of salmon and other fish has necessitated dramatic changed in the diet of the Indian people of the Columbia River Basin. They have experienced a steady decline in health as a result.*
>
> *Researchers worldwide state what Indians have known all along, that there are health benefits to consuming fish. . . .*
>
> *Ted Strong reported that when his relatives, many now deceased, spoke of those that came before them, they talked about people who lived long lives, into their 90's and beyond. "Those ancestors ate the traditional foods," he said. . . .*
>
> *Whatever other factors have contributed to the shortened lives and high death rate among the Indian people of the basin, there is little doubt dietary changes have had a significant impact.*
>
> *Joanna Meninick has watched the health of her people decline as the scarcity of salmon has increased, "diabetes, cancer, heart disease. All of these are on the increase."*
>
> *Many traditional foods are gone, or have become inaccessible. C'lày (pronounced chu-lie) is an example. Made from dried salmon, berries, and other oils and foods, the powdery preparation has multiple uses. "It is good medicine, said Bill Yal-lup, Sr. "You can mix it with certain roots, certain foods . . . very good for the heart."*
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> *But c'lày is in short supply. It takes many pounds of dried salmon to make. Whole salmon, needed for ceremonies and subsistence, comes first.*

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[319]Katharine J. Hornbarger, et al., *Targeted Audience Analysis: Recommendations for Effectively Communicating Toxic Fish Consumption Advisories to Anglers on the Detroit River* 26 (1994) (noting that anglers described several ways of frying: "pan frying, deep fat frying, and the most often cited method, coating the fish with cornmeal and then frying.").

Pierson Mitchell noted that he had salmon for lunch at home sometimes, when it was available, but he missed the c'lày. Getting it occasionally in the Christmas basket was a treat. "If our people had remained on the diet of the salmon, our health would be better today," he said.[320]

Similarly, Silas Whitman, Nez Perce, explains:

One thing I have noticed over the years is that the Nez Perce people are highly susceptible to minute changes in diet, especially those that revolve around fish. If we supplant native foods with other foods, often times the nutritive values of that supplanted product cannot be ingested or stay in the system to the degree that our bodies as Nez Perce people can use them. From that come health problems that are eroding our mortality. So as we help the salmon and other fish to recover we help ourselves.[321]

And it is no less a source of profound loss and anguish for those whose have already been forced to give up fish because of the gross contamination of their fishing places. It is no less *necessary* for these communities or peoples to fish in traditional places, and to catch, prepare and eat fish in accordance with traditional ways. They have been made to suspend or alter their practices, but they cannot be viewed as having "chosen" to abandon these practices. The strength and resilience of these affected communities and peoples cannot now be taken to justify a claim that fish are no longer important to their survival as individuals and peoples, such that it would be permissible to allow the contamination to continue and remain. Winona LaDuke recounts:

"This is a classic environmental justice site," says Ken Jock, a director of the Akwesasene Environment Program. A slight man, with soft eyes and a quiet manner, he spends much of his time arguing with agencies about implementation of the law. His huge office is full of reports and photos documenting the extent of the [PCB contamination at Akwesasne, on the St. Lawrence River]. The reports, photos, and sheer size of the Akwesasne Environment Program dwarf the infrastructure of most Indian nations in the country. Yet it seems that even with reams of paper, the action taken by federal agencies is minimal. "This all used to be a fishing village. That's all gone now. There's only one family that still fishes," Jock says. "We can't farm here because of all of those air emissions. Industry has pretty much taken the entire traditional lifestyle away from the community here."

Today 65 percent of the Mohawks on Akwesasne reservation have diabetes, says Jock. Henry Lickers, director of the environmental health branch of the Mohawk Council of Akwesasne echoes Jock: "Our traditional lifestyle has been completely disrupted, and we have been forced to make choices to protect our future generations," says Lickers.

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[320] Yvonne Smith and Laura Berg, *Ancient Tradition, Modern Reality: Is There a Future for a Salmon-Based Culture?* 1 Wana Chinook Tymoo 14 (1998).

[321] Dan Landeen and Allen Pinkham, *Salmon and His People: Fish and Fishing in Nez Perce Culture* 21 (1999).

"Many of the families used to eat 20-25 fish meals a month. It's now said that the traditional Mohawk diet is spaghetti."[322]

Thus, it may be impractical or impossible for those who are affected by contaminated aquatic environments to give up or alter their fish consumption practices. This may be so for economic, geographic, historical, traditional, cultural, religious, and/or legal reasons. Yet, the reality of gross contamination means that these practices may expose members of affected communities, groups and tribes to serious health risks – some of the contaminants contained in the fish, aquatic plants, and wildlife cause cancer, some wreak neurological damage, some are linked to reproductive and developmental damage, some disrupt endocrine functions, and some cause a range of these and other harms to humans. This poses a sad and dire dilemma.

What role should fish consumption advisories play in agencies' response? Broadly speaking, there are three possible policy options. These might be thought of as occupying a continuum. On the one end, agencies might rely exclusively on fish consumption advisories to address this dilemma. This option might reflect the view that it is cheaper and easier to address affected communities' and tribes' exposure by getting them to stop eating fish than it is to require risk-producers to prevent, reduce, and cleanup contamination. And, assuming the fish consumption advisories were effective (a question taken up in the next part of this chapter), affected communities would be protected from the harms of cancer and the like. There would, of course, be some losses – any substitute food sources might not be of equal nutritional quality or might not be what members of these communities would prefer to eat – but these losses would have to have been judged to be worth the benefits of not being exposed to the host of contaminants contained in the fish.

On the other end, agencies might abandon the use of fish consumption advisories altogether, and instead push aggressively for pollution prevention and cleanup. With this option, agencies' time and financial resources would be devoted entirely to preventing, reducing, and cleaning up contamination, such that aquatic environments would be returned to health and would be able to sustain fish, aquatic plants, and wildlife that were safe for humans to consume and use at the earliest possible time. This option might reflect the view that the only real way to protect health and safety of humans who consume or use these resources is to address the source of the health risk, i.e., the contamination. This option might reflect the view that it would be a misdirection of scarce agency time and money to continue to try to use and improve fish advisories – that this time and money would be better spent on prevention, reduction, and cleanup. Or it might reflect the view that even advising affected communities, groups, or tribes to alter their fish consumption practices is inappropriate, given the discrimination against and potential affront to those for whom these practices have cultural, traditional, or religious dimensions.

In the middle are a range of policy options that recognize some temporary role for fish consumption advisories but emphasize that they not become agencies' primary policy response to

[322]Winona LaDuke, *All Our Relations: Native Struggles for Land and Life* 17 (1999).

the adverse health effects of contaminated aquatic environments. These middle options would grow out of a sense that neither the first nor second options actually addressed the concerns of at least some communities of color, low-income communities, tribes, and other indigenous peoples. The first option would shift the burdens of contamination entirely from those who have produced the risks to those who bear them. This is unjust and unacceptable. It would also give continued license to real and grave harms – among them nutritional deficits, other health detriments, and cultural discrimination. It would stand idly by as aquatic food sources were ultimately allowed to remain or become poisoned and forever "off limits" to those groups that formerly relied on these resources. The second option would address some of these long-term concerns, but would fail to inform affected groups in the short term. This, too, is unjust and unacceptable. The second option would, as Daisy Carter puts it, withhold from those most affected precisely what they need and are entitled to: *"the information and knowledge to help themselves."*[323] It would turn its back to the reality that fish are already contaminated – and will remain contaminated for some time, even given the most ambitious cleanup schedules – and real people will suffer when they eat or use this fish. Finally, the options that chart a middle course recognize that there may be ways to address at least some of the concerns of those affected by fashioning *appropriate* advisories (e.g., appropriate in terms of language, cultural, and other group- and place-specific considerations).

Moreover, the range of options here might enable agencies to be attentive to and respectful of the different concerns of different communities, groups, and tribes. That is to say, a particular community or tribe could choose one of the other options as most appropriate for its needs. *This brings up the crucial point that it is for the affected group to determine what will be appropriate from its perspective.*

Note that tribes' particular circumstances need to be taken into account. Tribes are sovereign nations, and in their governmental capacities are in the position of deciding for themselves what role fish consumption advisories should play in their efforts to protect the health and safety of tribal people consuming or using fish, aquatic plants, and wildlife.[324] Some tribes have decided to issue fish advisories to protect their members from contamination – often contamination that was permitted not by the tribes themselves but by state and federal agencies.[325] Some tribes or groups of tribes have opted not to issue fish consumption advisories but instead to develop "tribal consumption guidelines." [326] These guidelines tend to focus on the first and third functions of the typical advisory, i.e., providing information and suggesting alternative ways to continue consuming fish, rather than on the second function, i.e., discouraging fish consumption

[323]Daisy Carter, Project AWAKE (Written Comments to FCW, undated).

[324]See, e.g., Swinomish Indian Tribal Community, *Comments on NEJAC Draft Fish Consumption Report* (Feb. 5, 2002).

[325]See, e.g., James Ransom, Director, Haudenosuanee Environmental Task Force, *Proceedings of the American Fisheries Society: Contaminants in Fish* 25 (1999) (describing fish advisory issued by St. Regis Mohawk Health Services).

[326]Telephone Interview with Nancy Costa, Fond du Lac Environmental Program (Jul. 31, 2001); Great Lakes Indian Fish & Wildlife Commission, Masinaigan Supplement: How to Enjoy Fish Safely (Fall 2000).

altogether. Tribal consumption guidelines may also offer information that the typical federal- or state-issued advisory doesn't about the health benefits to tribal members of eating a "Native diet" and the health risks of turning to a "western diet."[327] Nancy Costa, of Fond du Lac Environment Program, explains:

> "*The last thing we want to do is to discourage tribal members from eating fish – given (among other things) the serious health effects we have seen for those who have gotten away from a Native diet.*"[328]

Similarly, Elaine Abraham, a Tlingit elder from Yakutat, notes efforts to enhance appreciation of the cultural and nutritional value of Native foods, and cautions against focusing only on the potential health risks without acknowledging the important, multi-faceted benefits:

> *Why are you starting with talk about concerns? I have enough trouble getting my granddaughter to eat Native foods!*[329]

Tribal consumption guidelines may employ the indigenous language and artwork of those affected.[330] It is important to note that several tribes have indicated that they would like to be able to examine the question what role advisories or guidelines should play in their efforts to protect the health and safety of tribal people consuming or using fish, aquatic plants, and wildlife, and, potentially to fashion appropriate advisories or guidelines, but that they do not have sufficient technical and/or financial resources to do so. These tribes have stated that additional resources would, therefore, be crucial.

But tribes and tribal members are also affected by the environmental management decisions of federal and state agencies. In the Pacific Northwest, for example, federal and state agencies make numerous decisions that have permitted the contamination and depletion of the salmon and other culturally significant, treaty-protected tribal resources. Here, federal and state policy choices regarding the role of fish consumption advisories will have an impact on tribal members exercising their treaty-guaranteed rights to fish in all "usual and accustomed" areas, many of which are managed in whole or in part by federal and state agencies. To the extent that these agencies look to risk avoidance rather than risk reduction measures, they may risk running afoul of treaty obligations. Further, when these agencies issue fish consumption advisories that affect tribal members and resources, they have sometimes failed to communicate their actions to tribes as they should in accordance with tribes' status as sovereign nations and, for federal agencies, in compliance with the Executive Order on maintaining the appropriate "government-to-

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[327]Telephone Interview with Nancy Costa, Fond du Lac Environmental Program (Jul. 31, 2001).

[328]Id.

[329]Alaska Traditional Knowledge and Native Foods Database, *Resource Guide for Mini-Grants* available at www.iser.uaa.alaska.edu/projects/contam/ResourceGuide/index.htm

[330]Telephone Interview with Nancy Costa, Fond du Lac Environmental Program (Jul. 31, 2001); see also, Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Safely* (Fall 2000).

government" relationship with tribes. Issues particular to American Indian tribes and Alaskan Native villages are discussed further in Chapter Four.

Finally, even where agencies, together with affected groups, opt to continue to issue advisories, they need to redouble their efforts to prevent and reduce new sources of contamination and to cleanup and restore environments and fisheries that are already contaminated. *This caveat was strongly emphasized by affected groups everywhere.* Agency representatives acknowledge this need. For example, Elizabeth Southerland, Standards and Applied Science Division, Office of Science and Technology, Office of Water, opened this year's National Forum on Contaminants in Fish by describing "how water quality-based programs at both the federal and state levels seek not only to advise people on ways to minimize public health risks, but also to implement management measures to reduce the pollution problems so that measures like fish consumption advisories can be rescinded. No one wants consumption advisories in place any longer than necessary."[331] Yet, advisories have been in effect in some places since the 1970s and EPA has created a separate advisory program, which has been in place for about a decade. Furthermore, EPA appears to anticipate continued efforts to issue advisories and to ensure that those affected "comply" with them. In its Strategic Plan, for example, EPA states among its objectives: "[by 2005, consumption of contaminated fish will be reduced."[332] EPA's commitment to ensuring that advisories remain a temporary, second-best response to contamination and its effects on human health needs to be backed up by a reprioritization of goals – prevention, reduction and cleanup first and foremost – and by a redoubling of resources allocated to returning aquatic environments and fisheries to a state where it is safe for people to fish.

B. EFFECTIVENESS: BACKGROUND AND DEFINITION

1. Advisories' Components and Functions

In order to facilitate deliberation about this middle course, it seems useful to examine more closely the components and functions of a typical fish consumption advisory. A typical advisory might be thought of as comprised of three functional parts: (1) provide information about the nature and extent of the contamination and its adverse health effects (e.g., which waters are affected? which species? what are the contaminants of concern? what are the adverse health effects from these contaminants? which subgroups are affected?); (2) encourage avoidance by one or more of several means (e.g., refraining from eating fish altogether; reducing amount of fish consumed); and, sometimes, (3) suggest alternative means to continue eating fish (e.g., altering frequency of fish meals; altering preparation methods; fishing at other sites; fishing for and eating other species). These functions sometimes overlap. In addition, there are functions that advisories could usefully serve but that the typical advisory does not attempt to serve, e.g., capacity-building or empowerment in the affected group.

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[331]*Proceedings of the National Forum on Contaminants in Fish* I-10 (May 6 and 9, 2001).

[332]U.S. Environmental Protection Agency, Office of the Chief Financial Officer, *Strategic Plan* 29-30 (No. 190-R-97-002) (September 1997) available at www.epa.gov/ocfopage/plan/epastrat.pdf.

Consider this excerpt for the current advisory for organic contamination in Louisiana:

Water body	Causative pollutants	Recommendations	Approximate size affected
Devil's Swamp, Devil's Swamp Lake and Bayou Baton Rouge (Parish: East Baton Rouge)	Hexachlorobenzene, Hexachloro- 1,3-butadiene, PCBs, Lead, Mercury, Arsenic	Avoid swimming, limit fish consumption to TWO MEALS PER MONTH.	7.0 square miles
Capitol Lake (Parish: East Baton Rouge)	Priority organics (PCBs)	No fish consumption.	0.12 mile

This advisory provides information identifying the relevant contaminants, the affected waterbodies, the approximate geographical extent of the contamination, and, given that the recommendations apply to all "fish," the species covered. This information all serves the first function. Do the recommendations "limit fish consumption to two meals per month" and "no fish consumption" serve mainly to translate information about the nature and extent of the contamination and its health effects into a form that is readily usable by those who would otherwise consume these fish (an extension of the first function)? Or do they serve mainly to discourage fish consumption (the second function) – with all of the pros and cons of doing so, as discussed above in Part A? This information may serve both the first and second functions (and may be perceived to serve different functions by different communities, groups or tribes).

Note that this advisory's recommendations are not accompanied by suggestions of alternative means that would allow the continued consumption of fish, albeit of different species or according to different practices – the third function.

Finally, without more information about the process of fashioning and disseminating this advisory, it is difficult to determine to what extent it serves the additional functions of capacity-building and empowerment from the perspective of the affected groups. To highlight but one aspect of these additional functions: although this advisory identifies the "causative pollutants," it does not go on to provide information about the sources of those pollutants (e.g., particular industrial or other facilities) nor about upcoming risk assessment and risk management decisions relevant to the pollutants and sources of concern.

2. Defining "Effectiveness"

There are likely to be differences in how one defines "effective"in this context – differences among agencies and the various affected communities, groups and tribes. The first function of advisories – to provide information – is the least controversial. There is likely widespread agreement that an effective advisory is one that successfully *communicates* information about the nature and extent of the contamination and about the relevant adverse health effects. Advisories' first function is important to securing environmental justice. Although questions remain about whether current advisories actually communicate this information in understandable and appropriate ways (these will be taken up below, in Parts C and D), there seems to be little question that advisories or something akin to advisories *should* serve this function. As Ticiang Diangson, Supervising Planning and Development Specialist and Environmental Justice Advocate, Seattle Public Utilities, explains:

Although prevention would be the ideal solution, the essential question after contamination is, how can the harmed community be made "whole?" First and foremost, the community needs to be truly informed *about the range of harm/risk it has been exposed to. . . .*

Communication, of course, requires that information be conveyed in a language, via a medium, in accordance with cultural considerations, and generally in a way that will enable it to reach and be understood by those affected – these issues are the focus of Part D.

The second function of advisories – to discourage fish consumption – is more problematic. Given the grave losses along myriad dimensions that are occasioned by not fishing and consuming fish, "success" here comes at a considerable price. To the extent that agencies judge advisories' effectiveness according to whether they elicit a decrease in fish consumption, agencies may misfocus their efforts from the perspectives of at least some affected groups. A measure of success that focuses on getting people to reduce their fish consumption may fail to appreciate the traditional, cultural, or religious reasons that make reducing consumption inappropriate, and in so doing, perpetuate cultural discrimination. In these cases, affected people may well have access to, understand, and "believe" the relevant advisories, they may simply decline to "comply" with them. As Hawaii's Thousand Friends observes:

A barrier to making fish consumption advisories work in Hawai'i is that no one will listen because eating fish is part of the culture.[333]

The third function that advisories sometimes serve – to suggest alternative means (e.g., alternative fishing sites, alternative species, alternative preparation methods) to continue eating fish – is also problematic. To the extent that agencies judge advisories' effectiveness according to whether they convince people to switch to these alternative practices, agencies may again misfocus their efforts in a way that is an affront to the traditions, cultures, or religious beliefs of some of those affected. Consider, for example, the observations of the Asian Pacific Environmental Network:

The California Environmental Protection Agency (Cal EPA) health advisory recommends that people eat only fillet portions of fish, and bake, broil, steam or grill fish on a rack so that juices from the fat drip off during cooking. . . . The health advisory's recommendations for methods of cooking fish to lower one's risk of taking in harmful chemicals clearly are at odds with traditional ways of preparing fish and other seafoods.[334]

To the extent that agencies judge advisories' effectiveness according to whether they convince people to switch to alternative practices that haven't been identified as appropriate *by* the affected

[333]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[334]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 35 (1998).

group, agencies may fail to appreciate the economic, geographic, social, and other practical realities facing the affected group.

The fourth function that advisories might serve – capacity-building and empowerment – are important to securing environmental justice. It is crucial that those affected play central roles in developing and disseminating the information that they deem appropriate to their needs. Such efforts – *led* by those in the community, and *supported* by the EPA and other agencies – can contribute to the larger goals of what the Laotian Organizing Project calls "*participatory learning and culturally-appropriate organizing.*"[335] EPA and other agencies should view this as an opportunity to work with communities on the ground as they work to empower themselves. As Daisy Carter, Project AWAKE, observes:

> *The question is does the federal government (EPA) want to educate, inform, and enlighten citizens to become active in making decisions for themselves? The answer is no. Companies and the government would not be able to exploit these citizens who are at risk if this was done. Citizens would ask questions and become involved in their own destiny. However, without knowledge, communities who are at risk are prey. . . .*
>
> *One of the major roles of NEJAC is to find a way to empower local citizens who are in impacted areas to set up lines of communication and data bases to acquire information related to their needs.*

And, as noted above, advisories enhance their effectiveness in this regard when they provide information that enables affected communities and tribes to become educated about and involved in risk assessment and risk management decisions – that is, information that does not merely instruct "Do Not Eat the Fish," but that identifies the sources of contamination as well as relevant upcoming decisions about preventing, reducing, and cleaning up contamination for these sources.

Additionally, it seems that agencies' views of effectiveness are sometimes preoccupied by concerns that may bear little on effectiveness for communities of color, low-income communities, tribes, and other indigenous peoples. For example, state and federal agencies have devoted considerable effort to achieving "national consistency" in fish advisory programs. This effort was an "important objective" of the 1999 American Fisheries Society Forum on Contaminants in Fish (attended by 41 states, 7 federal agencies, and others). Yet few dividends from such efforts may accrue to communities of color, low-income communities, tribes, and other indigenous peoples: an affluent recreational fisher who lives in Ohio but vacations in Michigan might be confused by the differing approaches to fish consumption advisories taken by these two states, and so might benefit from consistency between them.[336] Fishers from environmental justice communities are

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[335]Maria Kong and Pamela Chiang, Laotian Organizing Project & Asian Pacific Environmental Network, *Fighting Fire with Fire* 5 (2001).

[336]Hugh F. MacDonald and Kevin J. Boyle, *Effect of a Statewide Sport Fish Consumption Advisory on Open-Water Fishing in Maine*, 17 Journal of Fisheries Management 687 (1997). Note, however, that consistency might be relevant to environmental justice communities where jurisdiction over a

less likely to be traveling about, fishing in multiple states – this may be so for historic, geographical, cultural, economic, or legal reasons, or some combination of these. These individuals are thus less likely to benefit from consistency among states.

In sum, "effectiveness" from the perspective of communities of color, low-income communities, tribes, and other indigenous peoples is likely to focus on the first and fourth functions, while for some affected groups, it is likely to include the second and third functions. However, definitions of effectiveness and appropriateness will likely vary with varying local and cultural contexts. Thus, it will be important to determine the perspective of the particular affected group on this question, and to look to this perspective to guide every aspect of any advisory process, including evaluation of its success.

C. EFFECTIVENESS: AVAILABLE EVIDENCE

Before discussing to what extent advisories are effective from the perspectives of communities of color, low-income communities, tribes, and other indigenous peoples, it is useful to canvass the available evidence on responses to the fish consumption advisories that have been issued. As a general matter, although advisories have been in effect in some places since the early 1970s, relatively little is known about how they affect humans' behavior.[337] Again, there is more evidence based on anecdote or local knowledge than based on formal study. For example, the California Department of Health Services notes that health advisories extending from Malibu to Newport Beach have been in place for many years, but that:

> *[O]utreach and education about the advisories has been difficult to accomplish. Of particular concern are the non-English speaking populations who may have difficulty obtaining and understanding health information.*[338]

To the extent that empirical data have been gathered, they tend to provide two kinds of information (1) whether people are aware of an advisory; and/or (2) whether people have altered their consumption practices as a result. "Awareness," in turn, includes (a) whether people are aware that an advisory exists, and (b) whether people are aware of an advisory's content and recommendations. Sometimes these data are gathered alongside studies of fish consumption rates and practices. These data-gathering efforts vary in the extent to which they gather socioeconomic and other data relevant to environmental justice communities.

According to one survey designed to gauge the effectiveness of Great Lakes sport fish consumption advisories, for example, "half the sport fish consumers were unaware of the fish advisory for PCBs in the Great Lakes. The lowest awareness was among women, minority

single estuary, river or other waterway fished by these groups is shared by neighboring states.

[337] Id.

[338] California Department of Health, Environmental Health Investigations Branch, *Palos Verdes Shelf Outreach and Education Project on Fish Contamination Issues* (fact sheet available from California Department of Health Services).

groups, and persons with no high school degree."[339] Another survey of fish consumption patterns and advisory awareness among anglers on the Fox River in Wisconsin found that 95% of anglers who ate fish were unaware of Wisconsin's fish advisory pamphlet and 50% of anglers who ate fish had neither heard nor read about the health risks of eating Fox River fish. Asians (primarily Hmong and Laotians) represented 70% of the anglers who had not heard about the health risks (although they represented only 19% of the total anglers surveyed).[340] The survey found further that most of the anglers surveyed did not eat the fish they caught in the Fox River (83%)and that of these, 75% said they did not eat the fish because they were concerned about the contaminants. Of those anglers who ate the fish they caught, Asians made up the largest group, comprising 59% of fish eaters. The survey's authors observed:

> *Eating fish forms a regular part of the diet and culture for the Asians (Hmong and Laotians) living in the Green Bay area. White Bass, listed in the advisory as "Do Not Eat," appears to be their fish of choice. Although the number of Asian anglers fishing along the Fox River decreased after being informed by an interpreter that White Bass is not safe to eat, there is concern that some of these anglers still may be eating White Bass caught from other nearby contaminated waters. Many Asian anglers may not understand the fish advisory because of the language barrier or may not believe the fish advisory because no immediate physical ill effects have been observed from eating contaminated fish.*[341]

A third survey, of Maine open-water anglers, examined the effect of a 1994 statewide fish consumption advisory.[342] 63% of all anglers knew about the issuance of a mercury advisory regarding covering fish from all lakes and ponds in Maine. All socioeconomic characteristics (here: gender, age, fishing "effort") except education and income were the same for the groups who were aware of the advisory and those who were not. Of the anglers who were aware of the advisory, 22% of Maine residents and 23% of non-residents altered their fishing behavior, indicating that but for the advisory they *would* have consumed more fish, fished more days, or fished more or different waters.[343] A fourth survey, of fish consumption patterns and advisory awareness among the Laotian communities in West Contra Costa County, California, found that 48.5% of survey respondents had heard of a health advisory about eating fish and shellfish from the San Francisco Bay. Only a fraction of these (59.5%), however, could recall what the advisory

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[339]John Tilden et. al, *Health Advisories for Consumers of Great Lakes Sport-Fish: Is the Message Being Received?*, 105 Environmental Health Perspective 1360 (December 1997).

[340]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[341]Dyan M. Steenport, et al., *Fish Consumption Habits and Advisory Awareness Among Fox River Anglers*, Wisconsin Medical Journal (November 2000) available at www.wismed.org/wmj/nov2000/fish.html.

[342]Hugh F. MacDonald and Kevin J. Boyle, *Effect of a Statewide Sport Fish Consumption Advisory on Open-Water Fishing in Maine*, 17 Journal of Fisheries Management 687 (1997).

[343]Id.

said and none could recall an advisory more specific than "pregnant women should not eat large amounts of Bay fish," or "Bay fish are not safe to eat."[344] The survey found a statistically significant difference in awareness of the health advisory among ethnic groups within the larger Laotian community, with Khmu respondents being more likely to have heard of the advisory.[345] Of those who were aware of the health advisory, 60.3% said that it had influenced a change in their fishing or fish consumption habits. Of those whose habits were influenced, 62.7% said they no longer eat fish from the Bay or eat less fish from the Bay and 29.9% said they no longer eat fish from any source or eat less fish from all sources.[346] An account of a fifth survey, by the Environmental Health Investigations Branch of the California Department of Health, concludes:

> *Although the health advisory has been in place since 1994, outreach and education about the advisory to different fishing populations has been difficult to accomplish. The recently completed San Francisco Bay Seafood Consumption Study indicates that about two thirds of people fishing have no awareness or limited understanding of the advisory.*[347]

With this and other available evidence to go on, it appears that people of color and people with low incomes, limited English proficiency, or relatively little education are less likely to be aware of fish consumption advisories; that some portion of the people of color who are aware of advisories alters their consumption patterns as a result, but that a significant portion does not alter their consumption patterns; that there are differences among various ethnic groups in these respects; and that while contamination and advisories are not influencing all individuals to reduce their fish consumption, they are influencing individuals at sufficient rates to contribute to suppression effects (discussed in Chapter 1). Additionally, here as elsewhere, there is a need to gather further information especially about those groups and subgroups about which less is known.

D. EFFECTIVENESS: RISK COMMUNICATION AND CONSUMPTION ADVISORIES

The discussion in this Part tracks the components of risk communication as identified in the EPA's *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume IV: Risk Communication*,[348] by the organizers of the 2001 National Risk Communication

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[344] Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 29 (1998).

[345] Id. at 31.

[346] Id. at 30; Great Lakes Indian Fish & Wildlife Commission, *Masinaigan Supplement: How to Enjoy Fish Safely* (Fall 2000) available at www.glifwc.org.

[347] California Department of Health, Environmental Health Investigations Branch, *San Francisco Bay Fish Consumption Outreach and Education Project* (fact sheet available from California Department of Health Services).

[348] U.S. Environmental Protection Agency, Office of Water, *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume IV: Risk Communication* 3 (1995).

Conference,[349] and in the risk communication literature more generally. That is, after discussing general risk communication issues in Section 1, issues of "audience identification" and "needs assessment" are examined in Section 2; issues of message content are explored in Section 3; issues of media choice are taken up in Section 4; issues of implementation are discussed in Section 5; and issues of evaluation are addressed in Section 6. In addition, the matters of funding and capacity-building are explored in Section 7.

1. Risk Communication – Overarching Issues

"Risk communication is a two-way street." This phrase is often repeated, but less often honored in practice – with the result that communication may not actually occur. How can the risk communication process be rehabilitated?

As a preliminary matter, EPA and other agencies should reexamine the terms conventionally used to describe the various participants in the risk communication process. Agencies often refer to the "public," the "community," or the "audience," on one hand, and agency and other "experts" on the other.[350] These terms set up a dichotomy that denies that members of affected groups are themselves "experts," with knowledge crucial to successful risk communication – including effective fish consumption advisories. A more appropriate terminology would recognize affected groups' expertise, and not withhold from them the appellation "expert." In a similar vein, agencies often refer to "target audiences," who are affected groups that receive messages, and distinguish these from "risk communicators," who are agencies that generate and disseminate messages.[351] These terms indicate a one-way flow of information (*from* agencies *to* affected groups) rather than a two-way process; and these terms may also carry the connotation of agencies as being active in the process whereas affected groups are passive. A more appropriate terminology might use words such as "partners" or (particularly in the case of tribes) "co-managers." While these may seem small quibbles over a few words, these words frame the relationship among the various participants in the risk communication process, and may serve to undermine successful, two-way communication before the process even gets off the ground.

Then, it is necessary to put into practice the concept of "partnership" or of "co-management." *Affected groups must be involved as partners or co-managers at every point in*

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[349]Proceedings from the National Risk Communication Conference. May 6-8, 2001. Chicago, IL. Sponsored by the Minnesota Department of Health, US. EPA and the Society Risk Analysis. EPA Cooperative Agreement Grant #X-82825101-0. August 2001. Available on line at http://www.epa.gov/ost/fish/forum/riskconf.pdf.

[350]U.S. Environmental Protection Agency, *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*, *Volume IV: Risk Communication* 3 and throughout (1995).

[351]Id; see also, *National Risk Communication Conference, Proceedings Document* I-5 (2001)(describing "Risk Communicator Presentation session, which described "getting to know the audience from the risk communicator's point of view.")

the risk communication process. This is the single most important lesson that EPA and other agencies should take away from this discussion of effective fish consumption advisories. All of the elements of effective fish consumption advisories will fall into place if agencies and affected communities or tribes consider together the questions and answers. That is to say, communities and tribes will articulate their needs; affected groups and agencies will each share their respective concerns; affected groups will help ensure that the content and medium of advisories are appropriate to their membership (e.g., in terms of language, literacy, culture, practice); affected groups will be able to contribute creative implementation strategies appropriate to their membership; and affected groups will have knowledge indispensable to the evaluation process. As in the case of research in general (discussed in Chapter One), communities and tribes have expertise relevant to risk communication that is simply not going to be able to be replicated by non-member researchers. This is supported by the large body of literature on "participatory research." Members of these affected groups ought to be recognized as the experts they are, and their work ought to be supported financially (whether though dispensing grants to community groups, tribes, and partnerships formed by affected groups, through hiring affected group members as expert consultants, or through other means). EPA and other agencies should recognize the difficulty of achieving full involvement – and thus actual risk communication – in the absence of financial support. This issue of funding is taken up at greater length below.

EPA and other agencies should work to reconceptualize risk communication approaches from large-scale, abstracted, one-time efforts to develop and disseminate various communication "products" (e.g, developing and posting fish consumption advisory signs) to local, contextualized, ongoing efforts to establish and maintain relationships with a particular affected community or tribe.[352] While this reconceptualization may be necessitated to a greater degree for some groups and contexts than others, the existence of an ongoing relationship will enhance communication regardless. And, while building and maintaining a relationship will likely require more time and resources than agencies have typically been able to devote to risk communication,[353] the dividends would seem to be worth it. For example, representatives of agencies and affected groups alike have suggested that a lack of familiarity or trust has been a barrier to effective fish consumption advisories in the past (resulting, e.g., in a reluctance by affected group members to participate in baseline consumption rate studies or other information-gathering efforts; or in a scepticism on the

[352]See, e.g., Telephone Interview, Diana Lee, Research Scientist, California Department of Health Services (Oct. 26, 2001)

[353]See, e.g., Ed Horn, Bureau of Toxic Substance Assessment, New York State Department of Health, National Risk Communication Conference II-25 (2001) ("The most effective ways of communicating with hard-to-reach populations are extremely labor intensive. They are going to require someone in the target community who has the respect of the community and an understanding of the community. It requires constant work; it's not just a matter of sending a brochure out. We can send 20,000 brochures out fairly easily and inexpensively, but if we have to travel to meet with the target population in small groups, then this requires additional staff.").

part of affected groups regarding the intent behind or the accuracy of agencies' messages).[354] To the extent this is the case, the existence of an ongoing, regular relationship would go far toward dismantling this barrier.[355] The importance of gaining trust and building a good relationship bears emphasis. Affected groups often cite agencies' lack of "follow through" as a source of mistrust. Chee Choy, Project Manager for the Columbia Slough Sediment Project, Bureau of Environmental Services, Portland, Oregon, elaborates:

> *After an agency has made a commitment to addressing environmental justice by committing the necessary resources, the next step perhaps is to work on gaining trust and credibility with ethnic minority, immigrant, and low-income communities. . . . Among these communities, there is a severe lack of trust that government will listen to or take care of their concerns.*
>
> *Many immigrant and low-income communities place a strong emphasis on quality relationships. They need to know you care, are sincere, have* their *interests in mind (as opposed to your agency's interest) and there is follow-through on your commitments. These relationship features do not come about in a short term, but rather must be developed over time. So, if your agency's outreach staff visits a community group only when you need their help, your commitment to that community may be seen as tokenism or serving your needs. One way to develop and maintain a long-term relationship is to have regular – perhaps once a month or a quarter – meetings (these could be over coffee, breakfast or lunch) or to pay routine visits to [a community group's] office, even when there is nothing you need their help on. During these visits, once must show genuine interest in the community group's activities, and where appropriate, find out if there are ways you can help them in some of their activities, even if those activities do not directly pertain to your project's objectives.*[356]

To this end, several affected groups have recommended partnering with existing community groups and local service providers. For example, Hawaii's Thousand Friends urges:

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[354]See, e.g., Ed Horn, Bureau of Toxic Substance Assessment, New York State Department of Health, National Risk Communication Conference II-23-25 (2001); Telephone Interview, Chee Choy, Portland Bureau of Environmental Services (Oct. 26, 2001); Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 36 (1998).

[355]See, e.g., Telephone Interview, Chee Choy, Portland Bureau of Environmental Services (Oct. 26, 2001); Telephone Interview, Diana Lee, Research Scientist, California Department of Health Services (Oct. 26, 2001).

[356]Chee Choy, Project Manager, Columbia Slough Sediment Project, Bureau of Environmental Services, City of Portland, Oregon, *Comments on the NEJAC Draft Fish Consumption Report* 4 (Feb. 1, 2002) (The commenter notes that the comments are "based on my personal experiences and opinions as a first-generation immigrant working as a Project Manager for the Bureau of Environmental Services, City of Portland, on the Columbia Slough Sediment Project in Portland, Oregon. This statement does not necessarily reflect the opinions of the City of Portland.").

To best reach Hawaii's diverse multi-ethnic and indigenous Native Hawaiian populations about the risk of fish consumption, we recommend the following: Work through existing community health centers since they have existing outreach infrastructure. This is especially true for health centers in communities with a predominantly Native Hawaiian population and Hawaiian homestead communities; . . . Form partnerships with organizations that work with the same nationality and culture as those targeted, using grants and technical assistance . . . [357]

Again, this relationship cannot happen without the involvement of communities and tribes; to facilitate this involvement, financial support will often by critical.

In order to realize actual communication – that is, a *process* of respectful information *exchange* – agencies, in particular, need to work to enhance their skills as active, flexible, and open listeners. Relevant information may come in unexpected or non-conventional forms – in anecdote rather than empirical study, in a conversation rather than in an article in a peer-reviewed journal, in a narrative (such as the narratives gathered in this Report) rather than in a table or chart, or in an indirect or non-verbal form, rather than bluntly and directly. In many cases, these may indeed be the sources of the most valuable information.[358] Chee Choy, Project Manager for the Columbia Slough Sediment Project, Bureau of Environmental Services, Portland, Oregon, offers one such example:

In some traditional Asian cultures, and perhaps in other cultures as well, feedback may be communicated in indirect ways (e.g., reading between the lines, so to speak) because it is seen as impolite to disagree with you, or that giving you an honest but negative comment may mean a loss of face for you. This is where having built a relationship with a community will help you to identify verbal and non-verbal cues about an indirect comment and to seek an honest comment that you can understand.[359]

[357]Hawaii's Thousand Friends (Written Comments, March 11, 2002); accord, id. (noting that "the City of Portland has been contracting with the International Refugee Center of Oregon (IRCO) and the Hispanic Access Center to hire people who are from the Russian, Southeast Asian, and Hispanic communities to conduct fish advisory outreach to their respective communities.").

[358]See, e.g., Katharine J. Hornbarger, et al., *Targeted Audience Analysis: Recommendations for Effectively Communicating Toxic Fish Consumption Advisories to Anglers on the Detroit River* 14-18 (June, 1994) (discussing considerable benefits of "conversational interviewing" techniques).

[359]Chee Choy, Project Manager, Columbia Slough Sediment Project, Bureau of Environmental Services, City of Portland, Oregon, *Comments on the NEJAC Draft Fish Consumption Report* 5 (Feb. 1, 2002) (The commenter notes that the comments are "based on my personal experiences and opinions as a first-generation immigrant working as a Project Manager for the Bureau of Environmental Services, City of Portland, on the Columbia Slough Sediment Project in Portland, Oregon. This statement does not necessarily reflect the opinions of the City of Portland.").

Often, this approach will not be easy. Not only will it take time – time to sit down and visit, time to ask further questions in order to understand – but also real work.[360] There may be language barriers to hurdle, differences in communication styles to decipher and address, large cultural differences to bridge. "Public comment periods" or "breakout sessions" may not provide useful avenues for conversation from everybody's perspective. Similarly, public meetings held in hotels or convention centers may not provide a very familiar, welcoming or accessible (e.g., by walking or using public transportation) site for many from affected groups.[361] Sometimes, where the participants in a conversation come from radically different cultures or start with radically incompatible worldviews, there may never be complete understanding. But even if there are glimpses of understanding, the process itself is important (e.g., to building good relationships). Moreover, if the conversations are ongoing, understanding is likely to increase over time. For example, Josee Cung, Program Manager, Southeast Asian Program, Minnesota Department of Natural Resources, describes a collaborative effort with the Minnesota Department of Health and community leaders to design and implement culturally appropriate education regarding consumption of contaminated fish, which includes "education delivery" methods such as:

> • *[Sessions in] anglers' homes, as a version of the storytelling tradition and often involving elders*
>
> • *Day field trips that include bus travel to fishing sites, the education component followed by a hands-on session of actual fishing and fish cutting and preparation*
>
> • *Several sessions have ended with a communal meal of the caught fish prepared jointly by instructors and students*
>
> • *All activities are planned and take place under community sponsorship. Heads of community organizations promote and publicize the educational sessions and work with [the Department of Natural Resources] to recruit and enroll participants*[362]

Agencies not only need to hear information that comes to them in unexpected forms, but also need to be open to information that provides unexpected substance. Agencies should work

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[360]See, e.g., Kerry Kirk Pflugh, Bureau Chief, Raritan Watershed, Division of Watershed Management, New Jersey Department of Environmental Protection, *National Risk Communication Conference, Proceedings Document*, "Community Outreach to At-Risk Urban Anglers: A Case Study in Risk Communication of Fish Consumption Advisories" II-36 (2001) (noting, among the "lessons learned:" "Be flexible, take time to visit, listen, and learn.").

[361]See, e.g., Chee Choy, Project Manager, Columbia Slough Sediment Project, Bureau of Environmental Services, City of Portland, Oregon, *Comments on the NEJAC Draft Fish Consumption Report* 5 (Feb. 1, 2002) (The commenter notes that the comments are "based on my personal experiences and opinions as a first-generation immigrant working as a Project Manager for the Bureau of Environmental Services, City of Portland, on the Columbia Slough Sediment Project in Portland, Oregon. This statement does not necessarily reflect the opinions of the City of Portland.").

[362]Josee N. Cung, Program Manager, Southeast Asian Program, Minnesota Department of Natural Resources, National Risk Communication Conference, Proceedings Document, II-52-53 (2001).

to accept information they don't (yet) know they need – e.g., the answer to the question that the member of an affected group *wishes* the agency had asked (because this is what is most important from her perspective), the community- or tribally- developed research agenda that frames the issues differently than the agency would. Agencies should work to take in (and redirect if necessary) information that appears to pertain to a related but different program or agency. Thus, in the context of fish consumption advisories, those in environmental agencies' fish advisory programs should work together with those in their water quality standards and clean up programs to ensure that the comments they hear – e.g., "clean up existing contamination so that advisories can be lifted" – get registered with those in relevant programs *as well as with those setting priorities among programs and efforts*. Similarly, those in health agencies should work together with those in environmental agencies to ensure that such comments get passed along and that there is a connection between relevant staff working to address the issues.[363] While it is never easy to hear information that may require one to reevaluate current priorities, methods, or approaches, this reevaluation may be the key to efforts that are defensible as a matter of science and social science, acceptable from the perspective of communities and tribes, and, ultimately, effective as a matter of risk communication.

Involvement by affected groups is necessary as well because they, ultimately, are the ones who will bear the brunt of harms from contamination not addressed and communication not achieved. They, among all "stakeholders," are the ones who face the most immediate and often irreversible losses – it is not just a matter of being out a few dollars on the profit side of the ledger but a matter of their health and the health of their children, a matter of their culture, traditions, and deeply-held beliefs. Given what is at stake for affected communities and tribes, they should be among the first to learn about contamination and its possible effects for them, and they should be among the first involved in determining how to respond. Richard Brown, Coordinator, Black United Front explains, in the context of the low-income and largely African American community in Northeast Portland, Oregon that fishes in, swims in, and is affected by the contaminated Columbia Slough:

> *The things that happen to people are devastating. You know you don't recover from a lot of these things because we don't find out about them until they've really taken its toll. Those are concerns I've always had about the way people in low-income communities have been treated as fare as environmental issues go."*[364]

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[363]Richard Greene, Delaware Department of Natural Resources and Environmental Control, for example, notes that Delaware is undertaking efforts to link fish advisories and water quality standards under the CWA's TMDL program, but comments that "state [water quality standards] program participants need to acquaint themselves with their fish advisory program counterparts and start a serious dialogue. They also need to establish common goals; improving water quality and lifting advisories can result from agency cooperation." *Proceedings of the National Forum on Contaminants in Fish* I-13 (2001).

[364]Videotape: The Water in Our Backyard (City of Portland, Bureau of Environmental Services).

Ticiang Diangson, Supervising Planning and Development Specialist and Environmental Justice Advocate, Seattle Public Utilities, observes:

> *[I]t takes inordinate effort on the part of harmed communities to gain acknowledgment of the impact of the contamination and to get real-life implementation to solutions to the impact.*

To the extent that research is conducted by and for communities and tribes, it can serve the additional important function of capacity building. This goal is important and an issue of environmental justice in and of itself, for both communities and tribes. And, to the extent that communities and tribes see that their concerns are shaping the research to be conducted, that the information gathered will be relevant from their perspective, and that their members stand to enhance their skills, knowledge and capacity in the process – as opposed to merely providing information that enables others to enhance *their* skills, knowledge and capacity – participation and trust are likely to be increased, and accuracy thereby enhanced.[365]

As noted in Chapter One in the context of research in general, funding is crucial to the ability of affected communities and tribes to be involved in research, including research about risk communication. This point is elaborated below, in Section 7.

Finally, it is important to note that there are considerable resources on which EPA and other agencies interested in improving risk communication with affected groups can draw – resources that have been developed by or with the involvement of communities of color, low-income communities, tribes, and other indigenous peoples. Rather than attempt to repeat their work here, this Report refers to several of these sources: the National Environmental Justice Advisory Council Public Participation Plan; the National Environmental Justice Advisory Council Indigenous Peoples' Subcommittee, Recommendation on Environmental Health and Research Needs Within Indian Country and Alaska Native Villages; the Outreach Strategy developed as a part of EPA's Asian American and Pacific Islander Initiative; and the (Draft) Strategy on Limited English Proficiency.

2. Different Communities and Tribes, Differing Concerns and Needs

The term "affected groups" here includes a large and diverse array of groups, each of which consumes and uses fish, aquatic plants, and wildlife in differing cultural, traditional, religious, historical, economic, and legal contexts. It will be crucial for any risk communication effort to recognize, therefore, the diverse contexts, interests, and needs that characterize affected

[365]See, e.g., id. at 37 (noting that the survey planning team made connections with the Laotian Organizing Project's ongoing capacity building efforts regarding community health and safety, which motivated many community members to participate in the survey and explaining: "The planning team was originally hesitate about the perception commonly held by community members of outsiders taking information from the community without community people seeing the benefits of research. Linking the survey to a community based organization helped counter this perception.").

groups, including but not limited to groups with limited English proficiency; groups with limited or no literacy; low-income communities; immigrant and refugee communities; African-American communities, various Asian and Pacific Islander communities and subcommunities (e.g., Mien, Lao, Khmu, and Thaidum communities within the Laotian community in West Contra Costa, CA); various Hispanic communities and subcommunities (e.g., Caribbean-American communities in the Greenpoint/Williamsburg area of Brooklyn, NY); various Native Americans, Native Hawaiians, and Alaskan Natives (including members of tribes and villages, members of non-federally recognized tribes, and urban Native people). "Affected groups" also refers to subgroups within these larger groups, including but not limited to nursing infants; children; pregnant women and women of childbearing age; elders; traditionalists versus modernists in terms of practices that implicate fish consumption; and subgroups defined by geographical region.

EPA and other agencies have increasingly recognized this diversity and its relevance to fish consumption advisories and other risk communication efforts. For example, EPA, in particular, has recognized the diversity of Asian and Pacific Islander communities, and provides an "Asian American and Pacific Islander Primer" on its Asian American and Pacific Islander Initiative website.[366] This primer identifies Asian Americans as those with origins in one or more of 28 Asian nations, and Pacific Islanders as those with origins in one or more of 19 island nations.[367] EPA has undertaken a number of efforts as part of this initiative that attend to the diversity of this group.[368] Important among these efforts is an extensive Outreach Strategy.[369] Nonetheless, EPA and other agencies need to do more to attend to the myriad groups and subgroups affected by their work. Agencies' efforts, moreover, have been uneven, such that there are some groups and subgroups about which EPA and its counterparts still know relatively little. It should be noted, too, that the composition of the affected groups may be changing rapidly in some areas, such as cities that are ports of entry for immigrant and refugee groups or rural and other areas where particular groups have settled.[370] Thus ongoing and constant efforts are necessary to learn about and attend to the changing contours of affected groups and subgroups. These efforts are most usefully undertaken together with the affected groups themselves, who will often be able to alert non-members to nuances about which they would otherwise not have knowledge. Even laudable agency efforts to identify and address the needs of a non-majority group may be partial to the extent that they fail to appreciate the existence of other affected groups or subgroups. The

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[366]U.S. Environmental Protection Agency, *Asian American and Pacific Islander Primer* available at www.epa.gov/aapi/primer.htm.

[367]Id.

[368]These efforts place EPA at the forefront of federal agencies in implementing Executive Order13216 (and its predecessor) on Increasing Opportunity and Improving Quality of Life of Asian Americans and Pacific Islanders.

[369]U.S. Environmental Protection Agency, Office of Administration and Resource Management, *Asian American and Pacific Islander Outreach Strategy*. (No. EPA-202-K-01-003) (September 2001) available at www.epa.gov/aapi/outreach.htm.

[370]See, e.g., Kerry Kirk Pflugh, Bureau Chief, Raritan Watershed, Division of Watershed Management, New Jersey Department of Environmental Protection, *National Risk Communication Conference, Proceedings Document,* "Community Outreach to At-Risk Urban Anglers: A Case Study in Risk Communication of Fish Consumption Advisories" II-32 (2001).

Laotian Organizing Project points, for example, to a state fish consumption warning sign at a popular fishing site in Richmond, CA written in English, Spanish, and Vietnamese and notes:

> *The Vietnamese language translation is useless to a predominantly Laotian population.*[371]

These different groups are likely to differ with respect to their concerns and needs relevant to risk communication. This is a crucial point. The risk communication literature, including Volume 4 of EPA's *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*, describes "needs assessment" or determining "what the audiences want and need to know" as an initial step in the risk communication process.[372] The answer to this question is likely to differ in important respects from group to group, and even from subgroup to subgroup. *The best – if not only – way to determine the concerns and needs of a particular group is to secure the involvement of group members in the process.* This involvement is crucial at every point in the risk communication process. It is especially important at the point of needs identification, if the resulting advisories and other communication efforts are to be relevant to the group – and if they are to be perceived by the group as being relevant.

The importance of affected group involvement at the point of identifying needs and defining a research agenda has been echoed by numerous communities and tribes. For example, consider the account of recent efforts by the Alaska Native Science Commission to this end as part of the Traditional Knowledge and Contaminants Project, by Pat Cochran, Executive Director:

> *The project objectives are, first of all, to use our own native ways of knowing, learning, and teaching to gather information. We held our own talking circles in our own communities. We did not send out survey forms. We didn't have people that had focus groups. We went and sat with our people for days at a time – laughing, singing, dancing, and eating a lot of food – because this is a part of what we all do. So, we could really gain the knowledge from our communities. Our communities, we understand, are the first observers of what happens on our land, to the people, in the air, in the water, and in the environment around us. Long before a researcher or scientist or anyone else enters the community, our people are the ones who perceive what happens every day, and also generationally over centuries and beyond from information that has come down from their people. We [are] providing grant opportunities to our communities and we are looking at developing a common research agenda that answers concerns and questions about our communities and not just somebody's Ph.D. dissertation topic. And we are also developing a database. We held regional meetings all across the state of Alaska*[373]

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[371]Laotian Organizing Project, *Fighting Fire with Fire* 5 (2001).

[372]See, e.g., *National Risk Communication Conference, Proceedings Document* 14 (2001); U.S. Environmental Protection Agency, *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*, *Volume IV: Risk Communication* 3 (1995).

[373]Patricia Cochran, Executive Director, Alaska Native Science Foundation, *National Risk Communication Conference, Proceedings Document* II-20 (2001).

3. Message Content

What constitutes appropriate and relevant message content is likely to differ from group to group. General, "one-size-fits-all" recommendations, therefore, are likely to be unuseful. Rather, the important point is that content that is appropriate and relevant to a particular affected group cannot be determined apart from the involvement of members of that group. In addition to local knowledge, group members will often have extensive expertise in message development and community outreach for their particular community or tribe. Their involvement in every aspect of content development and advisory design is indispensable.

Several considerations are relevant. Advisory content should be culturally appropriate from the perspective of the particular affected group or subgroup. As documented in Part A., above, it may be culturally inappropriate to include various recommendations – to eliminate or reduce fish consumption, or to alter practices including procurement of fish, species and parts consumed, and preparation methods. Here, there are likely to be vast differences among affected groups as to what is and is not acceptable. Advisory content thus needs to be developed in a manner that is respectful of these differences. Involvement by members of the particular affected group is, again, crucial.

Advisory content should address the needs identified by the particular affected community. This should include the needs of any subgroups within the larger group, such as nursing infants; children; pregnant women and women of childbearing age; elders; traditionalists versus modernists in terms of practices that implicate fish consumption; and subgroups defined by geographical region. Other needs, too, may emerge as important to a particular group. For example, according to the summary of the important themes that emerged from the breakout group designated "Cultural Enclaves – Native American and Other Cultural and Traditional Communities:"

> *Fish advisories should contain information on the nature and sources of the contamination so that the affected community is empowered to take action to reduce pollution source and clean up existing contaminated sites or obtain financial compensation for the loss of the natural resources.*[374]

To address the needs of some affected groups, advisories should emphasize the health and cultural benefits of eating fish or of participating in particular practices.

Advisories should be provided in the language(s) of the affected communities, groups, or peoples. Many members of affected groups are limited-English proficient; some, especially recent immigrants and refugees, may have no English. For example, EPA reports that "[a]n estimated 40-50% of [Asian American and Pacific Islanders] are limited-English proficient."[375] Many agencies have recently worked to provide language-appropriate warnings (perhaps as a result of

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[374] *National Risk Communication Conference, Proceedings Document* I-11 (2001).

[375] U.S. Environmental Protection Agency, *Asian American and Pacific Islander Primer* available at www.epa.gov/aapi/primer.htm.

studies showing a particular group's lack of awareness of advisories, as was the case on the Lower Fox River, where Wisconsin recently posted signs in English and Hmong), and there has been considerable progress in this regard. For example, Chee Choy, Project Manager for the Columbia Slough Sediment Project, Bureau of Environmental Services, Portland, Oregon, recounts the challenges and ultimate success – in important part because of the partnership between the City and the various affected groups – of one such effort:

> *A committee comprising people from various community organizations (such as [Environmental Justice Action Group] EJAG, [International Refugee Center of Oregon] IRCO, Urban League, Coalition of Black Men, Lutheran Family Services Center, Russian Oregon Social Services, Confederated Tribes, etc.) helped the City of Portland to rewrite the technical fish advisory brochure originally written by the Oregon Health Division. This process was challenging because of the differences in opinion among the various communities regarding the usage of appropriate words in the advisory. While many committee members did not object to literally translating the word "DANGER," which was stamped across a picture of a carp, into their respective languages, the Russian community representatives strongly insisted on using "CAUTION" rather than "DANGER." After much deliberation, the committee reached a compromise to use the word "CAUTION" [and translate the advisory into six appropriate languages].*[376]

Even where agencies have made progress, however, they may have yet to identify and address the needs of all the relevant communities for language-appropriate advisories. Recall the Laotian Organizing Project's dismay when a state fish consumption warning sign at a popular fishing site in Richmond, CA was written in English, Spanish, and Vietnamese: "*The Vietnamese language translation is useless to a predominantly Laotian population.*"[377] Similarly, Hawaii's Thousand Friends recommends that agencies:

> *Partner with local groups in Hawai'i to create information sheets/brochures in the Hawaiian language for distribution in immersion schools.*[378]

Advisories should be designed to account for limited literacy or illiteracy in the affected group. Some groups come from a tradition of orality.[379] They may not have a written language or may not be literate in their language to the extent it has been written down. Or they may be

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[376]Chee Choy, Project Manager, Columbia Slough Sediment Project, Bureau of Environmental Services, City of Portland, Oregon, *Comments on the NEJAC Draft Fish Consumption Report* 5 (Feb. 1, 2002) (The commenter notes that the comments are "based on my personal experiences and opinions as a first-generation immigrant working as a Project Manager for the Bureau of Environmental Services, City of Portland, on the Columbia Slough Sediment Project in Portland, Oregon. This statement does not necessarily reflect the opinions of the City of Portland.").

[377]Laotian Organizing Project, *Fighting Fire with Fire* 5 (2001).

[378]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

[379]See, e.g., id. ("The Native Hawaiian culture is an oral culture, so written information sheets and/or brochures will not always reach the intended audience, and more culturally sensitive methods should be developed.").

resistant to reducing communication to writing, preferring instead to give and receive information orally. Some groups have had less formal education, such that some of their members may be illiterate. In all of these cases, advisories should not rely on written words, but on devices such as spoken words, demonstration, or graphics.

Advisories should be accessible. They should use words that are understandable to the particular affected group; they should avoid jargon. To the extent possible, they should use short, manageable sentences. They should employ visual aids such as charts, pictures, models, posters, and hands-on demonstrations. Kristine Wong, the former Project Director of the Seafood Consumption Information Project, which focused on "conducting community-based research, education, outreach, and advocacy on the issue of contaminated fish consumption in San Francisco Bay," observes:

> *[M]any terms used frequently in health warnings need to be changed to reflect the common language of those who fish for food. For example, the term "sportfish" is used in the San Francisco Bay health advisory, yet those who catch and eat bay fish do not interpret the term "sportfish" as the fish that they themselves consume on a regular basis. During our regular visits to the fishing piers we conducted an informal survey to see if people actually understood that "sportfish" applied to all the fish that were being caught in the bay. Most interpreted the term "sportfish" to be the jumbo-sized fish caught on fishing boats, confirming our suspicions.*[380]

As Hawaii's Thousand Friends urges:

> *Use the local name of the fish in any outreach.*[381]

Although, in order to be sufficiently informative, advisories will need to convey complex information (e.g., about risk, contaminants' health effects, sources of contamination), there are more and less accessible ways to do this. Daisy Carter, Project AWAKE, Coatopa, Alabama, explains:

> *We believe enough books, pamphlets, policies, and manuals have been written. We have become a paper-filled society to the limit. But the question is, who is reading this material? Most people and especially the impacted communities do not take the time to read these large manuals; yet this is the method EPA and states use to get their information out. This is not the best approach to reach these communities. When asked what is being done, the reply is, "well, we have this book." What is the problem? Document upon document, volume upon volume is available, waiting to be read and complied with."*

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[380]Kristine Wong, Former Project Director, Seafood Consumption Information Project, *Comments to the National Environmental Justice Advisory Council* Vol III-65-67 (Annual Meeting Transcript) (Dec. 4, 2001).

[381]Hawaii's Thousand Friends (Written Comments, March 11, 2002).

Finally, advisories should be designed to facilitate the two-way exchange that is the hallmark of good risk communication. *Importantly, as many affected groups have noted, advisories need to make available information about the nature, extent, and sources of the contamination that is giving rise to the advisory.* Thus, at a minimum, they should include contact information for the appropriate agencies, tribal government bodies and/or community groups, so that there is a place to lodge comments, ask questions, or obtain further information. Posted signs, for example, often leave those affected with unanswered questions.[382] Advisories should also provide additional relevant information, including information about the nature, extent, and sources of contamination that would enable those affected to participate not only in risk communication efforts but also in risk assessment and risk management decisions. Joanne Bonnar Prado, of the Washington Department of Health, emphasizes just this perspective:

> *[O]ne of the things that I've learned . . . is that we need to incorporate really thoroughly issues of source and where the sources [of contamination] are coming from . . . We understand that, [but] we do not talk about it much within our – or at all within our – health communications about source and source reduction. . . . So supplying information about sources, source reduction that individuals and communities and governments and all the various strategies that can be used on a local, statewide, and worldwide basis to reduce mercury – and this would apply to really all contaminants I would think – is really appropriate for this particular issue.*[383]

4. Medium

What constitutes an effective and appropriate medium for conveying the message will vary from group to group. Sometimes, it will be most effective to try to reach people via multiple media routes. Again, general "one-size-fits-all" recommendations are likely to be unuseful. Again, members of the affected group will possess valuable knowledge about the best medium from their perspective, and should therefore be involved in choices among media.

Several observations can be made. The medium chosen should take into account the habits and customs of the affected groups; it should take into account the access enjoyed by the affected groups. There has been some recent work identifying different media sources as more or less likely to be used or preferred by various affected groups.[384] For example, of those in the Laotian communities in West Contra Costa County who had heard of the health warning in place

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[382]See, e.g., John M. Cahill, Director, Bureau of Community Relations, New York State Department of Health, *National Risk Communication Conference, Proceedings Document* II-43-44 (2001).

[383]Joanne Bonnar Prado, Washington State Department of Health, *Comments to the National Environmental Justice Advisory Council* Vol III-13 (Annual Meeting Transcript) (Dec. 4, 2001).

[384]See, e.g., John M. Cahill, Director, Bureau of Community Relations, New York State Department of Health, *National Risk Communication Conference, Proceedings Document* II-45-49 (2001) (presenting an extensive assessment of the advantages and disadvantages of twelve different categories of media/formats for various audiences, and cataloging available community channels and potential partners).

for San Francisco Bay fish, nearly 60% had heard of it through television news, 37.8% though word of mouth from friends and family, 18.9% via signs at various piers, and 14.4% through the newspaper; others had heard of the advisory though church, a local community-based organization, school, the doctor's office, and the welfare office.[385] Many members of affected communities of color, low-income communities, tribes, and indigenous peoples do not have access to the Internet as a means of apprising themselves of current advisories posted on agencies' websites. According to John Cahill, Director, Bureau of Community Relations, New York State Department of Health:

> *Last year, 56 percent of Americans used the Internet. However, only 23 percent of African Americans had Internet access, compared to 46 percent of White households. A majority, 82 percent, of Americans earning $75,000 or more had access, compared to only 38 percent of those earning less than $30,000.*[386]

Some of those affected may not have a telephone, and so cannot readily call numbers listed on signs or in pamphlets. To the extent information is distributed by agencies or others who give out fishing licenses, Native Americans and others who are not required to obtain a license to fish will not receive information distributed in this way; neither will those who for any number of reasons simply haven't obtained a license. John Cahill points out, for example, that a recent survey of anglers along New York's Hudson River revealed that only 57.5% of them had licenses; and a series of focus groups among Latino anglers in Buffalo found that only about half of them were licensed.[387]

The medium chosen should make advisory information easy to locate and access. Some current advisories may require several steps to locate and access (e.g., the need to consult a fishery regulations book, as in Maine; the need to write to the Department of Natural Resources or to go to local offices or state parks (or on-line), as in Wisconsin; the need to sort through fairly complex information, as in Michigan), which steps impose greater hurdles for those whose educational background or financial resources do not afford them the tools to navigate governmental bureaucracies.

Here again, agencies are making strides although there is work yet to do, and agencies need to ask those affected what would work for them.

5. Implementation

Members of affected communities and tribes will often be particularly well-positioned to take the lead in implementing the advisory and outreach strategy that has been developed by and for their group. Members of affected groups will be active in or aware of community

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[385] Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 30 (1998).

[386] John M. Cahill, Director, Bureau of Community Relations, New York State Department of Health, *National Risk Communication Conference, Proceedings Document* II-43 (2001).

[387] Id. at II-42-43.

organizations, churches and other religious organizations, clubs, schools, and other entities that could play a role in getting the message out and facilitating risk communication. Members of affected groups will likely know precisely which community festivals, ceremonies, or events are likely to be well-attended and appropriate venues for outreach. For example, Detroiters Working for Environmental Justice not only prepared a pamphlet, together with the Lake Erie Binational Public Forum, directed at those eating fish from Lake Erie, the Detroit River, and the Rouge River, but they also work to distribute the pamphlet at local health fairs.[388] Members of affected groups will often be able to put together creative ideas for outreach – a product of their knowledge of norms in the community or tribe; their on-the-ground connections; their shared experience – especially, shared practices exposing them to environmental risks; and their involvement in prior organizing efforts.

Implementation by members of affected groups may also facilitate environmental justice along multiple dimensions. In addition to capacity-building, discussed below, looking to affected groups for implementation may enable them to dovetail efforts regarding fish consumption with other health and environmental outreach efforts (e.g., regarding possible contaminants in breast milk, regarding the value of Native foods in countering diabetes, or regarding nutrition in general) and/or other community-building efforts – efforts that may already be well-established, which would in turn enhance the likelihood that data about fish consumption practices would be complete and accurate, and that advisories regarding these practices would be received. For example, the Asian Pacific Organizing Network explains, in the context of its survey of Laotian communities in West Contra Country, California:

> *Active participation by community leaders who are recognized and respected in the community brings trust and credibility to a survey that could otherwise be seen as intrusive. In this survey project, community leaders made the initial contact with people in the community, explained the goals of the survey to participants, and answered any questions and allayed any fears that people may have. Such collaborative work helped establish important relationships between community leaders and APEN's Laotian Organizing Project (LOP) as a young, emerging organization within the community.*
>
> *Organizationally, APEN is committed to working with youth, in order to foster new leadership within the community. Therefore, 'survey teams' of youth and established community leaders carried out the survey together.*[389]

Agencies, together with affected groups, should consider shifting current approaches to outreach so that it is primarily grassroots, community-based organizations and groups that do the outreach in their respective communities. Where this is appropriate, these groups should be funded to take on this responsibility. For example, they could be hired as contractors to the

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[388]Telephone Interview with Michelle Shewmaker, Detroiters for Environmental Justice (Oct. 26, 2001); Detroiters Working for Environmental Justice and Lake Erie Binational Public Forum, *A Family's Guide to Eating Fish from the Detroit Area* (pamphlet).

[389]Audrey Chiang, Asian Pacific Environmental Network, *A Seafood Consumption Survey of the Laotian Community in West Contra Costa County, California* 8 (1998).

relevant agency. Or, they could receive grants to conduct this work. As Marianne Yamaguchi, Director, Santa Monica Bay Restoration Project, notes, some agencies and others in Southern California are already taking this approach, with benefits not only in terms of effective and appropriate implementation but also in terms of capacity building.[390] Funding and capacity-building are discussed further below, in Section 7.

6. Evaluation

Affected group involvement is critical to evaluating the success of risk communication efforts in general and consumption advisory programs in particular. This involvement is important at every point of evaluation, but is particularly necessary to evaluation in the early stages of risk communication (what *Volume IV* and the risk communication literature term "formative evaluation") and at the point of assessing whether the objectives of risk communication efforts have been met (what *Volume IV* and the risk communication literature term "summative evaluation"). Given the potential for differences in the definitions of "effectiveness" adopted by agencies and various affected groups – and the likelihood that differences in objectives would flow therefrom – it will be important for those affected to be able to ensure that *their* perspectives are being incorporated into any evaluations.

Affected groups will be able to work together with agencies to determine the extent to which it is useful to focus evaluation on particular "products" (e.g., number of radio spots, number of pamphlets distributed, numbers of health fairs visited), on outcomes indicating awareness (e.g., awareness of advisories' content and recommendations), on behavioral outcomes (e.g., extent to which consumption levels are reduced so that they fall within recommendations, extent to which species consumed changes from less safe to safer species, extent to which preparation methods change so that exposure to contaminants is avoided), or on more broadly crafted outcomes (e.g., increased knowledge within effective group of contamination, its sources, and related regulatory efforts, increased involvement by community members in decision making regarding risk from contaminated aquatic ecosystems, improved trust and enhanced relationships among agencies and affected communities and tribes, improved health in the affected group).

Agencies should ensure that "evaluation" includes assessment not only of the particular advisory program or outreach effort, but of its risk communication efforts more generally. Affected groups can usefully aid agencies in evaluating their risk communication efforts, and in evaluating connections between risk communication and risk assessment and management. For example, related to the issue of two-way communication, consider the question: How should agencies *register* the responses of those affected?[391] For example, if an affected group receives and understands the information contained in an advisory but nonetheless rejects its advice that fish consumption be reduced, how should this response be incorporated into agencies' policy choices regarding the role of fish consumption advisories? How, in the first place, should agencies ensure that they are correctly interpreting the responses of affected groups – have the

[390]E-mail Communication, Marianne Yamaguchi, Director, Santa Monica Bay Restoration Project (Oct. 23, 2001).

[391]Catherine A. O'Neill, *Risk Avoidance and Environmental Justice* (forthcoming).

practices remained the same because those affected do not understand the advisories; because they understand but do not believe or agree with the advisories' accounts of the contamination or its health effects; because they understand and in some sense agree with the advisories' accounts of the contamination or its health effects, but nonetheless cannot for economic and/or for traditional, cultural, or religious reasons change their practices? The need for "interpreters" from within the relevant community, group or tribe seems clear. And to the extent that those who decline to "comply" with advisories should be taken to be lodging a kind of protest – that is, to the extent that noncompliance itself should be taken as an expressive act, indicating resistence to agencies' reliance on risk avoidance rather than risk reduction[392] – how will this view be taken into account when agencies decide how much to rely on advisories versus how much to focus on cleanup and prevention?

Finally, agencies should ensure that "evaluation" includes vigilant and careful re-assessment of the health of the resources that are the subject of advisory or closure, so that they are opened again for fishing and advisories are lifted as soon as is appropriate. This may be a particular issue in the case of shellfisheries closed due to the presence of acute contaminants, whose short-term life span means that re-certification may be appropriate in fairly short order.[393] This is especially important given communities' and tribes' reliance on these resources for economic, subsistence, and other reasons. Of course, agencies will need to be sure that fish are safe for consumption before doing so, and this implicates current limitations in agencies' ability to measure the presence of contaminants. For example, current methods are unable to detect below certain levels for some persistent and bioaccumulative contaminants (e.g., dioxins) – yet even very small quantities may have an effect on human and environmental health. Thus, even if it can be said that contaminant levels in a particular river stretch have been reduced to non-detectable levels, this may not mean that they have been reduced to safe levels – only that current measurement methods are at their limit. To remedy this gap in agencies' ability to determine the safety of fish for human consumption, agencies need to conduct research to improve current measurement abilities. In the meantime, agencies need to inform affected groups of the detection limit issue (and other relevant issues) if an agency chooses to alter or lift advisories under such circumstances.

7. Funding and Capacity-Building

As noted above, capacity-building or capacity-augmentation is in and of itself an environmental justice issue, for both communities and tribes. Involvement by those affected at each point in the risk communication process would go far toward enabling those affected to shape the process so that it is not only relevant and appropriate, but also useful and empowering from the perspective of the community or tribe. In addition to the aspects of capacity-building discussed above, affected groups will be able to identify other, current needs in this regard.

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[392]Id.

[393]Telephone Interview, Jay Zischke, Marine Fish Program Manager, Suquamish Tribe (Oct. 17, 2001).

Among the issues that have been identified is the need to ensure that the fruits of its work are returned to the affected group. The information gathered – e.g., as part of baseline assessment of fish consumption rates and practices, as part of evaluation processes, or otherwise – needs to get back to the affected group for them to use for their own purposes. Hopefully, the involvement of the affected group from the outset of the process means that its needs have been identified and the results meet those needs. Nonetheless, the information may be valuable to the group in the longer term, as a foundation for other projects, as historical documentation of practices at a particular point in time, or for any number of reasons. In some cases, a community or tribe may want to be custodian of the information about their group, to ensure that they have some amount of control over the ends to which it may be put in the future. Whatever the reasons, it may be important to capacity-building and empowerment that the information about a particular group be returned to that group. Daisy Carter, Project AWAKE, Coatopa, Alabama, highlights communities' lack of empowerment when information is gathered *from* them, but not necessarily for and with them:

> *EPA knows all the problems that exist in every community, state and country. EPA is aware of what is wrong. They know who is impacted by the various contaminants and to what degree citizens are unfairly treated. They know what injustices are being done. They also impose fines upon various companies. It is the policy of these companies and EPA to keep citizens who are at risk seeking and searching for answers and assistance to eliminate their problems and suffering. EPA wants to keep citizens, people of color, and impacted communities talking and asking for help so that EPA can stay informed and keep abreast of the status of the burdens and injustices in these communities.*

In addition, as noted in Chapter 1 in the context of research in general, funding is crucial to the ability of affected communities and tribes to be involved in research, including research about risk communication. Although community and tribal members have considerable expertise to offer, they often have minimal or no funding to support their work. *To a person*, community members, tribal members, inter-tribal organization staff, and state and local agency representatives who work with affected groups stressed the importance of adequate funding. Diane Lee, a research scientist with the California Department of Health Services who has worked extensively with communities as part of the Palos Verdes Fish Contamination Outreach and Education Project and other studies in the San Francisco Bay area, is emphatic:

> *I cannot underscore enough the need to provide funding to affected communities so that they can participate fully in every aspect of the research process, from needs assessment to dissemination of the results. Funding, moreover, needs to be provided on an on-going, rather than one-time, basis.*[394]

Again, EPA and other agencies have often provided much-needed support. For example, the EPA's Office of Water, together with Minnesota's Department of Health, recently sponsored the National Risk Communication Conference to bring together representatives of federal, tribal,

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[394]Telephone Interview, Diana Lee, Research Scientist, California Department of Health Services (Oct. 26, 2001).

state, and local health and environmental agencies, affected communities, tribes and Alaskan Native villages, and other interested in risk communication about contaminated fish. Importantly, EPA secured funding for several community, tribal, and village representatives who otherwise likely would not have been able to attend. This was an impressive undertaking that produced a rich exchange – and a source of information and experience that should continue to advance deliberation in this area. EPA also recently gave a small grant to the California Department of Health Services "to explore and develop methods of communicating with diverse communities about fish contamination issues" in San Francisco Bay, which CDHS was able to turn around and share with community organizations working on the issue.[395] As California Department of Health Services explains:

> *Our participatory approach aims to build local partnerships through collaboration with community-based organizations (CBOs) and local agencies that serve fishing populations. A limited number of stipends will be provided to selected groups to assist them in developing and pilot testing educational materials or activities.*[396]

Affected communities and tribes have commended EPA's efforts to this end.

However, they noted that the need for funding to enable communities and tribes fully to be involved in research and decisions affecting risk assessment, management, and communication far outstrips the funding that has been so far made available. Funding needs to be regularized and allocated as a part of agencies' budgets, so that affected groups can be assured on-going support for their efforts (rather than piecemeal or one-time funding). The participation of community groups is vital to the success of agencies' risk communication efforts; agencies should not count on community groups to donate their time and expertise when others important to risk communication efforts (e.g., agency staff and contractors) are compensated and supported. Among other things, agencies should contract with grassroots community groups to undertake outreach – these groups will be uniquely positioned to provide this service to agencies and they should be compensated for doing so. Agencies should also combine financial support with technical and other in-kind support. Here again, agencies and affected groups can be creative, as some have demonstrated. For example, as part of its Palos Verdes Fish Contamination Outreach and Education Project, California Department of Health Services held a free "train the trainer" workshop for community-based organizations, agencies, and others, during which participants were trained in conducting their own educational programs for fishing populations.[397] After the

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[395]California Department of Health, Environmental Investigations Branch, *San Francisco Bay Fish Consumption Outreach and Education Project* (factsheet available from California Department of Health Services).

[396]Id.

[397]California Department of Health, Environmental Investigations Branch, *Palos Verdes Shelf Outreach and Education Project on Fish Contamination Issues* (factsheet available from California Department of Health Services).

training, community-based organizations received a stipend to develop and implement a pilot educational activity for the community they serve. The type of activity was determined by the community-based organization and included a wide range of activities (e.g., organizing a table at a health fair, conducting a workshop, putting together a media kit).[398]

[398] Id.

CHAPTER IV: AMERICAN INDIAN TRIBES AND ALASKAN NATIVE VILLAGES

In determining how EPA should improve the quality, quantity, and integrity of aquatic ecosystems, what special considerations should EPA take into account when protecting the health and safety of federally recognized tribal governments and their members?

American Indian tribes and Alaskan Native villages and their members ("AI/ANs") share many of the concerns explored in the preceding chapters. However, the particular circumstances of AI/ANs also warrant separate discussion. Tribes' political and legal status is unique among affected groups. Tribes are governmental entities, recognized as possessing broad inherent authority over their members, territories and resources. As sovereigns, federally recognized tribes have a government-to-government relationship with the federal government and its agencies, including the EPA. Tribes' unique legal status includes a trust responsibility on the part of the federal government. For many tribes, it also includes treaty rights. Other laws and executive commitments, too, shape the legal obligations owed to AI/AN tribes and villages and their members.

There are some 556 federally recognized tribal governments in the United States, including 223 Alaska Native villages.[399] At the time of the 1990 census, about 1.9 million AI/ANs lived in the United States.[400] In 1993, the Bureau of Indian Affairs estimated that 1.2 million AI/ANs lived within Indian country on lands reserved for their tribes as permanent homelands.[401] "Indian country," which includes reservations, dependent Indian communities, and Indian allotments, comprises approximately 53 million acres of land, much of which is found in remote areas of the nation.[402] The remaining AI/ANs live in urban areas and comprise a growing segment of the Native population.

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[399]"Federally recognized" means that these tribes and groups have a special legal relationship with the United States. Additionally, a number of tribes and indigenous groups do not have federally recognized status, although some of these tribes are state-recognized or are in the process of seeking federal recognition.

[400]AI/ANs are among the fastest growing ethnic/minority populations in the nation. The 1990 census showed a 37.9% increase over the population of AI/ANs in the 1980 census. For additional facts and general information, see the Bureau of Indian Affairs' homepage at www.doi.gov/bia/aitoday/q_and_a.html.

[401]For additional facts and general information, see the Bureau of Indian Affairs' homepage at www.doi.gov/bia/aitoday/q_and_a.html.

[402]The term "Indian country" is defined by federal law as including "(a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights of way running through the reservation, (b) all dependent Indian communities . . . and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same." See 18 U.S.C. § 1151.

Part A of this chapter outlines the legal status of AI/ANs. Part B of this chapter addresses the particular issue of treaty rights. Part C of this chapter outlines issues particular to Alaska Natives. Finally, Part D examines tribes' susceptibilities and co-risk factors; while some of these will also be applicable to other affected groups, the particular combination discussed here is unique to AI/ANs.

A. LEGAL STATUS

Federally recognized Indian tribes possess a unique political and legal status that distinguishes them from all other ethnic and minority groups in the United States. Although subject to applicable federal law, tribes have long been recognized as separate sovereigns possessing broad inherent authority over their members and territories. As governments, the relationship between federally recognized tribes and the federal government is described as "government-to-government" and, in 1994 and 2000, President Clinton explicitly directed each federal agency to operate within this relationship[403] and to maintain it through meaningful consultation and coordination with tribes.[404] Among other things, the government-to-government relationship means that federal agencies may not treat Indian tribes as "interest groups" or simply as part of the general public.

The cornerstone of the government-to-government relationship is the federal government's trust responsibility to federally recognized Indian tribes to protect their status as self-governing entities and their property rights. The trust responsibility is based on treaties, statutes, executive orders, and the historical relations between the federal government and tribes. In practice, the trust responsibility gives rise to distinctive fiduciary obligations on the part of federal agencies that must be "exercised according to the strictest fiduciary standards."[405] The United States Supreme Court has stated that federal officials are "bound by every moral and equitable consideration to discharge the federal government's trust with good faith and fairness" when dealing with tribes.[406]

Also related to the trust doctrine is Congress' plenary power over Indian affairs. Under the plenary power doctrine, the federal government is vested by the Constitution with exclusive authority over relations with Indian tribes.[407] Because the power of Congress is exclusive, states

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[403]See Executive Memorandum on Government-to-Government Relations with Native American Tribal Governments (Apr. 29, 1994).

[404]See Executive Order No. 13084 (May 14, 1998). On November 6, 2000, President Clinton issued a new order strengthening the policy on tribal consultation. See Executive Order No. 13175 (Nov. 6, 2000).

[405]Nance v. Environmental Protection Agency, 645 F.2d 701, 710 (9th Cir. 1981).

[406]United States v. Payne, 264 U.S. 446, 448 (1924).

[407]See Morton v. Mancari, 417 U.S. 535 (1974).

generally lack authority over Indian tribes and tribal members within Indian country, unless Congress has expressly delegated that authority to states.

Due to the special legal status of tribes, and because the jurisdictional rules applicable to Indian country left EPA unable to pursue its usual practice of delegating primary enforcement responsibility to states that so request, EPA developed special regulations and policies concerning environmental regulation on Indian reservations and the role to be played by tribal governments. On November 8, 1984, EPA adopted a formal policy, the "EPA Indian Policy for the Administration of Environmental Programs on Indian Reservations" ("Indian Policy"). The Indian Policy sets forth nine principles by which the EPA will pursue its objectives including, but not limited to EPA's commitment to work with tribes on a government-to-government basis, to recognize tribes as the primary decision-makers for environmental matters on reservation lands, to help tribes assume program responsibility for reservations, to remove existing legal and procedural impediments to tribal environmental programs, and to encourage tribal, state, and local government cooperation in areas of mutual concern. Following the adoption of the Indian Policy, every EPA Administrator since has reaffirmed the principles set forth therein. Most recently, on July 11, 2001, EPA Administrator Christine Todd Whitman again reaffirmed the Agency's commitment to the Indian Policy.

A major goal of the Indian Policy is to eliminate statutory and regulatory barriers to the assumption of federal environmental programs by Indian tribes. As originally enacted, most of the federal environmental laws mentioned tribes or Indian reservations and none provided for direct participation by tribal governments. To date, however, tribal amendments to four major federal environmental laws--the Safe Drinking Water Act, Clean Water Act, Clean Air Act, and Comprehensive Environmental Response, Compensation, and Liability Act--have been enacted.[408] Despite these amendments and the Indian Policy, federal funding for tribal environmental programs and environmental enforcement within Indian country has been inadequate and inequitable, particularly in light of the billions of federal dollars spent on state environmental efforts over the last three decades. While funding for tribal programs has increased substantially in recent years, inadequate funding for tribal programs is considered by many to be an environmental justice issue and also is one of the key factors impeding effective consultation with tribes due to the limited capacity of tribal environmental programs. As discussed further in Chapter 2, while some tribal governments are moving forward in participating under federal environmental programs, few tribes have actually been authorized by EPA to assume primary regulatory and enforcement responsibilities for these program on their reservations. Where tribes have not yet assumed these responsibilities, EPA remains responsible for implementing and enforcing the federal environmental laws within Indian country pursuant to these laws and the federal trust responsibility owed to tribes.

[408]See, generally, Jane Marx, Jana L. Walker, and Susan M.. Williams, *Tribal Jurisdiction Over Reservation Water Quality and Quantity*, 43 South Dakota Law Review 315 (1998).

As noted in Chapter 2, tribes may be involved as co-managers of cleanup and restoration efforts. For example, the Lower Elwha Klallam Tribe recently signed an agreement with federal and state agencies recognizing its role in overseeing cleanup of a contaminated (with dioxins and PCBs) area affecting important off-reservation resources.[409] The Menominee Indian Tribe of Wisconsin and the Oneida Tribe of Indians of Wisconsin are among the Natural Resource Trustees addressing cleanup and restoration of the Fox River and Green Bay.[410] In these roles, tribes will have environmental justice concerns of a different and often complex nature.

B. TREATY RIGHTS

Treaties preserve important tribal rights. "A treaty, including one between the United States and an Indian tribe, is essentially a contract between two sovereign nations."[411] The United States entered into more than 400 treaties with Indian tribes under which tribes typically gave up large parts of their aboriginal territories in exchange for explicit promises from the federal government. Because the United States received rights to land from the tribes, the United States Supreme Court has described a treaty as a grant of rights from the Indians with a reservation of all those rights not granted.[412] Thus, a treaty does not have to reserve expressly hunting and fishing rights within an Indian reservation for such rights to exist; rather, such on-reservation rights exist unless expressly given up by the tribe.[413] In many treaties, tribes expressly reserved certain rights in lands and waters outside their reservations. For example, today, many tribes possess treaty rights to fish, hunt, and gather at all "usual and accustomed" places. In 1871, Congress ended the practice of entering into treaties with Indian tribes, but subsequently engaged in the practice of ratifying agreements with tribes negotiated by the Executive Branch. While the United States Supreme Court has ruled that Congress has the power to break treaties with tribes, unless clear congressional intent exists to abrogate a treaty, a treaty continues in effect.[414]

C. ALASKA NATIVES

The term "tribe," and the recognition of a particular political and legal status that this term entails, applies to Alaska Native villages as well as to American Indian tribes in the forty-eight

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[409] L. Harris, *Tribe Will Oversee Pulp Mill Cleanup*, Northwest Indian Fisheries Commission News 8 (Spring, 2000).

[410] U.S. Environmental Protection Agency, *Intergovernmental Partners Negotiate Fox River Interim Agreement* (factsheet, 2001).

[411] See Washington v. Washington State Commercial Passenger Fishing Vessel Assoc., 443 U.S. 658, 675 (1979).

[412] See United States v. Winans, 198 U.S. 371 (1905) ("In other words, the treaty was not a grant of rights to the Indians, but a grant of rights from them—a reservation of those not granted.")

[413] See Menominee Tribe of Indians v. United States, 391 U.S. 404 (1968).

[414] See United States v. Dion, 476 U.S. 734 (1986).

contiguous states.[415] Indeed, as noted above, of the 556 federally recognized tribal governments within the United States, 223 of these are Alaska Native villages. While several aspects of tribes' particular political and legal status are common to American Indian tribes and Alaska Native villages, there are also important differences. This section, therefore, briefly outlines the unique circumstances of Alaska Native villages in this regard.

Consistent with their status as federally recognized tribes, Alaska Native villages have a government-to-government relationship with the federal government and its agencies, including the EPA. The rights and responsibilities that flow from this relationship are described above, in Section A, and apply equally to Alaska Native villages. Among other things, under current federal law and policy, federal agencies are directed to operate within the government-to-government framework, and to consult with tribes, including Alaska Native villages, as sovereign entities.

The federal trust responsibility is similarly applicable to Alaska Native villages.[416] The trust responsibility requires the federal government and its agencies to uphold the highest fiduciary standards when its actions affect the well-being of Alaska Native villages, their property (including subsistence rights),[417] resources, and culture. The object of the trust responsibility is the furtherance of the self-determination and cultural integrity of tribes and Alaska Native villages.

However, there are also important differences between the legal, political, historical and other circumstances of Alaska Native villages and their members and those of tribes and their members in the lower forty-eight states. For example, Alaska Native villages and the United States government did not enter into any treaties. And, while Alaska Natives have been included by Congress in legislation generally applicable to American Indians,[418] Congress has also legislated separately with respect to Alaska Native villages and their members. Alaska Native land and subsistence rights, for example, are importantly affected by the Alaska Native Claims Settlement Act (ANSCA)[419] and by the Alaska National Interest Lands Conservation Act (ANILCA).[420] In addition, special recognition of and exceptions for Alaska Native subsistence rights have been

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[415]See, e.g., *Noatak v. Hoffman*, 896 F.2d 1157 (9th Cir. 1990); *Native Village of Tyonek v. Puckett*, 890 F.2d 1054 (9th Cir. 1989); see generally, Eric Smith and Mary Kancewick, *The Tribal Status of Alaska Natives* 61 University of Colorado Law Review 455 (1990).

[416]*People of Togiak v. United States*, 470 F. Supp. 423 (D.D.C. 1979).

[417]Id.

[418]See, e.g., Indian Self-Determination Act, Public Law No. 93-638, 88 Stat. 2206 (codified in scattered sections of the United States Code; see especially 43 U.S.C. §§ 1601-1624; Indian Financing Act of 1974, 25 U.S.C. § 1452(c).

[419]43 U.S.C. §§ 1601-1628.

[420]16 U.S.C. §§ 3101-3133.

included in federal statutes and treaties concerned with protection of animals, birds, and their habitat, such as the Marine Mammal Protection Act[421] and the Endangered Species Act.[422]

The special circumstances of Alaska Native villages are also relevant to their ability to choose to accept responsibility for administering federal environmental statutes. For example, because the United States Supreme Court held in *Alaska v. Native Village of Venetie*,[423] that only one Indian "reservation" -- the Annette Island Reserve -- exists in Alaska and that land conveyed by the federal government to Alaska Native villages under ANCSA was not "Indian country," and because the language of the Clean Water Act recognizes the power of tribes to establish water quality standards throughout their "reservations," Alaska Native villages are unable to assume regulatory authority or to participate in the same manner or to the same extent under the Act as tribes located in the lower forty-eight states. Alaska Native villages and their members have also identified other hurdles particular to their efforts to manage (or co-manage) and to access resources that are important for subsistence uses. Important among these has been a historical lack of attention to, funding for, and technical assistance supporting the environmental management efforts of Alaska Native villages.

Finally, it is important to recognize that the particular historical, economic, ecological, and cultural circumstances of Alaska Native villages and their members give rise to several issues that are less likely to be of concern elsewhere. These circumstances range from Alaska's unique climates, including its Arctic climate;[424] to its historical military use by the U.S. Department of Defense and the continuing legacy of contamination at the hundreds of formerly- and currently-used defense sites;[425] to the exploitation of its wealth of mineral and petroleum resources and the

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[421] 16 U.S.C. § 1371(b).

[422] 16 U.S.C. § 1539(e).

[423] 118 S. Ct. 948 (1998).

[424] See, e.g., Interagency Collaborative Paper, *Contaminants in Alaska: Is America's Arctic at Risk?* (issued by the U.S. Department of the Interior, U.S. Environmental Protection Agency, Alaska Department of Environmental Conservation, Alaska Department of Health and Social Services, University of Alaska Institute for Circumpolar Health Studies, Alaska Federation of Natives, Alaska Native Science Commission, Alaska Inter-Tribal Council, Native American Fish and Wildlife Society, Alaska Native Tribal Health Consortium, Alaska Community Action on Toxics, and North Slope Borough, September 2000). This paper describes the cold, northern Arctic as a sink for numerous environmental contaminants transported from elsewhere; notes the particular persistence of these contaminants in this environment, given the slower rate of breakdown in the colder climate; and citing POPs, as well as metals as among the contaminants of concern for Arctic fish, wildlife, and people. Id.

[425] Alaska hosts approximately 700 formerly-used defense sites, five military Superfund sites, and weapons testing ranges encompassing an area equal in size to the state of Kansas. These sites are contaminated with PCBs, dioxins, radioactive waste, and a variety of other pollutants resulting from the use of solvents, fuels, and chemical munitions. See, e.g., Pamela K. Miller, Director, Alaska Community Action on Toxics, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony).

resulting environmental harms; to the remoteness and relative poverty of many of its rural villages, resulting, among other things, in the fact that only 40% of Alaska Native families have basic sanitation services such as piped drinking water and flush toilets, and more than half of these systems are rudimentary at best.[426] For example, Pamela K. Miller, Director, Alaska Community Action on Toxics, relates:

> *The north has become a hemispheric sink for persistent organic (POPs) . . . Many persistent pollutants originate from thousands of miles away, traveling northward via wind and ocean currents and in the bodies of migratory animals. . . . Northern ecosystems, wildlife, and people are the ultimate repositories for persistent pollutants. . . . Cold-water bodies of the Arctic are important sinks [for example] for lindane. Levels of [lindane] in seawater are an order of magnitude higher in the Arctic than in tropical and subtropical regions. . . . Lindane was among the organochlorine contaminants detected in blood samples from Alaska Native women participating in a pilot study conducted [in 1996].*[427]

June Gologergen Martin, Coordinator, National Environmental Health & Justice, St. Lawrence Island Project, explains:

> *Whanga aatqa yupiigestun Yatgawen, Sevungami allgeqawunga. Hello, my name is June Gologergen Martin. My Siberian Yupik name is Yatgawen. I was born on St. Lawrence Island in the village of Savoonga, Alaska. As a Siberian Yupik native, I grew up going to North East Cape during the summer months in the mid-1960s. . . .*
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> *We live a subsistence lifestyle. We are rich in our culture; our Siberian Yupik language is very strong. Our families still hunt walrus, seals, bowhead whales, halibut, crabs, different species of seabirds and fish in the Bering sea, lakes, and rivers, like the Suqi River in North East Cape . . . We also gather edible plants, roots, seabird eggs, marine plants and seaweed.*
>
> *During the earlier years of my life, there were talks of not consuming fish and wildlife and edible plants around the North East Cape military site. These warnings came from our elders and leaders. We were told not to subsistence fish in the Suqi River at North East Cape. We were confused and alarmed about this warning from our elders and leaders. If we cannot consume our subsistence fish, marine mammals and other plants due to contamination by military debris left behind, our spirit slowly dies within us!*

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[426]See, e.g., Videotape: *The Forgotten America -- Alaska's Rural Sanitation Problem* (The Media Support Center for the Alaska Department of Environmental Conservation).

[427]Pamela K. Miller, Director, Alaska Community Action on Toxics, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony).

Our uncles and possibly our fathers and others who have spent time at North East Cape military site began dying of cancer-related illnesses. Our elders knew why this was happening. They knew that whatever contaminants the military left behind might have been the cause of these deaths. . . .

[We] urge NEJAC to review information on St. Lawrence Island regarding North East Cape and the Native Village of Gambell military clean-up project and recommend that St. Lawrence Island be considered a Superfund site so that there is complete restoration . . .[428]

Rosemary Ahtuangaruak, Native Village of Nuiqsut, explains:

I am from the Native Village of Nuiqsut on the north slope of Alaska, 60 miles west of Prudhoe bay and 130 miles southeast of barrow. We are an Inupiat village, which relies upon the subsistence resources for our survival. The land, sea, and air provide for us and we, in turn, protect them . . .

The long dark months of winter can have many starvation moons until the natural resources of subsistence return. The concerns now are not only can we put enough away but if the supply is safe to consume. . . . [O]ur attempts to harvest are coming back empty and our nets are getting few fish. . . .

The national need for energy is ignoring the need we have for subsisting. We are going without multiple subsistence resources for the benefit of our nation's energy need. There are not means for us to address the assault on our resources, which our elders have taught us to use. The recognition of our loss is belittled in the many public meetings, which come to our village as a public process without the incorporation of our concerns into the proper framework to address them. . . .

The people of Nuiqsut rely upon the fish harvesting and the last six years have seen the devastation of our fish stocks. . . . I feed three families with the harvesting I do and they go without as well as me. I eat fish or whale two times a day and 5-7 days out of the

[428]June Gologergen Martin, Coordinator, National Environmental Health & Justice, St. Lawrence Island Project, Testimony to National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony); accord, Kendra Zamzow, National Institute of Environmental Health Sciences Grant Researcher, Testimony to National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony)(noting that the U.S. Department of Health and Human Services disseminated a fish consumption advisory urging that no fish from the Suqi River be eaten, given PCB contamination in even very small (4" long) fish, and pointing out that the Suqi and its fish and wildlife are also contaminated with five PAHs (polycyclic aromatic hydrocarbons), dissolved arsenic, lead, and zinc).

week. I have to dig through the ice and in three days, I got only 1-2 fish. This cannot feed my family as well as the extended family members. We are concerned about the quality of the fish, as the meat has changed, they are yellow and not as fat as usual, and they have a bitter taste. Every fisherman in our village has faced the same hardships. We depend on the healing qualities of this resource and now it is being considered a bad thing. The social, economical, cultural, and medicinal [aspects] of our resources are needed to sustain our health . . .[429]

Dr. Delores Garza, Alaska Native Science Commission, explains:

In rural Alaska we have many communities that are still relegated to the "honey bucket." That means that there is no sewer system. The sewage goes into a five-gallon white-lined bucket that's lined with a garbage bag. It goes out to the dump and it's thrown out on the surface. In Southwestern Alaska, primarily in the Yupik area where you have communities built in areas that you might consider bogs, they have high water tables. The sewage is leaching and is contaminating the fresh water source. . . . So you have communities that now may have 70, 80 percent unemployment trying to find the gas money to take their boat upriver or to take their four-wheeler farther out to get fresh water, and while Alaska has worked to reduce the number of communities that have to rely on this honey bucket system, that is still a big issue in many communities in Southwestern Alaska.[430]

Thus, while Alaska Native villages and their members may share many of the concerns articulated by various affected groups throughout this Report, it is critical that EPA and other agencies listen and attend to the particular issues articulated by Alaska Native villages and their members. And, here as elsewhere, this will mean recognizing that there will often be differences *among* the concerns of various Alaska Native villages.

D. TRIBES' UNIQUE SUSCEPTIBILITIES AND CO-RISK FACTORS

Commonly cited statistics all seem to agree that AI/AN's economic wealth, public health, and education are the worst of any group in the nation. Poverty and unemployment rates among AI/ANs are the highest for any ethnic group in the country, and education, per capita income, and home ownership are among the lowest.[431] One out of every three AI/ANs lives

[429]Rosemary Ahtuagaruak, Native Village of Nuiqsut, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Testimony).

[430]Delores Garza, Alaska Native Science Commission, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Annual Meeting Transcript, Vol III-89).

[431]See, e.g., *National Gambling Impact Study Commission Report*, "Native American Tribal Gambling" 6-5 (Jun. 18, 1999).

below the poverty line; approximately 90,000 AI/AN families are homeless or underhoused; and one out of every five AI/AN households lacks adequate plumbing.[432] The statistics are even more disheartening for Alaska Native villages. Only 40% of Alaska Native families have basic sanitation services such as piped drinking water and flush toilets, and more than half of these systems are rudimentary at best.[433] Climate poses a significant challenge to the use of conventional sanitation systems in these communities, which are typically far removed from urban areas. And, the lack of economic development in most Alaska Native villages makes it impossible for these subsistence-based families to pay the cost of bringing in appropriate and sustainable sanitation services.[434]

Health care data on AI/ANs is scarce and unreliable. Significantly, the health status of AI/ANs is far below the health status of the general population in this country, and unmet AI/AN health needs are alarmingly high. This disparity in health status is reflected clearly in the death rates for AI/ANs. For example, AI/ANs have the highest suicide rate (70% higher than the rate for the general population) and the lowest life expectancy of any population in this hemisphere except Haitians.[435] Compared to death rates for all other races in the United States, AI/ANs have a death rate for diabetes mellitus that is 249% higher; a death rate for pneumonia and influenza that is 71% higher; a death rate for tuberculosis that is 533% higher; and a death rate from alcoholism that is 627% higher.[436]

AI/ANs also have a unique set of cancer problems ranging from inadequate screening to under-diagnosis and -reporting of cancer to lack of access to quality health care and new cancer treatments. For example, the leading cause of death for AIs is lung cancer, and AN women have the highest cancer and lung cancer mortality rates of any major racial female group.[437] Recently, the Association of American Indian Physicians reported that cancer is the third leading cause of death for all AI/ANs of all ages; the second leading cause of death for all AI/ANs over age 45; and the leading cause of death for AN women. The Association also reported that, in most parts

[432]Id.

[433]See, e.g., Videotape: *The Forgotten America -- Alaska's Rural Sanitation Problem* (The Media Support Center for the Alaska Department of Environmental Conservation).

[434]Id.

[435]See, e.g., Wallwork Winik, Lyric, "There's A New Generation with a Different Attitude," Parade Magazine 6-7 (July 18, 1999).

[436]Proposed IHCA Amendments of 2000, Section 2(h), prepared by the National Steering Committee for the Reauthorization of the Indian Health Care Improvement Act, P.L. 94-437 (Oct. 6, 1999), and based on data used by the Indian Health Service for the FY 2001 budget development.

[437]See National Cancer Institute, National Institute of Health, HHS, Office of Special Populations Research Web Site, *The Cancer Burden* available at www.ospr.nci.nih.gov.burden.htm.

of the country, AI/ANs have poorer survival rates from cancer than do whites, African Americans, Hispanics, and Asians.[438]

AI/ANs are particularly susceptible to health impacts from pollution due to their traditional and cultural uses of natural resources and, in fact, AI/ANs "have greater exposure risks than the general population as a result of their dietary practices and unique cultures that embrace the environment."[439] Fishing, hunting, and gathering often are part of a spiritual, cultural, social, and economic lifestyle, and the survival of many AI/ANs depends on subsistence hunting, fishing, and gathering. In some instances, the right to engage in these activities is legally protected by treaty. Additionally, many AI/ANs also use water, plants, and animals in their traditional and religious practices and ceremonies. As a result, contamination of the water, soil, plants, and animals and the subsequent accumulation of these contaminants in the people through ingestion, inhalation, and contact not only endangers the health of AI/ANs, but also threatens the well-being of their future generations[440] and undermines the cultural survival of tribes and Alaska Native villages. For example, tribes near the Hanford Nuclear Reservation have been working with the Agency for Toxic Substances and Disease Registry to design health assessments focusing on exposure effects from food consumption and other activities. These tribes want to learn if the Hanford releases affect native food items and local materials used in tribal products like storage and cooking baskets, mats, and clothing.[441] Similarly, tribes located in coastal northern California are concerned about the pesticide exposure of some 300 traditional basketmakers who gather their own materials from the forests and roadsides. Basketweavers are exposed to pesticides as they tend and gather basketry materials; as they weave (weavers often hold one end of the grasses

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[438]K. Marie Porterfield, *American Indian Cancer Statistics Under Reported*, Indian Country Today C-1 (Jul. 26, 2000).

[439]See Agency for Toxic Substances and Disease Registry, *Focus on American Indian and Alaska Native Populations* 1-2.

[440]A number of studies have shown that children are uniquely susceptible to pollution and contaminants. For example, since 1992, the Agency for Toxic Substances and Disease Registry has funded research in the Great Lakes states focusing on the health effects of high risk populations, including American Indians, from persistent toxic substances found in fish. One study found that newborns born to mothers who consumed only 2.3 PCB-contaminated Great Lakes fish meals per month scored lower on the Neonatal Behavioral Assessment Scale. See Agency for Toxic Substances and Disease Registry*, Focus on American Indian and Alaska Native Populations* 2-3. Additionally, in Oklahoma, Indian children also suffer harm from their environment. The Tar Creek Superfund Site, a former lead and zinc mine, occupies 40 square miles within the boundaries of the former Quapaw Indian Reservation. Both the Quapaw Tribe's powwow grounds and campgrounds are contaminated from mine tailings, and the EPA Region 6 reports that approximately 25% of the Quapaw children have elevated blood lead levels compared with a statewide average of 2%. See U.S. Environmental Protection Agency, *Region 6 Environmental Justice Update* 7 (May 2000).

[441] See Agency for Toxic Substances and Disease Registry, *Focus on American Indian and Alaska Native Populations* 5.

or other materials in their mouths as they weave); and as they wear, cook with, and use the finished baskets. Because a disproportionate number of American Indian residents in Humboldt County, California have been diagnosed with cancer, tribes believe studies are needed to determine the exact cause of such cases.[442]

Significantly, where such traditional, cultural, and subsistence activities are involved, federal and state environmental standards used to protect the general non-Indian/non-Native population may not afford tribes and Alaska Native villages adequate protection from environmental harm.[443] Again, although several of the major federal environmental laws have been amended to allow federally recognized tribes to assume primacy for certain programs,[444] to date, only a few tribes have EPA- approved or -promulgated environmental programs.[445] Based on all of the foregoing, federally recognized tribes and AI/ANs suffer a disproportionate burden of health consequences due to their exposure to pollutants and hazardous substances in the environment. This is particularly so for AI/AN infants and children.[446]

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442 See Chuck Striplen, Mutzun Oholone Tribe, *Native Subsistence in a Toxic Environment: A Tribal Viewpoint* 14, (EPA's OPPTS Tribal News) (Fall/Winter 1999-2000).

443 See, e.g., City of Albuquerque v. Browner, 97 F.3d 415 (10th Cir. 1996), *cert. denied*, 118 S. Ct. 410 (1997) (upholding the EPA's approval of the Pueblo of Isleta's water quality standards that were more stringent than the state water quality standards, and which included a ceremonial use standard).

444 Since 1986, the Safe Drinking Water Act, Clean Water Act, and Clean Air Act have been amended to afford tribes substantially the same opportunities as states to assume responsibility for certain programs or purposes.

445 For example, as of July 13, 2000, the EPA reported that only 15 tribes have EPA-approved or -promulgated water quality standards and no tribes are authorized to administer the National Pollutant Discharge Elimination System or to establish Total Maximum Daily Loads. See 65 Fed. Reg. 43,585 (Jul. 13, 2000).

446 For example, a New York State Department of Health study of lactating women and their infants linked breast feeding and infant exposure to hazardous substances. This study compared PCB levels in the breast milk of Mohawk women who gave birth between 1986 and 1992 with a control group. The study found that although the PCB concentrations in the breast milk of Mohawk mothers decreased over time, their infants had urine PCB levels ten times higher than that of their mothers. See Agency for Toxic Substances and Disease Registry, *Focus on American Indian and Alaska Native Populations* 3-4. See also Winona Laduke, *All Our Relations, Native Struggles for Land and Life* 11-23 (1999).

APPENDIX A: NEJAC EXECUTIVE COUNCIL MEMBERS

List of Members by Stakeholder Category

ACADEMIA - 5

Veronica Eady - 1 year
Tufts University
Department of Urban and Environmental Policy
Tufts University
97 Talbot Avenue
Medford, MA 02155
Phone: (617) 627-2220
Fax: (617) 627-3377
E-mail: Veronica.Eady@tufts.edu

Tseming Yang - 2 years
Professor
Vermont Law School
Chelsea Street, Whitcomb House
South Royalton, VT 05068
Phone: 802/763-8303 ext 2344
Fax: 802/763-2663
E-mail: tyang@vermontlaw.edu

Eileen Gauna - 1 year
Professor
Southwestern Univ. School of Law
675 South Westmoreland Avenue
Los Angeles, CA 90005
Phone: (213)738-6752
Fax: (213)383-1688
E-mail: egauna@swlaw.edu

Graciela I. Ramirez-Toro-1 year
Director for the Center for Environmental Education, Conservation and Interpretation
Inter American University of PR
P. O. Box 5100
San Germán, PR 00683
Ph: (787) 264-1912 ext. 7630
Fax: (787) 892-2089
E-mail: cecia@prtc.net

Richard Gragg, III - 2 years
Assistant Professor/Associate Director
Environmental Science Institute
Florida A&M University
Tallahassee, FL 32307-6600
Phone: (850) 599-8549
Fax: (850) 561-2248
E-mail: richard.graggiii@famu.edu

INDUSTRY/BUSINESS - 4

Robert L. Harris - 2 years
Vice President
Environmental Affairs
Pacific Gas and Electric Company
P. O. Box 770000
San Francisco, CA 94177-0001
Ph: (415) 973-3833
Fax: (415) 973-1359
E-mail: rlh6@pge.com

Jana L. Walker- 1 year
Law Office of Jana L. Walker
141 Placitas Trails Road
Placitas, NM 87043
Phone: (505) 867-0579
Fax: (505) 867-0579
E-mail: ndnlaw@sprintmail.com

Kenneth J. Warren, Esq. - 2 years
Chair of Environmental Department
Wolf, Block, Schorr and Solis-Cohen
1650 Arch Street, 22nd Floor
Philadelphia, PA 19103
Phone: (215) 977-2276
Fax: (215) 977-2334
E-mail: kwarren@wolfblock.com

COMMUNITY-5 (1 vacancy)

Larry Charles - 2 years
Executive Director
ONE/CHANE, Inc.
2065 Main Street
Hartford, CT 06102
Phone: (860) 525-0190
Fax: (860) 522-8266
E-mail: lcharles@snet.net

Harold Mitchell - 1 year
Director
Regenesis, Inc.
101 Anita Drive
Spartanburg, SC 29302
Phone: (864) 542-8420
Fax:: (864) 582-0001
E-mail regenesisinc@aol.com

Mary Nelson - 1 year
President
Bethel New Life, Incorporated
4950 West Thomas
Chicago, IL 60651
Phone: 773-473-7870
Fax: 773-473-7871
E-mail: mnelson367@aol.com

Peggy Shepard – 1 year
Executive Director
West Harlem Environmental Action
271 West 125th Street, Suite 211
New York, NY 10027
Phone: (212) 961-1000
Fax: (212) 961-1015
E-mail: peggy@weact.org

NON-GOVERN/ENVIRONMENTAL GROUP -5 (1 vacancy)

Wilma Subra - 2 years
LEAN Representative
Subra Company, Inc.
P. O. Box 9813
3814 Old Jeanerette Rd.
New Iberia, LA 70562
Phone: (337) 367-2216
Fax: (337) 367-2217
E-mail: SubraCom@aol.com

Jason S. Grumet – 3 years
Executive Director
National Commission on Energy Policy
1616 H St., NW 6th Floor
Washington, DC 20006
Phone: 202-637-0400 x12
Fax: 202-637-9220
E-mail: hreese@energycommission.org

Judith Espinosa - 3 years
Director, ATR Institute
University of New Mexico
1001 University Blvd., SE, Suite 103
Albuquerque, NM 87106-4342
Phone: 505-246-6410
Fax: 505-246-6001
E-mail: jmespino@unm.edu

Rev. Adora Iris Lee - 3 years
Director of EJ Programs
United Church of Christ
Justice and Witness Ministries
110 Maryland Ave., NE, Suite 207
Washington, DC 2002
Phone: 202-543-1517
Fax: 202-543-5994
E-mail: adoracrj@aol.com

STATE/LOCAL - 4 (1 vacancy)

Jane Stahl - 1 year
Deputy Commissioner
Department of Environmental Protection
State of Connecticut
79 Elm Street, 3rd Floor
Hartford, CT 06106
Phone: (860)424-3009
Fax: (860)424-4054
E-mail: jane.stahl@po.state.ct.us

Walter S. Handy, Jr. – 3 years
Assistant Commissioner of Health
3101 Burnet Avenue
Cincinnati, OH 45229
Phone: (513) 357-7271
Fax: (513) 357-7290
E-mail: walter.handy@chdburn.rcc.org

Lori F. Kaplan – 3 years
Commissioner
Indiana Department of Environmental Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, IN 46206-6015
Phone: (317) 232-8611
Fax: (317) 233-6647
E-mail: lkaplan@dem.state.in.us

TRIBAL/INDIGENOUS - 3

Anna Frazier - 2 years
Coordinator
DINE' C.A.R.E.
HCR-63, Box 263
Winslow, AZ 86047
Phone: (928) 657-3291
Fax: (928) 657-3319
E-mail: dinecare@cnetco.com

Pamela Kingfisher - 2 years
Indigenous Women's Network
13621 FM 2769
Austin, TX 78726
Phone: 512-288-6003
Fax: (512) 258-1858
E-mail pame@indigenouswomen.org

Terry Williams - 3 years
Fisheries and Natural Resources Commissioner
The Tulalip Tribes
6700 Totem Beach Road
Tulalip, WA 98271-9694
Phone: (360) 651-4000
Fax: (360) 651-3701
E-mail: dwilliams@tulalip.nsn.us

Terms of Expiration:
1 year = 12/31/2002
2 years = 12/31/2003
3 years = 12/31/2004

APPENDIX B: NEJAC FISH CONSUMPTION WORK GROUP MEMBERS

Coleen Poler (Work Group Co-Chair)
NEJAC Indigenous Peoples Subcommittee
Sokaogon Defense Committee
2915 Ackley Circle Road
Crandon, WI 54520
Ph: 715-365-8995
Fax: 715-365-8977
polersdc@newnorth.net

Leonard E. Robinson (Work Group Co-Chair)
NEJAC Air & Water Subcommittee
TAMCO Steel
12459 Arrow Highway
Rancho Cucamonga, CA 91739
Ph: 909-899-0631 x.203
Fax: 909-899-1910
RobinsonL@tamcosteel.com

Daisy Carter
NEJAC Air & Water Subcommittee
PROJECT AWAKE
Route 2, Box 282
Coatopa. AL 35470
Ph: 205-652-6823
fax: 205-652-6823 or 205-652-9343
pawake@sumternet.com

Patricia Cochran
Alaska Native Science Commission
University of Alaska Anchorage
3211 Provident Drive
Anchorage, Alaska 99508
Ph: 907-786-7704
Fax: 907-786-7731
anpac1@uaa.alaska.edu

Josee Cung
Minnesota Department of Natural Resources
Southeast Asian Program- Commissioner's Office
500 Lafayette Road, Box 10
St. Paul, MN 55155-4010
Ph: 651-297-4745
Fax: 651-296-6047
josee.cung@dnr.state.mn.us

Ticiang Diangson
Supervising Planning and Development Specialist
Seattle Public Utilities
710 Second Ave. #505
Seattle, WA 98104
Ph: 206-684-7643
Fax: 206-684-8529
ticiang.diangson@ci.seattle.wa.us

Pamela Kingfisher
NEJAC Health & Research Subcommittee
Indigenous Women's Network
13621 FM 2769
Austin, TX 78726
Ph: 512-401-0090
Fax: 512-258-1858
pjkingfisher@yahoo.com

Brian Merkel
University of Wisconsin- Green Bay
College of Human Biology
Green Bay, WI 54311-7001
Ph: 920-465-2262
Fax: 920-465-2769
MerkelB@uwgb.edu

Bark Merrick
Earth Conservation Corps
1st and Potomac Ave.
Washington, D.C.
Ph: 202-554-1960

Lawrence Skinner
New York State Dept. of Environmental Conservation
Bureau of Habitat
50 Wolf Rd. R. 576
Albany, N.Y. 12233-4750
Ph: 518-457-0751
Fax: 518-485-8424

Moses D. Squeochs
NEJAC Indigenous Peoples Subcommittee
14 Confederation Bands of Yakama Nation
P.O. Box 151
Toppenish, WA 98948
Ph: 509-865-5121
Fax: 509-865-6850
mose@yakama.com

Velma Veloria
1265 South Main Street, Suite 203
Seattle, WA 98144 or
P.O. Box 40600
Olympia, WA 98504-0600
Ph: 360-786-7862
Fax: 360-786-7317
veloria_ve@leg.wa.gov

Jana L. Walker
Attorney
NEJAC Indigenous Peoples Subcommittee
Law Office of Jana L. Walker
141 Placitas Trails Road
Placitas, New Mexico 87043
Ph: 505-867-0579
ndnlaw@sprintmail.com

Patrick West
Professor Emeritus, University of Michigan
29377 Sunny Beach Additive Road
Grand Rapids, MN 55744
Ph: 218-326-2170
pswest@paulbunyan.net

Damon Whitehead
NEJAC Air & Water Subcommittee
Earth Conservation Corps
1st Street and Potomac Avenue, SW
Washington, DC 20003
damon@anacostiariverkeeper.org

Terry Williams, Commissioner
Fisheries & Natural Resources
Tulalip Tribes
7615 Totem Beach Road
Marysville, WA 98271
Ph: 360-651-4471
Fax: 360-651-4490
twilliams@tulalip.nsn.us

Marianne Yamaguchi
NEJAC Air & Water Subcommittee
Santa Monica Bay Restoration Project
320 West 4th Street, Suite 200
Los Angeles, CA 90013
Ph: 213-576-6614
Fax: 213-576-6646
myamaguc@rb4.swrcb.ca.gov

Alice Walker (WorkGroup DFO)
Co-Designated Federal Official
Office of Water
NEJAC, Air and Water Subcommittee
OW Environmental Justice Coordinator
Ph: 202-564-0498
Fax: 202-529-7534
Walker.Alice@epa.gov

Danny Gogal (WorkGroup DFO)
DFO, NEJAC Indigenous Peoples Subcommittee
USEPA Headquarters
Office of Environmental Justice- 2201A
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Ph: 202-564-2576
Gogal.Danny@epa.gov

Charles Lee (NEJAC DFO)
Associate Director for Policy and Interagency Liaison
Office of Environmental Justice- 2201A
USEPA Headquarters
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Ph: 202-564-2597
Lee.Charles@epa.gov

Catherine O'Neill (Meeting Report Consultant)
Associate Professor
Seattle University School of Law
900 Broadway
Seattle, Washington 98122
Ph: 206-398-4030
Fax: 206-398-4077
oneillc@seattleu.edu

APPENDIX C: FISH CONSUMPTION WORK GROUP PROPOSALS

The following proposals were developed by the National Environmental Justice Advisory Council (NEJAC) Fish Consumption Work Group (FCWG) for deliberation and action by the NEJAC Executive Council. While elements of these proposals were incorporated into the six Consensus Recommendations adopted by the NEJAC Executive Council, these proposals were not adopted by the NEJAC Executive Council.

The following proposals of the FCWG are set forth as "Overarching Proposals" and "Focused Proposals." Overarching proposals are intended to set forth the FCWG's proposals in broad terms. Each group of overarching proposals is in turn elaborated by one or more focused proposals. In every case, the proposals should be understood to refer to the contamination and depletion of aquatic ecosystems and all of their components, including fish, shellfish, marine invertebrates, aquatic plants, and wildlife. They should be understood to apply to efforts to address contamination wherever it may affect aquatic ecosystems, including contamination in surface waters, sediments, groundwater, soils, and air. Finally, they are meant not only to cleanup current contamination and prevent future contamination, but to do so in a manner that rectifies disproportionate impacts, so that all affected people or groups – including people of color, low-income people, American Indians, Alaska Natives, Native Hawaiians and other Pacific Islanders, and other indigenous people located within the jurisdictional boundaries of the United States – are able to live in a healthful environment, in this generation and all generations to come.

Chapter One

The contamination of fish, aquatic plants, and wildlife is an especially pressing concern for many communities of color, low-income communities, tribes, and other indigenous peoples, whose consumption and use practices differ – often profoundly so – from those of the general population. Members of these groups often consume far greater quantities of fish, aquatic plants, and wildlife; they consume fish, plants, and wildlife at different frequencies, in accordance with seasonal availability and other cultural considerations; they consume and use different species and parts; and they employ different methods in procuring and preparing the fish, aquatic plants, and wildlife that they use. Thus, communities of color, low-income communities, tribes, and other indigenous peoples are among the most highly exposed to contaminants in the fish, plants, wildlife, and aquatic environment. For example, empirical studies document 90th percentile fish consumption rates for various affected communities and tribes at 225 g/day, 242 g/day, and 489 g/day (respectively, urban fishers on Los Angeles Harbor; ten Asian and Pacific Islander communities in King County, WA; and the Suquamish Tribe). Although EPA's revised default assumptions of 17.5 g/day, representing the 90th percentile of the general population, and 142.4 g/day, representing the 99th percentile of the general population are a marked improvement over its previous assumption of 6.5 g/day, the revised defaults still considerably underestimate exposure for many affected communities and tribes.

Overarching Proposals

I-1. The FCWG proposes that EPA work with affected groups to develop and use fish consumption rates that are appropriate for various higher-consuming communities and tribes whenever EPA conducts activities that affect these higher-consuming groups, for example, when it develops water quality criteria; when it sets and approves state and tribal water quality standards; when it sets and approves cleanup levels for water and sediments; when it addresses cross-media contamination (e.g., mercury emissions to air); and when it provides other relevant guidance.

FCWG proposes that EPA work in particular with those affected groups for which few or no empirical data exist, ensuring that studies are undertaken systematically to provide a full account of all affected groups' consumption practices. FCWG notes that, among other things, an appropriate fish consumption rate must account for affected groups' different consumption frequencies or patterns due to seasonal availability and other cultural considerations, particularly those that result in acute or peak exposures.

I-2. The FCWG similarly proposes that EPA account for other aspects of communities' and tribes' different exposure circumstances when it conducts these various activities, including practices that mean different species are consumed, different parts are used (e.g., the highly contaminated hepatopancreas of crabs, often consumed by Asian and Pacific Islanders and by other island people), and/or different preparation methods are employed than those typically assumed by agencies.

I-3. The FCWG proposes that EPA remedy, in measurable and reportable ways, the disparities in the level of protection provided by water quality criteria and standards, cleanup standards, air emissions standards, and other relevant environmental standards as between the general population and "subpopulations" comprised of communities of color, low-income communities, tribes, or other indigenous peoples.

Focused Proposals

I-1 through I-3

1. FCWG proposes that EPA work with affected groups to facilitate research documenting these groups' different fish consumption and use practices, focusing on communities of color, low-income communities and tribes:

    a. FCWG proposes that EPA work with affected groups from the outset, so that research questions are framed and studies are designed to reflect accurately the needs and practices of the affected groups;

    b. FCWG proposes that, among other issues to be identified together with affected groups, studies document not only the different quantities of fish consumed by these groups, but also other aspects of these groups' different practices, including the extent to which they consume fish, plants, and wildlife at different frequencies; the extent to which they (or particular members of the relevant group, such as children or elders) consume and use different species or parts; and the extent to which they employ different methods in procuring and preparing the fish, aquatic plants, and wildlife;

    c. FCWG proposes that EPA prioritize research documenting those consumption and use practices about which relatively little is known and/or for which there are not reasonable proxies among current data, including research documenting the consumption and use of subsistence foods other than fish; research documenting consumption and use frequencies that result in acute or peak exposures (e.g., in the case of various Alaska Natives or others for whom seasonal availability or cultural considerations determine practices); and research documenting consumption and use among groups or in regions of the country for which few data exist (e.g., Native Hawaiians, among others).

2. FCWG proposes that EPA work with affected groups to ensure that EPA accurately and appropriately accounts for these groups' different fish consumption and use practices in all of its activities, including instances in which:

    a. EPA develops water quality criteria;

    b. EPA approves state or tribal water quality standards;

    c. EPA sets state or tribal water quality standards;

    d. EPA approves or sets cleanup levels for surface water and sediments;

e. EPA addresses relevant cross-media contamination (e.g., mercury emissions to air);

f. EPA undertakes relevant programs and initiatives (e.g., the Persistent Bioaccumulative and Toxic (PBT) Control Program); and

g. EPA provides other relevant guidance (e.g., its Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories).

3. FCWG also proposes that EPA act expeditiously to issue CWA § 304(a) water quality criteria that reflect affected groups' consumption and use practices; FCWG notes that EPA has sufficient data documenting the exposure circumstances of communities of color, low-income communities, tribes, and other indigenous peoples to warrant the issuance of revised criteria and emphasizes that it is unacceptable that criteria are still in effect that employ the outdated 6.5 grams/day fish consumption rate.

4. Specifically, FCWG proposes that EPA take a more active role in ensuring that state and tribal water quality standards are protective of affected groups' consumption and use practices, by assisting states, tribes, and affected groups in their data-gathering efforts; by encouraging states and tribes to employ protective assumptions (e.g., in reliance on EPA's Ambient Water Quality Criteria Methodology), even in advance of federally-mandated deadlines; and, crucially, by disapproving state and tribal standards that do not adequately account for these groups' different practices.

5. FCWG proposes that EPA work together with affected groups to revise its research methods and protocols to ensure that they result in the accurate depiction of these groups' exposure circumstances.

6. FCWG proposes that EPA should then produce and distribute a manual of methods and protocols for determining health risks for persistent and bioaccumulative toxics, for use by tribes and other affected groups who wish to employ local data in investigating and documenting human health risks in their own communities from the consumption and use of fish, shellfish, and other aquatic resources. This manual should include methods that permit analyses of both acute and chronic effects, and incorporation of multiple exposures and cumulative risks.

The contamination of fish, aquatic plants, and wildlife is also troubling to many communities of color, low-income communities, tribes, and other indigenous peoples, because these groups consume and use fish, aquatic plants, and wildlife in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American." For example, many tribes have treaty-guaranteed rights to take fish; the unique legal obligations entailed by these treaties are relevant to EPA's decisions affecting the health of the fish and the fisheries resource. The presence of these different contexts is abundantly demonstrated by both testimonial and social scientific evidence. For some or all of these reasons, particular fish consumption practices are in an important sense indispensable for many of these affected groups.

Overarching Proposals

I-4. FCWG strongly proposes EPA to work with affected groups to enhance its understanding of the ways in which these groups consume and use fish, aquatic plants, and wildlife in different cultural, traditional, religious, historical, economic, and legal contexts than the "average American" fish consumer and to incorporate this evidence into its risk assessment, risk management, and risk communication policies in measurable ways. FCWG proposes EPA, in collaboration with other appropriate federal agencies, to provide funding to affected groups so that they may document their particular cultural, traditional, religious, historical, economic, and legal circumstances, in a manner and for purposes they deem appropriate.

Focused Proposals

I-4

1. In each instance in which these issues are implicated, FCWG proposes that EPA work with the affected group(s) to develop a process for enhancing EPA's understanding of the particular cultural, traditional, religious, historical, economic, and legal context relevant to EPA's decisions in that case. These efforts should be among the first of EPA's fact-finding undertakings, e.g., for each cleanup of contaminated water and sediments under CERCLA. Among other things, such efforts should attend to:

   a. The existence of applicable treaties, e.g., many tribes' treaty-guaranteed rights to hunt, fish, and gather;

   b. The effects of the decision on resources, places, or sites that are culturally important to Native peoples or other affected groups, including sites protected by the National Historic Preservation Act, other sacred places, and culturally-important resources (whether located on- or off- reservation).

2. FCWG proposes that EPA and each office within EPA develop a strategy for recruitment, retention, and upward mobility for members of affected groups in order to enhance the extent to which EPA staff are familiar with and equipped to understand the particular relevant cultural, traditional, religious, historical, economic, and legal contexts in which they set priorities, undertake research and develop policies.

3. FCWG proposes that EPA increase its efforts to fund and publicize opportunities for community-based and tribally-conducted research documenting the particular cultural, traditional, religious, historical, economic, and legal contexts in which these groups consume and use aquatic resources. FCWG welcomes EPA's recent efforts to this end; however, as noted below in Proposals I-10 through I-11(1), even greater efforts are necessary.

A "suppression effect" occurs when a fish consumption rate for a given group reflects a current level of consumption that is artificially diminished from an appropriate baseline level for that group. The more robust baseline level is suppressed, inasmuch as it does not get captured by the fish consumption rate. Suppression effects may occur because of contamination (people would consume more fish but refrain because the fish are contaminated) and/or depletion (people would consume more fish but cannot because there are fewer fish to be consumed, for a variety of reasons). Such effects have been noted, for example, at Akwesasne, home to the St. Regis Mohawk, where large-scale PCB contamination of the Grasse and St. Lawrence rivers by General Motors, ALCOA, and Reynolds has left tribal members with little choice but to reduce their consumption of fish from these waters. Similarly, the depletion and contamination of salmon and other fish in the usual and accustomed fishing areas of the Tulalip Tribes has left tribal members with fewer fish to catch and consume. When standards are set based on fish consumption rates that do not capture fully this suppressed consumption, they set in motion a sort of downward spiral whereby the further contamination or depletion is permitted, fish consumption rates are further suppressed, and so on.

Overarching Proposals

I-5. FCWG proposes EPA to work with communities of color, low-income communities, tribes, and other indigenous peoples to identify instances in which these groups believe consumption to be suppressed due to contamination and/or depletion, and to conduct research, together with the affected group, to ascertain whether a suppression effect is at work; if so, cleanup and restoration there should be a high priority.

I-6. FCWG further proposes that, wherever suppression effects are at work, EPA employ appropriate baseline levels in providing guidance for states and tribes, and in setting and approving water quality standards, cleanup standards, and other environmental standards in order to avoid the downward spiral due to suppression effects.

Focused Proposals

I-5 through I-6

1. FCWG notes that suppression effects need to be accounted for in gathering and interpreting data, and proposes that EPA work with communities of color, low-income communities, tribes and other indigenous peoples to document the existence and extent of suppression effects due to contamination and/or completion. In many cases, increased research documenting the particular cultural, traditional, religious, historical, economic, and legal contexts in which these groups consume and use aquatic resources, proposed above in Proposal I-4(3), will go hand in hand with research documenting suppression effects.

2. FCWG proposes that wherever suppression effects are believed to be at work, EPA work together with the affected group to develop appropriate baseline levels for use when EPA provides guidance for states and tribes, and when EPA sets and approves water quality standards, cleanup standards, and other relevant environmental standards. This proposal might be applicable, for example, to EPA's current cleanup work at the Superfund Site on the Duwamish Waterway.

Current risk assessment methods do not adequately account for susceptibilities and co-risk factors that affect individuals' responses to environmental contaminants. These factors include underlying health status (including existing body burdens), baseline diet quality, genetics, socioeconomic status, access to health care, limited English proficiency, age, gender, pregnancy, lactation, and other factors.

Overarching Proposal

I-7. FCWG proposes further research into the extent to which susceptibilities and co-risk factors are clustered in certain subpopulations, including the extent to which there are disparities in current health status and body burden. To the extent that clusters emerge relevant to communities of color, low-income communities, tribes, or other indigenous peoples, FCWG proposes that EPA incorporate these factors into its risk assessment, risk management and risk communication efforts.

Focused Proposal

I-7

1. FCWG proposes that EPA undertake research to permit a more thorough understanding of these susceptibilities and co-risk factors and how they are distributed between communities.

2. FCWG proposes that, to the extent that clusters emerge relevant to affected groups, EPA develop methods to incorporate this information into its risk assessment, risk management, and risk communication efforts.

Current risk assessment methods evaluate risks as if humans were exposed to only a single contaminant at time, by a single route of exposure (e.g., consuming fish). Members of communities of color, low-income communities, tribes, and other indigenous peoples, however, are often exposed to multiple contaminants at a time or in succession, and often via more than route of exposure. For example, the Fourteen Confederated Tribes and Bands of the Yakama Nation fish in the Columbia River system, where it is the norm for over 100 contaminants to be identified in fish tissues; the northern Ojibwa Tribes are exposed to mercury via multiple natural resource pathways, given its uptake in fish and its presence in and on wild rice; and African-American and low-income communities living along the Mississippi are subject to multiple exposures, including from sources other than surface waters (e.g. consumption of contaminated fish; ingestion of polluted well water; inhalation of toxic air pollutants from surrounding incinerators, refineries, chemical manufacturers, and other industrial sources; and contact with and ingestion of particles from contaminated soils). Some of these multiple exposures and cumulative effects (and their interactions) are known; the vast majority are not well understood.

Overarching Proposals

I-8. Where the nature of cumulative effects are known, FCWG proposes their incorporation into EPA's environmental policy and specific standard setting practices. Where they are not well known, FCWG proposes this as a high priority area for research, given that the potential for cumulative effects are perhaps where the greatest danger to human health lurks.

I-9. Although EPA has made some inroads in accounting for multiple exposures and cumulative risks, it is FCWG's view that EPA simply must take a more aggressive, holistic, and integrative approach, especially where fish consumption levels are very high for communities of color, low-income communities, tribes, and other indigenous peoples and where the mix of contaminants to which these people are exposed may be highly toxic.

Focused Proposals

I-8 through I-9

1. FCWG proposes that EPA study the health impacts of chemical mixtures present in fish tissues, given that consumption and use of fish tissues represent one of the most significant and widespread instances of real life (as opposed to hypothetical) environmental exposures to chemical mixtures. FCWG further proposes that EPA incorporate the results of such studies in its risk assessment, risk management, and risk communication efforts.

2. At the same time, FCWG proposes that EPA avail itself of existing data characterizing the health risks of PCB-mercury mixtures present in fish tissues (e.g., data from the Seychelles and Faroe Islands). Given the availability of this data, and the large number of instances in which fish and wildlife consumption advisories are issued because of contamination from both PCBs and mercury, FCWG proposes that EPA not delay use of this data on the basis of the need for "further study."

Affected communities and tribes are integral to producing relevant, accurate, scientifically defensible data. Affected communities and tribes need, therefore, to be involved at every stage of the research on the issues identified above – from identifying research needs, to designing research methods, to interpreting the resulting data, to determining its importance to agencies' risk assessment, management, and communication efforts. Research should thus be a joint project reflecting and augmenting both affected communities' expertise and EPA and other agencies' expertise.

Overarching Proposals

I-10. FCWG proposes EPA to recognize the expertise of members of affected communities and tribes (including but not limited to tribal and non-governmental reservation-based organizations and organizations serving Alaska Natives), and to involve them or consult with them throughout the process of researching the various issues outlined above. FCWG proposes EPA to expand and publicize effectively the availability of financial and technical assistance for community-based organizations and tribes so that they may be directly involved in conducting research on these issues.

I-11. Importantly, FCWG proposes EPA to make available additional financial and technical resources to communities and tribes to conduct their own research (as was done for the Asian and Pacific Islander fish consumption study in King County, WA (EPA) and for the Suquamish Tribe fish consumption study (ATSDR)), and thereby to augment their expertise.

Focused Proposals

I-10 through I-11

1. FCWG proposes that EPA recognize the need for studies to be designed and administered *by and for* particular communities, groups, or peoples, and that it facilitate this process by, among other things:

a. Expanding financial and technical assistance to community-based organizations and tribes to conduct appropriate studies;

b. Taking the lead in identifying and coordinating financial and technical resources that are available through other federal agencies; and

c. Publicizing these expanded and coordinated resources to affected groups in a regular and timely fashion;

FCWG commends EPA's recent grant initiatives to this end (established together with the ATSDR), including two programs: *Lifestyle and Cultural Practices of Tribal Populations and Risks from Toxic Substances in the Environment* and *Superfund Minority Institutions Program: Hazardous Substance Research.* However the need for funding to enable communities and tribes fully to be involved in research and decisions affecting risk assessment, management, and communication far outstrips the funding that has been so far made available.

2. FCWG proposes that EPA take an active role in establishing and maintaining a system enabling affected groups to share and access results from community-based and tribally conducted research, as well as other research relevant to affected groups' efforts to document and address the nature, extent, and health impacts of contamination in their own communities. Such a system would assist tribes' and communities' efforts to conduct more efficiently their own research, and to participate in or consult with EPA in a timely and informed manner.

3. FCWG emphasizes that, while further research regarding various affected groups' exposure is important, it should not be undertaken at the expense of research that aims to identify the sources of the contamination that burdens these groups and to understand the mechanisms by which substances that have been or are being emitted or discharged from these sources make their way through the environment. Thus, FCWG proposes that further research be conducted to connect the contaminants found in fish, shellfish, and other aquatic resources to the sources of those contaminants.

Current risk-based methods remain controversial as a matter of science, policy and justice.

Overarching Proposals

1-12. To the extent that EPA continues to rely on risk-based and other quantitative methods (e.g., cost-benefit analysis), FCWG proposes EPA to revisit, together with affected communities and tribes, the fundamental assumptions of these methods and to revise these methods to incorporate eco-cultural and spiritual components of risk.

I-13. FCWG strongly proposes that EPA employ the Precautionary Principle at every opportunity as an alternative to risk-based methods.

Focused Proposals

I-12 through I-13

1. FCWG proposes that EPA consider seriously alternative decision making models that permit the multiple and interrelated dimensions of the harms to be acknowledged and addressed. Among these, EPA should consider the model for enlarging current risk assessment methods suggested by Stuart G. Harris and Barbara L. Harper, *Using Eco-Cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures*.

2. FCWG proposes that EPA, together with communities of color, low-income communities, tribes, and other indigenous peoples, work to explore and specify the contours of the precautionary principle. FCWG notes that there is a considerable and growing body of work to this end, and proposes that EPA draw on this body of work and support efforts further to develop it.

3. FCWG proposes that EPA actively identify and make use of opportunity for precautionary approaches within existing legislative and other authority, and that EPA consider and advocate appropriate changes to existing laws in order to facilitate precautionary approaches.

4. FCWG notes that preventive and precautionary measures will often at the same time reduce costs to regulated entities (e.g., savings through reduced use of toxic inputs, savings through reduced need to treat and dispose of toxic outputs); these cost savings will be particularly important where the particular regulated entities are an important source of jobs for communities of color, low-income communities, tribes and other indigenous peoples. FCWG proposes, therefore, that EPA make it a priority to identify and undertake prevention opportunities where this is the case.

Chapter Two

Aquatic environments remain contaminated, despite the existence of considerable environmental legal authorities designed to address contamination. About 40% of the waters assessed in the United States still do not support "fishable-swimable" uses; about 10% by volume of all sediments under U.S. waters are seriously contaminated; the list of contaminated soils, sediments, and surface waters yet to be cleaned up is long; and the number of fish consumption advisories in effect has increased steadily over the last several years. Contaminated aquatic environments are the result of releases to various environmental "receiving media" – to surface waters, groundwater, sediment, soils, and air – and movement among these interconnected media. Because people of color, low-income people, American Indians/Alaska Natives, and other indigenous people are disproportionately among the most exposed to this contamination, any lapses in agencies' efforts to prevent, reduce, clean up, and restore contaminated aquatic environments will disproportionately burden these affected groups.

Overarching Proposals

II-1. Given that five contaminants--mercury, PCBs, dioxins, DDT, and chlordane--are responsible for the majority of fish and wildlife consumption advisories, FCWG proposes that the prevention and cleanup of these pollutants in the Nation's waters and restoration of aquatic ecosystems following such contamination be a priority. FCWG further proposes that prevention, cleanup, and restoration efforts focus on all contaminants that are highly toxic, bioaccumulative, and persistent, especially those identified by the Convention on Persistent Organic Pollutants (POPs); and on other contaminants of concern, including lead and other metals, radioactive materials, pesticides, fecal coliform and other bacterial and viral contaminants, sediment and silt loading, water quantity, water temperature changes and other alterations to aquatic ecosystems, and climate change.

II-2. FCWG cannot emphasize strongly enough the need for redoubled, aggressive prevention, cleanup, and restoration efforts to address these contaminants of concern in the surface water, groundwater, sediments, soils and air. FCWG proposes EPA to ensure that efforts to cleanup and restore contaminated aquatic ecosystems are coupled with measures to prevent future contamination.

II-3. Specifically, because mercury is responsible for nearly 79% of all fish and shellfish advisories and because air emissions account for 80% of mercury depositions in water, FCWG proposes that the prevention and cleanup of mercury in the Nation's waters be a top priority for EPA, and that regulations and other efforts here address all significant sources of mercury, regardless of the initial "receiving medium" (e.g., air, soils, water, sediments). Moreover, FCWG *proposes EPA to ensure that reductions in mercury accrue equitably to all, and that mercury reduction efforts do not have the effect of creating "hot spots" or other disparate impacts.*

II-4. Further, FCWG proposes that prevention and cleanup of dioxin address all significant sources, and that cleanup of PCBs, DDT, and chlordane (production of which are banned), address all significant sources. Similarly, FCWG proposes that prevention and cleanup of all Persistent Bioaccumulative Toxins(PBTs)/Persistent Organic Pollutants (POPs) address all significant sources.

II-5. Finally, because the concentrations in aquatic organisms of mercury and some other contaminants of concern, such as lead, cannot be reduced by cleaning, trimming, and or cooking, FCWG proposes that regulatory authorities should not rely on advisories suggesting these methods as a way to protect public health.

Focused Proposals

II-1 through II-5

1. FCWG proposes that EPA work expeditiously to *prevent* and *reduce* the release of contaminants of concern and to *clean up* and *restore* aquatic ecosystems contaminated by these pollutants. FCWG emphasizes that, in every instance, EPA must set the relevant environmental standards at levels that protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples. FCWG also emphasizes that, in every instance, EPA account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes:

a. With respect to mercury:

(i) EPA address these concerns and expedite the issuance of a Maximum Achievable Control Technology (MACT) standard for emissions from utilities, including coal-fired power plants (a MACT standard for utilities is not scheduled to be proposed until December, 2003; meanwhile, coal-fired power plants are the largest single source of mercury air emissions);

(ii) EPA address these concerns in issuing a Maximum Achievable Control Technology (MACT) standard for emissions from institutional, industrial, and commercial boilers;

(iii) EPA address these concerns in issuing a Maximum Achievable Control Technology (MACT) standard for emissions from chlor-alkali plants (although there are only about a dozen chlor-alkali plants in the United States, each plant is the source of large quantities of mercury. Further, chlor-alkali plants may in some cases constitute the most significant sources locally, as in Louisiana, where the two chlor-alkali plants statewide contribute more mercury than all of the coal-fired power plants statewide combined.[447]);

(iv) EPA address these concerns and expedite the (re)- issuance of its Hazardous Waste Combustor rule, and that, in the meantime, EPA not rely on an interim rule that is less protective than the original final rule – which was struck down by a court because it was insufficiently protective;

(v) EPA address these concerns in ensuring compliance with its recently-issued Maximum Achievable Control Technology (MACT) standard for emissions from medical waste incinerators, and in identifying and facilitating further efforts to reduce and eliminate the use of mercury in the first place (including, e.g., efforts similar to OPPTS' voluntary agreements with hospitals and other medical facilities to reduce mercury use; state and local governments' bans on the use of mercury-containing

[447]Telephone Interview with Barry Kohl, Department of Geology, Tulane University (October 17, 2001).

medical products;[448] and potential partnerships with private industries to develop and produce alternative, mercury-free products);

(vi) EPA's Office of Air and Radiation and its Office of Water address these concerns and redouble their efforts to address cross-media mercury contamination through various initiatives, including through the TMDL program;

(vii) EPA address these concerns in supporting the United Nations Environment Program's (UNEP) global mercury study and facilitating and participating in the resulting UNEP efforts toward negotiations on global reductions in mercury emissions;

b. With respect to PCBs:

(i) EPA give priority to these concerns in setting or approving cleanup standards under CERCLA; that EPA conduct robust cleanups and decline to employ "use-restricted" or "risk-based" methods for sites affecting communities of color, low-income communities, tribes, and other indigenous peoples; and that, in any event, EPA refuse to rely on projected or current reductions in fish, shellfish, and aquatic resource consumption and use as a justification for less protective cleanup standards or assumptions;

c. With respect to dioxin:

(i) EPA move expeditiously to release the final Dioxin Reassessment and that EPA ensure that the "need for further study and peer review" not be used as a reason to delay further its publication and use, given that dioxin has already been the subject of over a decade of study and sound scientific evidence supports the findings of the draft Dioxin Reassessment;

(ii) EPA address these concerns in ensuring compliance with its recently-issued Maximum Achievable Control Technology (MACT) standard for emissions from medical waste incinerators, and in identifying and facilitating further efforts to reduce and eliminate the use of products that, ultimately, result in releases of dioxin;

(iii) EPA address these concerns in issuing rules and undertaking initiatives to reduce further dioxin emissions to air, particularly from those sources that remain un- or under-controlled, including backyard burning;

(iv) EPA address these concerns in undertaking cleanup of sediments and soils contaminated from historical emissions and discharges of dioxin, given the increasing relative contribution of sediments and soils to dioxin contamination (as other sources are controlled);

(v) EPA work expeditiously to conduct surveys of sediments and soils likely to be contaminated with dioxin, in order to facilitate effective cleanup;

(vi) EPA, as part of its Dioxin Exposure Initiative, work systematically to characterize the exposures of communities of color, low-income communities, tribes, and their members and to link these exposures to their sources;

(vii) EPA ensure the efficacy of standards regulating dioxin, by working expeditiously to improve its ability to measure dioxin levels – because dioxin is highly toxic in even very small quantities and because current methods are not sensitive enough to detect dioxin in very small quantities, EPA cannot ensure that releases at "non-detect" levels are in fact protective of the health of communities of color, low-income communities, tribes, and other indigenous peoples;

[448] These bans have the effect not only of requiring the use of alternative, mercury-free health care products and but also of providing incentives for the development and production of improved mercury-free technology and products. Indeed, such alternative, mercury-free health care products are already becoming available. See, e.g., Sustainable Health Care Project website at: www.uml.edu/centers/LCSP/hospitals.

d. With respect to these and other contaminants of concern:

(i) EPA begin expeditiously to include additional contaminants of concern on its list of Persistent and Bioaccumulative Toxics (PBTs), including lindane, endosulfan, lead and a host of other highly toxic, persistent, and bioaccumulative substances, especially those affecting the aquatic resources on which communities of color, low-income communities, tribes, and indigenous peoples depend;

(ii) EPA, under the auspices of its PBT Initiative and otherwise, place a priority on efforts to reduce and eliminate the use of PBTs, and to clean up and restore those ecosystems already contaminated with PBTs.

2. FCWG proposes that, similarly, with respect to its efforts under the Clean Water Act and other statutes addressing water quality and quantity, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA issue guidance clarifying that water quality standards (WQS), whether issued by states, tribes or the EPA, account to the greatest extent possible under law for these affected groups' different consumption and use of aquatic resources by, among other things:

(i) requiring "designated uses" to reflect appropriate rates of consumption and use of fish, shellfish, plants and wildlife by subsistence fishers and other higher-consuming groups;

(ii) requiring that such "designated uses" be recognized not only for those water bodies where subsistence and other fishing currently occurs, but also for those water bodies where subsistence and other fishing *would* occur, but for the contamination and depletion that give rise to suppressed consumption (described in Chapter One of the Report);

(iii) requiring that designated uses support cultural, traditional, and ceremonial uses of aquatic resources, particularly where the quality of the relevant water bodies affects tribal and other culturally important resources (whether located on- or off-reservation);

(iv) requiring triennial reviews of water quality standards under CWA § 303(c)(1) to consider whether state or tribal criteria protect subsistence fishers and other higher-consuming groups where subsistence and other fishing exists, and stipulating that EPA disapprove any criteria that do not protect these groups;

b. EPA issue a Total Maximum Daily Load (TMDL) rule that protects highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and accounts for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources – especially given that the impaired waters affected by the TMDL rule occur primarily and disproportionately in locations that impact these affected groups;

c. EPA issue a rule for Large Feedlots (also called Concentrated Animal Feeding Operations (CAFOs)) that protects the health and resources of communities of color, low-income communities, tribes, and other indigenous peoples in the process of addressing the siting and regulation of new facilities and the clean up of contamination from existing and former facilities; and that incorporates the NEJAC Resolution on CAFOs;

d. EPA issue a rule for Metal Products and Machinery that protects the health and resources of communities of color, low-income communities, tribes, and other indigenous peoples while attending to issues of economic justice, particularly to the extent those small businesses affected by the rule are an important source of jobs and economic health for members of affected groups (e.g., by focusing on measures that both prevent contamination and reduce costs to regulated sources);

e. EPA make every use of its authority under the National Pollutant Discharge Elimination System (NPDES) program to protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources, by among other things:

(i) imposing appropriate permit conditions, when EPA possesses the permitting authority;

(ii) disapproving permits that do not impose appropriate conditions, when states or tribes possess the permitting authority; and

(iii) incorporating the NEJAC proposals regarding permitting: *Environmental Justice in the Permitting Process: A Report from the Public Meeting on Environmental Permitting, Convened by the National Environmental Justice Advisory Council in Arlington, Virginia, Nov. 30-Dec. 2, 1999;*

f. EPA explore and implement additional strategies to address non-point source discharges and runoffs to waters that threaten aquatic ecosystems and human health, including but not limited to discharges from agricultural, construction, forestry, and land disposal operations; stormwater runoff; and applications of FIFRA-approved herbicides along irrigation canals and other waterways;

g. EPA make full use of its authority to ensure non-degradation of clean or "pristine" waters;

h. EPA work to protect and restore wetlands, and to oppose efforts by the Army Corps of Engineers that would relax rules designed to restrict development and degradation of streams and wetlands and to limit cumulative adverse effects on the aquatic environment and ecosystem;[449] EPA should take seriously and literally the commitment to "no net loss;"

i. EPA, in writing regulations under the CWA and in acting other authorities, consider the effect of human-controlled timing and quantity of water flows on water temperature, pollutant concentrations, the health and propagation of fish and wildlife, and the overall health of aquatic ecosystems;

j. EPA attend to urban (e.g., Oakland) and rural (e.g., towns along the U.S.-Mexico border; Alaska Native villages; elsewhere in Indian country; Hawai'i) sanitation issues and their impact on the health of humans and aquatic ecosystems.

3. FCWG also proposes that, with respect to its efforts under the Clean Air Act and other statutes addressing air emissions that affect the health of aquatic ecosystems, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA work with Congressional staff, testify before Congress, and otherwise seek to ensure that the National Energy Plan currently being debated:

(i) places stringent limits on releases of NOx, SO2, and mercury from power plants in order to protect communities of color, low income communities, tribes, and other indigenous peoples and the aquatic ecosystems on which they depend; and

(ii) in the event that it includes an emissions trading program for mercury, employs a "cap" that requires significant aggregate reductions in mercury and includes mechanisms to guarantee that disproportionate burdens from these sources on communities of color, low income communities, tribes, and other indigenous peoples are not exacerbated or newly created by trading;

b. EPA evaluate more thoroughly the impacts of air deposition on the health of fish, aquatic plants, and wildlife, and, in turn, on communities of color, low income communities, tribes, and other indigenous peoples that depend on these resources, and that EPA address these impacts, including:

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[449] The Washington Post Online, "Army Corps Seeks to Relax Wetlands Rules," by Michael Grunwald, p. A01 (June 4, 2001). See also http://washingtonpost.com:80/wp-dyn/articles/A16798-2001June3.html.

(i) through expanded cross-program initiatives; and

(ii) when it considers the residual risks after the application of MACT, as part of the 10-year reviews required under CAA § 112(f);

c. EPA better control NOx to prevent acidification and eutrophication;

d. EPA make every use of its authority under the Title V Air Operating Permit program to protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources, by among other things:

(i) imposing appropriate permit conditions, when EPA possesses the permitting authority;

(ii) disapproving permits that do not impose appropriate conditions, when states or tribes possess the permitting authority; and

(iii) incorporating the NEJAC proposals regarding permitting: *Environmental Justice in the Permitting Process: A Report from the Public Meeting on Environmental Permitting, Convened by the National Environmental Justice Advisory Council in Arlington, Virginia, Nov. 30-Dec. 2, 1999.*

4. FCWG also proposes that, with respect to its efforts under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and other statutes addressing cleanup and restoration of contaminated environments, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA expand its current efforts under its Contaminated Sediment Management Strategy so that in addition to assessing the nature and extent of contamination sediments, it focuses on and prioritizes cleanup and restoration of contaminated sediments, and that in the process, EPA attend to disposal issues raised by contaminated sediments that have been removed;

b. EPA conduct robust cleanups and decline to employ "use-restricted" or "risk-based" methods for sites affecting communities of color, low-income communities, tribes, and other indigenous peoples, and that, in any event, EPA refuse to rely on projected or current reductions in fish, shellfish, and aquatic resource consumption and use as a justification for less protective cleanup standards or assumptions;

c. EPA work through every avenue possible to oppose efforts to eliminate funding for CERCLA's "Superfund;" to ensure that, to the extent these efforts are successful, EPA nonetheless continues to place a high priority on cleanup and restoration of those sites contaminated with pollutants likely to bioaccumulate in the fish, aquatic plants, and wildlife consumed or used for subsistence, traditional, cultural or religious purposes; and to ensure that any resulting delay in addressing such sites not be used to justify less protective cleanup standards;

d. EPA work to retain and effectuate the "polluter pays" principle under CERCLA, by, among other things, looking to potentially responsible parties (PRPs) to ensure funding for full restoration of those ecosystems that support fish, shellfish, aquatic plants and wildlife on which affected groups rely; ensure funding for adequate communication with affected tribes and communities and; if appropriate from the perspective of those affected, funding for alternatives that may serve as substitutes for the contaminated resources until such time as the restoration is complete (Please note, however, that such alternatives will NOT be appropriate from the perspectives of some affected groups – the provision of alternative resources, for example, is not endorsed by the Indigenous Peoples Subcommittee);

e. EPA improve cooperation among EPA offices on cleanup and restoration strategies, particularly initiatives targeted at restoring those aquatic ecosystems that are contaminated with pollutants likely to bioaccumulate in the fish, aquatic plants, and wildlife consumed or used for subsistence, traditional, cultural or religious purposes;

f. EPA revise its Principles for the Ecological Restoration of Aquatic Resources to focus not only "on scientific and technical issues"[450] but also on the historical, cultural, legal, and social contexts within which restoration takes place; that EPA revise these Principles to reflect the interrelation between "physical"structures and functions on the one hand and social and cultural structures and functions on the other hand, such that restoring and maintaining "ecological integrity" includes restoring and maintaining cultural integrity; and that EPA work with tribes and other affected groups to undertake "eco-cultural restoration."[451]

5. FCWG also proposes that, with respect to its efforts under the Toxic Substances Control Act (ToSCA), and other statutes regulating new and existing chemical substances, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA's Office of Pesticides, Prevention, and Toxic Substances (OPPTS) flag to its Office of Water (OW) those chemicals that it registers that are expected to be produced or used in high volume and that will potentially affect aquatic ecosystems; OW should then work with OPPTS to secure additional and higher level testing, and where potential contamination of fish and aquatic resources is suspected, to ensure that additional testing and rulemaking are expedited.

6. FCWG also proposes that, with respect to its efforts under other statutory authorities, EPA protect highly-exposed populations, including communities of color, low-income communities, tribes, and other indigenous peoples and account for the particular cultural, traditional, religious, historical, economic, and legal contexts in which these affected groups consume and use aquatic resources.

Specifically, FCWG proposes that:

a. EPA issue a rule regulating coal combustion waste under the Resource Conservation and Recovery Act (RCRA), especially given the presence of arsenic in this waste and the fact that, in many places, this waste is still being disposed of in unlined facilities and leaching into drinking water sources;

b. EPA tighten hazardous waste rules to prohibit toxic wastes, such as dioxins, mercury, lead, cadmium, and other contaminants of concern from being "recycled" into fertilizer, and eliminate the exemption for steel mill waste;[452] and that EPA rewrite its ten-year-old treatment standard for hazardous waste, ensuring that the new rule does not create disincentives (such as those created by permissive provisions regarding recycling) for developing and implementing improved treatment technologies.

7. In undertaking compliance and enforcement efforts affecting the quality of aquatic ecosystems, FCWG proposes EPA to improve its cooperation, coordination, and collaboration with states and tribes, and, in the case of federally recognized tribes, to improve its consultation with tribal governments.

In setting or approving standards and in making other risk management decisions meant to address these contaminants, EPA aims for a level of risk to human health deemed "acceptable" or safe. That is

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[450]U.S. EPA, Principles for the Ecological Restoration of Aquatic Resources (2000), available at www.epa.gov/owow/wetlands/restore/principles.html.

[451]See, e.g., Jeffrey P. Thomas, Director, Forest Resource Protection Program, Fisheries Department, Puyallup Tribe of Indians, Testimony to the National Environmental Justice Advisory Council, Dec. 4, 2001 (Written Comments) (describing the potential role for the Inter-Tribal Cultural Advisory Group (in Washington) to this end).

[452]Toxic wastes from pulp and paper mills, steel mills, tire incinerators and cement kilns is currently "recycled" into fertilizer and applied to crops, grazing lands and gardens. This waste has been found to contain dioxins, mercury, lead, cadmium, and other contaminants of concern. Although hazardous waste regulations address this practice, (1) they may still permit unacceptable levels of these contaminants, and (2) they contain a loophole that exempts steel mill waste. See, e.g., Washington Toxics Coalition, Visualizing Zero: Eliminating Persistent Pollution in Washington State (2000).

to say, for carcinogens or non-threshold contaminants, EPA in effect determines that it will view the increased incidence of cancer in some number of humans (e.g., 1 out of every 1,000,000 humans) to be "acceptable," and will permit environmental standards to be set accordingly. To the extent that EPA's guidance and standards deem a greater level of cancer risk to be "acceptable" for "more highly exposed subgroups" than for the general population, this is inequitable and deeply troubling as a matter of environmental justice, given that we *know* – and EPA *knows* – that it is people of color, low-income people, American Indians/Alaska Natives, and other indigenous people that comprise the "more highly exposed subgroups." Moreover, in the view of FCWG, human lives are not expendable. EPA should strive for standards that do not find "acceptable" the increased risk of cancer for *any* humans.

Overarching Proposals

II-6. FCWG proposes that as a general matter, EPA should ensure that the federal environmental laws are implemented and enforced equitably and effectively to protect the health of all people consuming fish, aquatic plants, and wildlife.

II-7. FCWG proposes that substantive environmental standards be set so as to provide equitable levels of protection to all – levels that protect not only the health of the general population, but also the health of people of color, low-income people, American Indians, Alaska Natives, Native Hawaiians and other Pacific Islanders, and other indigenous people located within the jurisdiction of the United States.

II-8. Specifically, FCWG proposes that EPA rescind any guidance setting "acceptable" risk for subsistence and other higher-consuming subgroups at levels greater than the general population (e.g., EPA's revised Ambient Water Quality Criteria Methodology, which defines "acceptable" cancer risk for higher-consuming subgroups as risk that permits up to 1 in 10,000 people to suffer from cancer whereas it defines "acceptable" cancer risk for the general population as risk that permits a fewer number of people to suffer from cancer – between 1 in 100,000 and 1 in 1,000,000, and perhaps as few as 1 in 10,000,000), and to reissue guidance that prevents such a disparity in protection. Moreover, FCWG proposes EPA to reconsider in every relevant context its determination that some greater number of human cancers due to environmental contamination is "acceptable" for more highly exposed subgroups and to strive for standards that do not find "acceptable" the increased risk of cancer for any *humans, i.e., standards that aim for zero risk.*

In setting or approving standards and in making other risk management or regulatory decisions meant to address these contaminants, EPA needs to respect and accommodate the different cultural, traditional, religious, historical, economic, and legal contexts in which affected groups consume, use, and depend on aquatic resources.

Overarching Proposal

II-9. FCWG proposes EPA to work with affected groups better to understand the various different cultural, traditional, religious, historical, economic, and legal contexts in which these groups consume, use, and depend on aquatic resources and to develop methods to incorporate these groups' particular circumstances into the standards EPA sets or approves and into the other risk management and regulatory decisions EPA makes.

Focused Proposals

II-9

1. FCWG proposes that EPA use its authority under CWA § 101(e) and elsewhere to encourage states to improve their public participation processes in the development of water quality standards through translation for non-English speaking groups and through greater outreach.

2. FCWG proposes EPA to work together with affected communities and tribes to explore creative, culturally appropriate ways to inform its prevention and reduction efforts regarding communities' and tribes' actual practices, where these practices expose these groups to contaminants in fish, shellfish, plants, and wildlife within aquatic ecosystems.[453]

3. FCWG proposes that EPA reconceptualize its role in understanding affected groups' circumstances of exposure, so that it focuses on building longer-term relationships with affected groups. In the context of these relationships, iterative conversations and other on-going processes would then serve to better inform efforts to prevent and reduce contamination in the first place.

4. EPA's Principles for the Ecological Restoration of Aquatic Resources suggest that restoration efforts "involve the skills and insights of a multi-disciplinary team," and cite among the relevant disciplines "ecology, aquatic biology, hydrology and hydraulics, geomorphology, engineering, planning, communications and social science."[454] FCWG proposes that EPA broaden its understanding of the kinds of expertise relevant to restoration, and include among those it consults elders, anthropologists, ethnobiologists, historians, and others who can provide insight into the "eco-cultural" aspects of restoration.[455]

Prevention, cleanup, and restoration of aquatic ecosystems implicates not only EPA but also numerous other federal departments, agencies and programs (e.g., the Department of Defense, the Department of Energy, the Federal Energy Regulatory Commission, the U.S. Forest Service, the National Marine Fisheries Service, the U.S. Geological Survey, the Bureau of Indian Affairs, the Indian Health Service, the National Institute of Environmental Health Services). Prevention, cleanup, and restoration efforts would be greatly improved and hastened by coordination among these various entities.

Overarching Proposal

II-10. FCWG proposes EPA to take the lead in coordinating the various federal departments, agencies and programs in order to improve prevention, cleanup, and restoration efforts, and to ensure that the results of these efforts, as well as the process for achieving the results, are just.

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[453]Communities' and tribes' knowledge here simply cannot be replicated by non-members. At the same time, agencies' familiarity with laws, regulations and guidance is crucial. In some cases, affected communities and tribes have already begun to develop relevant processes, e.g., for documenting consumption and use practices and the contexts in which these occur, or to assemble other relevant informational resources. For example, the Tulalip Tribes are gathering "cultural stories" that will help inform their natural resources and environmental management efforts.

[454]U.S. EPA, Principles for the Ecological Restoration of Aquatic Resources (2000), available at www.epa.gov/owow/wetlands/restore/principles.html.

[455]Dennis Martinez, Presentation, Indigenous Ecology and Cultural Restoration Workshop (San Francisco, Sept.21, 1999).

Focused Proposals

II-10

1. FCWG proposes EPA to improve cooperation among EPA offices, as well as among federal agencies, on pollution prevention strategies, particularly initiatives targeted at preventing the discharge or release of pollutants likely to bioaccumulate in the aquatic ecosystem and people.

2. FCWG proposes that EPA use Interagency Working Group as vehicle for disseminating information on prevention, cleanup and restoration that is attentive to the issue of contamination of aquatic ecosystems and its impact on communities of color, low-income communities, tribes, and other indigenous peoples.

3. FCWG proposes EPA to coordinate effectively with other federal agencies to ensure that *sufficient quantities* of water are maintained and protected to support a sustainable and healthy aquatic ecosystem, and to ensure that other actions are undertaken (e.g., under the Endangered Species Act (ESA) to guarantee the health of fish, shellfish, plant, and wildlife species and the habitats on which these species depend.

Tribal governments or EPA are responsible for implementing water quality standards (WQS) within Indian country and on Alaska Native lands. Yet, because only 16 of the 565 federally recognized tribes and Alaska Native villages have EPA approved and/or promulgated water quality standards, there are still considerable gaps in water quality standards coverage in Indian country.

Overarching Proposal

II-11. FCWG proposes that EPA address promptly existing gaps in water quality standards coverage in Indian country and on Alaska Native lands to protect tribal resources and treaty-protected rights as well as the health of American Indian/Alaska Native people who are heavily reliant on subsistence activities and diet. FCWG proposes EPA to make the development, adoption, implementation, and enforcement of water quality standards throughout all of Indian country a high priority. This includes support for tribal WQS in accordance with EPA's Indian Policy and promulgation of enforceable federal core WQS for reservation and other Indian country waters for which tribal WQS are not in effect. FCWG proposes that, consistent with the federal trust responsibility to the tribes, EPA use all available existing authorities under the federal environmental laws to protect tribal resources, treaty-protected rights, and the health of American Indian/Alaska Native people; provided that *EPA should cooperate with and support tribal regulatory efforts in those instances where tribes choose to carry out various responsibilities under the federal environmental laws. In the context of Alaska Native lands that are not considered Indian country, FCWG proposes EPA to engage in consultation with Alaska Native tribes and the State of Alaska on the possible revision of WQS better to protect subsistence traditions, such as the adoption of designated uses for subsistence harvesting of fish and wildlife.*

Focused Proposals

II-11

1. FCWG proposes that EPA, in consultation with tribes, proceed with rulemaking on the Core Federal Water Quality Standards for Indian Country:[456]

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[456]See U.S. EPA, Office of Water, Federal Water Quality Standards for Indian Country and Other Provisions Regarding Federal Water Quality Standards (unofficial pre-publication copy, Jan. 19, 2001) (available at www.epa.gov/ost/standards/tribal/) [hereinafter "Proposed Core Standards"].

a. The Proposed Core Standards currently call for a four-part hierarchy for selecting a fish consumption rate for use in setting water quality standards in Indian Country. This hierarchy sets up a preference for using "the results of any existing fish consumption surveys of local Indian country watersheds to establish fish intake provisions that are representative of the population being addressed," but in the absence of such data, would look to a default fish consumption rate as low as 17.5 grams/day.[457] In FCWG's view, this default fish consumption rate does not accurately reflect the consumption practices of most tribes. FCWG proposes EPA to employ a default consumption rate that is appropriate for higher-consuming tribes and their members. EPA should select this default rate in consultation with tribes. FCWG further proposes EPA to account for other aspects of tribes' different exposure circumstances, including practices that mean different species are consumed, different parts are used, and/or different preparation methods are employed than those typically assumed by agencies. Again, EPA should consult with tribes to understand the nature and import of these practices. Finally, FCWG commends the fact that the proposed hierarchy sets up a preference for local data, but emphasizes the need for EPA to fund additional, tribally conducted fish consumption surveys in Indian country watersheds. As discussed in Chapter One, currently only a handful of such studies exist;

b. EPA should, in consultation with tribes, develop guidance for EPA permit writers charged with implementing the Proposed Core Standards in order to ensure that permit writers tailor NPDES permits to each individual tribe's circumstances, including their particular cultural practices;

c. EPA should provide adequate funding and technical assistance to enable tribes who wish to do so to develop a plan for adopting their own water quality standards under the Clean Water Act or for developing individualized federal standards together with the relevant Regional Administrator within a reasonable amount of time, as required in order to be excluded from the rule adopting Core Federal Water Quality Standards for Indian Country.[458]

The contamination of aquatic environments and the harmful effects of this contamination are matters of global concern. Pollution, of course, does not respect political boundaries and many of the contaminants of concern persist in the environment and travel great distances, cycling through the air, water, soils, and sediments and affecting people and places far from the source.

Overarching Proposals

II-12. FCWG proposes EPA to be mindful of the interconnected and international nature of contaminated aquatic ecosystems. FCWG proposes that EPA work to ensure the development, ratification, implementation, and enforcement of international law and policy addressing the contaminants of concern.

II-13. Specifically, FCWG proposes EPA to expend every effort to see that the United States ratifies the Convention on Persistent Organic Pollutants (POPs) and to develop, together with affected communities and tribes, an implementation plan for the United States that assures compliance with this treaty.

Chapter Three

Fish and wildlife consumption advisories are one component of a comprehensive health risk control strategy and can serve the useful function of aiding affected communities in determining to what extent they will take the proposed steps to avoid health risks.

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[457]See Proposed Core Standards at 17.
[458]See id. at 4-6.

Overarching Proposals

III-1. However, FCWG strongly emphasizes that advisories must be coupled with ongoing and aggressive efforts to curb existing and future pollutant sources through stringent implementation and enforcement of water quality and other environmental regulations and cleanup of historic contaminant sources. FCWG proposes EPA to work with affected groups and be proactive in identifying and implementing alternatives that protect the health of disproportionately exposed groups in the meantime, that is, until prevention and cleanup are fully achieved.

Focused Proposals

III-1

1. Fish consumption advisories – which shift the burden to risk-bearers to avoid the risks they have been made to face – should never be allowed to become the primary method by which agencies address risks. Rather, FCWG proposes EPA to require risk-producers to prevent, reduce and cleanup contamination, and to view fish consumption advisories as a short-term, interim strategy to inform and to protect the health of those who consume and use fish, aquatic plants, and wildlife while cleanup is proceeding. To this end:

   a. FCWG proposes EPA to focus, during planning and priority setting, on reducing risk and addressing communities' and tribes' health and safety needs rather than on securing communities' and tribes' "compliance" with fish advisories or other risk avoidance measures;

   b. FCWG emphasizes that EPA needs to couple the use of fish consumption advisories designed to protect people's health "in the meantime" with a real, aggressive push to cleanup, reduce and prevent contamination in the first place;

   c. FCWG proposes a focus in particular on prevention now so that in the future EPA and states will not be faced with having to employ fish consumption advisories.

2. FCWG proposes that EPA develop, and help states and tribes to develop, measures to ensure that reliance on fish consumption advisories is truly a temporary strategy. Given that advisories have been in effect in some places for nearly 30 years (e.g., the Great Lakes), it seems that a renewed commitment is in order. To this end, FCWG proposes EPA to consider a wide variety of measures, including sunset provisions, periodic reevaluation, etc., that would help EPA and other agencies guard against the advisory program taking on a life of its own.

3. FCWG proposes that EPA develop, and help states and tribes to develop, mechanisms to ensure that agency risk communicators coordinate with agency risk managers so that affected groups' responses to fish consumption advisories inform future risk management decisions, including planning and priority-setting. FCWG notes that this coordination is especially important where the affected community or tribe declines to *"*comply*"* with a fish advisory: to the extent that such a response expresses a protest with current priorities (e.g., reliance on risk avoidance rather than risk reduction), EPA needs to ensure, and help states and tribes to ensure, that this protest gets registered with and taken into account by those setting priorities.

4. FCWG proposes EPA to increase financial and technical support to tribes who wish to determine for themselves what role fish consumption advisories should play in their efforts to protect the health and safety of tribal members and who may wish to fashion tribal consumption guidelines. This would include funding basic research by the tribe into the nature and extent of the contamination of concern, and its health effects for tribal members. FCWG notes that tribes are often the only ones in the position to frame the research questions in a way that reflects their unique knowledge of tribal resources and their sense of what is appropriate for tribal members. Further, FCWG proposes EPA to require states that issue advisories to notify directly all tribes whose land and resources (including resources both on- and off-reservation) are affected by the advisory.

5. FCWG proposes EPA to increase financial and technical support to affected communities to participate in decisions, including decisions at the state and local levels, about what role of fish consumption advisories should play in efforts to protect the health and safety of community members.

6. FCWG proposes that EPA consider how it might meet the immediate needs of communities of color, low-income communities, tribes, and indigenous peoples who are burdened by existing contamination.

Specifically, FCWG proposes that:

a. EPA work together with affected groups to identify useful alternatives for those who would avail themselves of alternative means of catching or consuming fish or alternative ways of meeting at least some nutritional needs;

b. EPA consider, *together with those affected*, whether there is a role for providing such things as subsidized construction of alternative fishing ponds; subsidized bus passes or other transportation vouchers to alternative fishing sites; subsidized vouchers for purchasing uncontaminated fish; subsidized vouchers for purchasing alternative sources of protein; subsidized aquaculture; or other measures to meet affected groups' immediate needs. *However, FCWG emphasizes that EPA should proceed cautiously here, working closely with the particular affected group(s) and attending to the possible negative effects of such alternatives* (e.g., government "surplus" foods are notoriously high in fat and sugar and providing such foods could exacerbate existing health conditions – such as diabetes, the incidence of which is much greater among Native American populations and some other affected subgroups). *FCWG implores EPA to recognize that the provision of alternatives will be inappropriate from the perspective of some affected groups.* (The Indigenous Peoples Subcommittee, for example, does not endorse the provision of alternatives or "substitutes" for contaminated aquatic resources.);

c. EPA make greater use of fines imposed on violators as part of CERCLA enforcement actions that result in settlement to fund studies by and for affected groups, and to otherwise meet affected groups' immediate needs.

7. FCWG proposes that EPA work with state and local environmental and health agencies to ensure that not only is initial testing of fish, shellfish, and aquatic resources undertaken expeditiously but that follow up testing is also conducted, particularly given the importance of fisheries for subsistence and economic needs. Thus, for example, a state may in some cases act to close shellfisheries due to contamination that it has confirmed by testing, but neglect to conduct further testing in order to determine at earliest possible date that the threat from contamination over and it is appropriate to reopen the fishery. FCWG notes that, as a general matter, testing is too episodic at both ends.

While advisories are useful, in order for them to be effective they must be tailored to specific locales and specific communities – there is no one-size-fits-all, and "consistency" across broad regions or population groups may not be useful. The term "affected groups" here includes a large and diverse array of groups, each of which consumes and uses fish, aquatic plants, and wildlife in differing cultural, traditional, religious, historical, economic, and legal contexts. It will be crucial for any risk communication effort to recognize, therefore, the diverse contexts, interests, and needs that characterize affected communities, including but not limited to groups with limited English proficiency; groups with limited or no literacy; low-income communities; immigrant and refuge communities; African-American communities, various Asian and Pacific Islander communities and subcommunities (e.g., Mien, Lao, Khmu, and Thaidum communities within the Laotian community in West Contra Costa, CA); various Hispanic communities and subcommunities (e.g., "Caribbean-American" communities in the Greenpoint/Williamsburg area of Brooklyn, NY); various Native Americans, Native Hawaiians, and Alaskan Natives (including members of tribes and villages, members of non-federally recognized tribes, and urban Native people); and subgroups such as children, pregnant women, or elders within these groups.

Overarching Proposal

III-2. FCWG proposes EPA to learn about and attend to the fact that "affected groups" includes a large and diverse array of groups, each of which consumes and uses fish, aquatic plants, and wildlife in differing cultural, traditional, religious, historical, economic, linguistic and legal contexts. It will be crucial for any risk communication effort to recognize, therefore, the diverse contexts, interests, and needs that characterize affected groups.

Focused Proposals

III-2

1. FCWG proposes that EPA work with each of the large and diverse array of affected groups to determine priorities for defining, gauging, and enhancing advisories' effectiveness *from the perspectives of those affected.* FCWG emphasizes that EPA can better identify the real problems that exist in communities and tribes by listening to and consulting with those affected. FCWG commends EPA's recent efforts, together with the State of Minnesota, to bring together and fund the participation of representatives from communities and tribes in order to discuss some of these issues in the context of its *National Forum on Contaminants in Fish* in May, 2001.

2. FCWG commends the fact that EPA has dedicated resources and staff to be devoted to environmental justice issues and applauds the considerable work that has been done to identify the large and diverse array of affected groups and to attend to the particular cultural, traditional, religious, historical, economic, linguistic, and legal contexts in which these groups consume and use fish and other aquatic resources. FCWG proposes that EPA maintain and expand the resources and staff it devotes to environmental justice, and that EPA encourage states to do the same.

3. FCWG suggests that a focus on national or regional consistency among state and tribal advisory programs is misplaced from the perspective of most communities of color, low-income communities, tribes, and other indigenous peoples, whose concerns tend to be more localized; FCWG proposes, instead, that agency resources be redirected toward preventing, reducing, and cleaning up the contamination that gives rise to advisories.

Affected communities and tribes are integral to relevant, appropriate and effective risk communication. Affected communities and tribes need, therefore, to be involved as "partners" or, in the case of tribal governments, "co-managers" at every stage of the communication process – from identifying needs and priorities, to developing group-appropriate advisory content, language(s), and communication methods, to interpreting community responses and determining their import for agencies' risk assessment and management efforts.

Overarching Proposals

III-3. FCWG proposes EPA to recognize the expertise of members of affected communities and tribes, and to involve them or consult with them throughout the risk communication process. FCWG proposes EPA to follow NEJAC's Model Plan for Public Participation and NEJAC's Guide on Consultation and Collaboration with Indian Tribal Governments and the Public Participation of Indigenous Groups and Tribal Members in Environmental Decision Making.

III-4. Importantly, FCWG proposes EPA to make available additional financial and technical resources to communities and tribes to ensure that they can participate or engage in consultation effectively.

III-5. FCWG emphasizes the importance of capacity-augmentation in communities and tribes, and proposes that EPA recognize and facilitate this as a separate objective of full community and tribal involvement in risk communication.

III-6. To this end, FCWG specifically proposes that EPA, in issuing its advisories and in providing guidance to states and tribes :

(A) Ensure that affected communities and tribes are involved in the identification, design, implementation, and evaluation of culturally appropriate and effective communication of fish advisory information.

(B) Ensure that advisories present information in a form that is culturally appropriate and readily understood by the fisher and fish consumer (i.e. no jargon and in the language(s) of the affected communities, utilizing graphics as appropriate).

(C) Ensure that, where culturally appropriate and practicable, advisories suggest alternative means that would allow for the continued consumption of fish, including alternative fish species or alternative preparation and cooking methods.

(D) Ensure that affected communities and tribes are able to participate in or consult on the development of proposals about alternative or substitute food sources, and alternative preparation and cooking methods.

Focused Proposals

III-3 through III-6

1. FCWG proposes that, depending on the affected group, EPA use the NEJAC's *Model Plan for Public Participation* and/or NEJAC's *Guide on Consultation and Collaboration with Indian Tribal Governments and the Public Participation of Indigenous Groups and Tribal Members in Environmental Decisionmaking* as a guide for informing those affected not only of the fact of contamination and advisories, but also of the nature and extent of the contamination and its impacts on the health and well-being of the affected group. FCWG emphasizes the need to allow adequate time for those affected to digest and discuss the information and then to participate in or consult on relevant decisions.

2. FCWG notes that, in many cases, it will be appropriate for the regional EPA office to take the initiative to organize and collaborate with affected communities and tribes regarding contaminated fish and other aquatic resources. FCWG proposes that the regional EPA office, again using the *Model Plan* and/or the *Guide on Consultation*, as appropriate, assist affected groups to develop and communicate possibilities that would make the group whole. The regional EPA office, together with the affected group, should discuss, evaluate and negotiate which possibilities should be implemented and agree on an implementation plan and timelines; and should then be accountable to the group for "follow through," (e.g., ensuring *and communicating to the group the fact that* the measures identified are in fact implemented.

3. FCWG proposes EPA to set up data bases and other means by which affected groups may access information from and communicate with EPA, working with affected group to identify and meet their needs. FCWG emphasizes the need for EPA to provide financial and technical assistance to communities and tribes that are working to inform themselves in order to participate meaningfully in or consult meaningfully on EPA decisions affecting the aquatic ecosystems on with these groups depend. FCWG notes that this is a matter of capacity augmentation, and proposes EPA to make it a priority.

4. FCWG proposes that EPA, as it works with affected groups, be mindful of the various considerations outlined in Chapter Three, Part D of the Report, and that it encourage state and local agencies to look to the various approaches that have been cited in the Report as successful from the perspectives of those affected as potential models for their current risk communication efforts.

Chapter Four

Although American Indian tribes, Alaska Native villages, and their members share many of the concerns discussed in the preceding chapters, tribes' political and legal status is unique among affected groups and so warrants separate treatment. Tribes are governmental entities, recognized as possessing broad inherent authority over their members, territories, and resources. As sovereigns, federally recognized tribes have a government-to-government relationship with the federal government and its agencies, including the EPA. Tribes' unique legal status includes a trust responsibility on the part of the federal government. For many tribes, it also includes treaty rights (e.g., the rights of the treaty tribes of the Pacific Northwest to take fish "at all usual and accustomed grounds and stations;" or similar rights of treaty tribes elsewhere to fish, hunt and gather). Other laws and executive commitments, too, shape the legal obligations owed to tribes, American Indians and Alaska Natives.

Additionally, due to their special susceptibilities such as poverty, remote location, poor health and extremely high unmet health needs, subsistence-based living, and traditional and cultural uses of natural resources, tribes, American Indians, and Alaska Natives suffer a disproportionate burden of health consequences due to their exposure to pollutants and hazardous substances in the environment.

Overarching Proposals

IV-1. Where tribes and American Indians/Alaska Natives are affected by polluted aquatic ecosystems and contaminated fish, aquatic plants, and wildlife, federal agencies must respond and resolve these threats and environmental and health impacts in ways that fulfill the federal trust responsibility owed to tribes and that are respectful of and consistent with the recognition of tribal sovereignty and tribal rights under federal laws and treaties. In the context of Alaska Natives, federal agencies must respond to and resolve these threats and environmental and health impacts in ways that preserve for Alaska Natives the ability to carry on their traditional practices of providing for their subsistence needs from the lands and waters that they have used historically.

Focused Proposals

IV-1

1. FCWG proposes EPA to support legislative initiatives that will eliminate inequities in federal funding to address the alarmingly high levels of unmet environmental and health needs of AI/ANs, regardless of where they live. Although the EPA leads federal efforts in protecting the environment within Indian country and Alaska Native villages, the Indian Health Service is the principal federal health care provider and health advocate for AI/ANs. The provision of these health-related services arise from the trust responsibility and special government-to-government relationship between the federal government and federally recognized Indian tribes. However, the level of funding for Indian Health Service has long been utterly inadequate to meet the environmental and general health needs of Indian country and Alaska. In 2000, the Indian Health Service was funded and staffed at only 34% of the level of need.

2. FCWG proposes EPA to assert a leadership role among federal agencies in developing new financing mechanisms and leveraging all available resources to fund and implement environmental health-related projects and research in Indian country and Alaska Native villages.

3. FCWG proposes EPA to support regional meetings and a national summit of federal agencies, federally recognized tribes, and concerned tribal organizations to discuss the environmental health needs of AI/AN and design a comprehensive environmental health research agenda to address those needs.

4. FCWG proposes EPA to review available baseline environmental health data for Indian country and Native Alaska villages and take prompt steps to remedy all data insufficiencies, and retain and store environmental and health data on each federally recognized tribal government and provide a means for each tribe to access easily the information applicable to its members and territory. FCWG proposes EPA to request that the Indian Health Service make its annual data on health status readily available to each federally recognized tribe and other federal agencies.

5. FCWG proposes EPA, in consultation with federally recognized tribes and with the involvement of concerned tribal organizations, to conduct environmental research, studies, and monitoring programs to determine the effects on, and ways to mitigate the effects on the health of AI/AN communities due to exposure to environmental hazards, including but not limited to persistent organic pollutants and persistent bioaccumulative and toxic pollutants, nuclear resource development, uranium and other mine tailing deposits, petroleum contamination, and contamination of the water source and/or food chain. *This is critical where the health of such communities is particularly susceptible to environmental harm because they are known to rely on subsistence fishing, hunting, and gathering*.

6. Because federal environmental missions and resources are divided among and in some cases overlap between various agencies, FCWG proposes that EPA take the lead in coordinating and pooling available technical and financial resources to provide environmental health-related services to federally recognized tribes equitably, efficiently, and effectively. Towards this end, the Bureau of Indian Affairs, EPA, Department of Housing and Urban Development, and the Indian Health Service should appraise the usefulness and implementation of a national Memorandum of Understanding (MOU) and take appropriate steps to enhance and better promote interagency coordination and collaboration pertaining to the protection of health and the environment within Indian country and Alaska Native villages. Additionally, interested tribes should be considered appropriate parties to similar regional MOUs addressing the protection of health and the environment on their particular reservations. FCWG proposes EPA, in consultation with federally recognized tribes, to develop a federally-funded, comprehensive, interagency program on environmental health that will address fully the environmental justice needs within Indian country and Alaska Native villages.

7. FCWG proposes EPA to make regulatory decisions and develop federal policies affecting the health of AI/AN communities in consultation with federally recognized tribes. To the greatest extent possible, such decisions should be based not only western notions of what constitutes "science, but also should address and incorporate the traditional knowledge of the AI/AN community. For example, limitations on the consumption of traditional foods such as fish, aquatic plants, and wildlife due to pollution danger may trigger unique social, economic, and health effects within AI/AN communities – effects that are most fully and appropriately understood only in consultation with affected tribes.

8. FCWG proposes EPA to ensure that agency staff and managers have a thorough understanding of federal Indian law and policies, tribal culture, and the unique governmental structure of federally recognized Indian tribes, including Alaska Native villages.

9. FCWG encourages EPA and each office within EPA to develop a strategy for recruitment, retention, and upward mobility of American Indians and Alaska Natives in order to increase the quality of planning and priority setting, standards development, and program implementation. Such diversity in hiring, retention, and promotion at EPA will help to ensure that staff is familiar with and comfortable in affected AI/AN communities.

10. FCWG proposes that EPA focus educational efforts on environmental justice and the cause, effect, and remediation of specific environmental hazards. These efforts also should strive to improve the understanding of these issues among AI/AN communities and health professionals serving these communities, including but not limited to medical, nursing, and public health practitioners.

11. FCWG proposes that EPA acknowledge and learn from the determination, creativity, and expertise possessed by tribes, tribal members, tribal scientists, and other tribal professionals in developing stewardship and restoration programs for the environment and aquatic ecosystems.

12. FCWG proposes EPA to increase the number of professionals specializing in environmental health issues confronting AI/AN communities. Because persons who have been exposed to certain hazardous substances such as lead, mercury, pesticides, TCE, and PCBs are at risk for developing permanent disabilities or diseases such as intelligence and behavioral impairments, endocrine disruptions, and cancer, the Indian Health Service, in particular, should be strongly encouraged to focus on preventing these exposures among AI/ANs, monitoring and educating AI/ANs whose health is at risk due to pollution and hazardous substance exposure, and providing equitable and fair medical treatment and long-term assistance to affected AI/ANs.

13. FCWG proposes EPA to recognize that contamination from past and ongoing mining activities are of particular concern for many AI/ANs. Abandoned mines are a concern for many tribes and Alaska Native villages. Abandoned uranium mines, for example, is a pressing issue in the four corners region and in Santa Fe.

Overarching Proposal

IV-2. Importantly, in order to facilitate tribes' efforts to address contaminated and depleted aquatic ecosystems, FCWG proposes EPA to make available additional financial and technical resources to tribes to conduct their own research, to manage (or co-manage) tribal and culturally-important natural resources whether on- or off-reservation, and to consult on environmental decisions that affect them but that are made at the federal and state levels.

Focused Proposals

IV-2

1. FCWG proposes EPA to promote the federal policy of tribal self-determination and self-sufficiency by building the environmental protection and environmental health capabilities of federally recognized tribes so that they can participate fully and effectively in the protection of the human health and environment of AI/AN communities. Equitable funding for tribal programs is critical.

2. FCWG proposes EPA to promote collaborative efforts to identify the various environmental exposures affecting each AI/AN community as an ongoing task, undertaken in consultation with federally recognized tribes. Specifically, data about the susceptibilities of AI/AN communities to various environmental agents is needed to help these communities understand and ameliorate some of their excess and disproportionate risk of exposure.

3. FCWG emphasizes EPA's obligation to consult with federally recognized tribes and involve members of AI/AN communities in designing, planning, and implementing specific environmental health research that reflects not only the traditional and cultural practices of such communities, but also their needs and concerns. FCWG proposes EPA to ensure that environmental health research data is reported back to tribal governments and AI/AN communities promptly and in an understandable manner.

4. Whenever possible and appropriate, FCWG proposes EPA to include state and local governments in collaborative efforts with tribes:

   a. to address human health and environmental justice issues within Indian country and Alaska Native villages. Because pollution does not respect jurisdictional boundaries, collaborative efforts in the human health and environmental justice arena similarly should eclipse political differences. Additionally, states must be swayed to incorporate environmental justice principles and goals into their laws, policies, and practices;

   b. to collect environmental and health data relevant to Indian country and Alaska Native villages. For example, state environmental protection agencies may have access to monitoring information on off-reservation facilities that may be causing or contributing to adverse health consequences in AI/AN communities, or the aquatic ecosystems used by these communities, located nearby, down-stream, and/or down-wind;

   c. to ensure that state and locally issues fish advisories that may affect tribal treaty fishers or tribal fish resources are communicated to tribal governments.

5. FCWG proposes EPA to be proactive in helping federally recognized tribes identify financial and technical resources throughout the federal government to address their environmental concerns and related health needs. By marshaling all available resources, federal agencies can promote "one-stop" shopping for tribal environmental and health-related programs and transcend traditional agency boundaries.

6. FCWG proposes EPA to consult with tribes on fashioning restoration approaches or remedies appropriate to the specific tribe that will address situations where tribal fisheries or treaty fishing resources have been decimated or impaired.

Overarching Proposals

IV-3. FCWG proposes EPA to respect and accommodate the particular cultural, traditional, spiritual, historical, economic, and legal contexts that characterize the various Alaska Native peoples, and to recognize the ways in which their circumstances may be different than those of American Indian tribes located within the contiguous forty-eight states.

Focused Proposals

III-3

1. Consistent with its Indian policy and the federal trust responsibility, FCWG proposes EPA to work with Alaska Native villages in developing effective and appropriate strategies to address the special circumstances that exist in Alaska and to protect the health of Alaska Natives from environmental threats, particularly those threats associated with their extensive subsistence activities.

2. Consistent with its policy of promoting tribal self-determination and self-sufficiency, FCWG proposes that EPA work with Alaska Native villages to address the hurdles particular to Alaska Natives' efforts to manage (or co-manage) and to access resources that are important for subsistence uses. For example, because the United States Supreme Court has held that only one Indian "reservation" -- the Annette Island Reserve -- exists in Alaska, and because the language of the Clean Water Act recognizes the power of tribes to establish water quality standards throughout their "reservations," Alaska Native villages are unable to assume regulatory authority or to participate in the same manner or to the same extent under the Act as tribes located in the lower forty-eight states. Accordingly, FCWG further proposes EPA to cooperate with the State of Alaska in developing such strategies including, but not limited to the adoption of appropriate designated uses for water bodies that are culturally significant and essential to Alaska Native villages. Similar impediments to the participation of Alaska Native villages may also exist under other federal environmental laws.

3. FCWG proposes EPA to work closely with Alaska Native villages and to assist them in accessing relevant research, data, and studies and in applying for and obtaining grants that support efforts to address the concerns of Alaska Native villages with respect to contaminated aquatic ecosystems and impacts on the health of Alaska Natives. FCWG commends EPA's recent support, together with a host of other state and tribal agencies and groups, for the Aleutian/Probilof Islands Association's research project, *Dietary Benefits and Risks in Alaskan Villages* and proposes EPA to continue to provide and enlarge financial and technical support for this and other initiatives.

4. Because the financial resources of Alaska Native villages are severely limited, FCWG proposes EPA to fund and/or facilitate local forums or to provide other effective means wherein rural Alaska Native villages and communities may express their concerns to EPA on environmental health and environmental justice issues; EPA should contact Alaska Native villages and community groups, and others currently working toward this goal (e.g., the Alaska Native Science Commission; the Manilaq Association; Alaska Community Action on Toxics) to identify appropriate opportunities. A number of Alaska Native village representatives traveled great distances to Seattle, Washington at great expense to participate in the public comment period held during FCWG's December 2001 meeting. This burden should be borne by EPA, not Alaska Native villages. Morever, to further its environmental justice efforts, EPA should strive to ensure that at least one Alaska Native village representative is appointed to participate as member of FCWG or its various subcommittees.

5. FCWG proposes that EPA, in collaboration with other federal agencies, ensure adequate priority funding and technical assistance for the design, construction, and operation of safe drinking water, sanitation, and wastewater facilities to protect Alaska Native communities whose health and aquatic ecosystems are imminently threatened by the absence or inadequacy of such facilities. Because only 40% of Alaska Native families have basic sanitation services such as piped drinking water and flush toilets, and more than half of these systems are rudimentary at best, this effort should be given priority.

From: Don.Essig@deq.idaho.gov
Sent: Friday, April 05, 2013 2:47 PM
To: skirsch@acwa-us.org
Cc: Gildersleeve, Melissa (ECY); Niemi, Cheryl (ECY); Braley, Susan (ECY)
Subject: April 17th MSA call and EPA's Fish Consumption rate FAQ's
Attachments: Fish Consumption Water Quality.pptx; General population data and relevance to HHC development.docx

Susan,

Like WA DOE Idaho is working on updating its human health criteria as well. I have been in close communication with Cheryl and others in WA DOE as we try to figure out the best path forward and sort out EPA likes and wants from Clean Water Act mandates. Melissa forwarded me today your reply to Susan Barley and suggested I reply to you directly with some thoughts for the April 17th call in Cheryl's absence.

There is no doubt some people eat a lot more fish than the general population, but it is not at all clear what that means to water quality management. We are trying to sort out what science can tell us (fish consumption rates), from maters of science policy (such as choice of uncertainty factors in reference doses), from purely public policy decisions on risk management: What is an acceptable risk? What does it mean to be protective of a use? I see EPA tending to push things up this hierarchy, couching as science things that are not, and making decisions they say, at least in their published *guidance*, are best left to the states and tribes. See slide 6 in the attached presentation I made last week at the Spokane River Forum.

The first question I asked of EPA on the call last Tuesday was: How does EPA define high exposure or a high risk population? The answer Cheryl and I received from Beth Doyle was that EPA used the 99th percentile of the general population, as representing what they figured approximated the <u>median</u> consumption rate for subsistence fishers. This is what is stated in their 2000 Human Health Criteria Methodology *guidance*. While I think there is some legitimate question about their numbers, setting that aside it is interesting to me that they have in essence defined in terms of a upper percentile of the general population. I think this is good and important as we are getting pressure from EPA region 10 to ignore the general population and just focus on acknowledged high rate consumers of fish, particularly tribes. But that begs the question of which tribe, or should it be some other higher risk group, or as in the case of the recent Lummi tribe survey, male boat owning fisherman over 45 years of age, the high of the high of the high. It becomes a moving target if not grounded in the context of the general population.

EPA in their 2012 disapproval of Idaho's 2005 HH criteria update, in which we used their recommended 17.5 grams/day FCR, EPA said we did not consider, as suggested in their *guidance*, local or regional data indicating some people eat more fish than their national recommendation (maybe that's a definition of higher risk?). Anyway, we did look at other data, principally the 1994 CRITFIC study. That study reported pooled results form 4 trines in the Pacific NW and we were unable to get data for just Idaho. So although we did not use the CRITFIC data, we did consider it. In that consideration we also looked at EPA's *guidance* and the range of cancer risk they say is allowable, namely 10^{-6} to 10^{-5} for the general population, so long as the high risk consumers are protected at no less than 10^{-4} incremental increase in cancer.

Now we in Idaho are told by EPA Region 10 that they do not support a general population survey, see no value in it. And furthermore they are asserting that we must protect the high risk population (whatever that is) at 10^{-6} for a 90th, or maybe greater, for that higher risk group. That is a clear departure from published *guidance* and seems to be usurping "**risk management decisions that are, in many cases, better made at the State, Tribal, or regional level."**

At the end of the call last week Beth caught me a bit unbalanced, she asked "Are you going to base your FCR on a general consumption rate?"

My immediate answer was no. I should have proved a more considered and elaborate answer. Her question I think implied are you going to use the 90th percentile FCR from the general population. The answer to that is no, and my mind immediately went there even though it should not have.

My more considered answer, to the question she actually asked (instead of what my mind thought) is this: "No, not directly, or solely, but we will consider the general population data in putting high risk consumption data into context and choosing the FCR that is appropriate for all."

That may be a 90th percentile from some yet undetermined high risk group, but whatever the rate chosen for basing criteria on it will also correspond to some higher percentile for the general population as well, so in the end we could state it either way. Much like EPA related the 99th percentile of the general population to the median (50th percentile) for subsistence fishers in their 2000 guidance. Only Idaho will be more sure of the relation if we have data on both a general population and some high risk sub group (s). The would seem to be a state choice and a prudent one.

So to recap a bit, I'd still like to know:

How does EPA define high exposure, or is it an undefined moving target?

What does it mean to consider, does consider equate to must use?

Has EPA backed off from the position espoused in their 2000 guidance that **"EPA believes that ambient water quality criteria inherently require several risk management decisions that are, in many cases, better made at the State, Tribal, or regional level."**

Has their guidance become more than guidance, what latitude does a state, or tribe, really have?

I have also attached a series of talking points Cheryl and I put together for a call we had with EPA Tuesday of last week.

Don A. Essig
Water Quality Standards Coordinator
Idaho DEQ
1410 N. Hilton
Boise, ID 83706-1255

Don.Essig@deq.idaho.gov
208-373-0119
208-373-0576 (fax)

Conf. call w/ EPA + ID

Call in: 866 299 3188

3/20/13

Niemi, Cheryl (ECY)

Meeting with:

code: 206-553-1256

Jeff Bigler, National Program Manager
Fish Advisory Program
U.S. Environmental Protection Agency
Office of Science and Technology (4305T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Also
Claudia Fabrano - WQS
Rose ~~Kieter~~ Galer WQS

The

Beth

Lead EPA Scientist is Elizabeth Doyle, Ph.D., Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U. S. Environmental Protection Agency.

Heidi L. Bethel (bethel.heidi@epa.gov), Health and Ecological Criteria Division (4304T), U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460

Matthew Doyle's Overview

Current

- **AAAS Science and Technology Fellow** at **US EPA**

Past

- AVMA AAAS Congressional Science and Technology Fellow at U.S. House of Representatives
- Public Health Committee Member at Michigan Veterinary Medical Association
- Associate Veterinarian at Roose Animal Hospital

R10
- Lisa Macchio
- Mary Lou Soscia
- Matt Szelag
- Lon Kissinger
- Angela Chung

Cheryl A. Niemi
Surface Water Quality Standards Specialist
Department of Ecology
P.O. Box 47600
Olympia WA 98504
360.407.6440
cheryl.niemi@ecy.wa.gov

~~on~~
How does EPA define "high exposure"

- Beth - shoot to protect 95%ile
  - 95-100%ile is usually high per capita
- 99th per ~~capita~~ per capita = high consumers

per capita includes "0"
99th = ≈ 140 g/day

To do a state survey:
- need to get all of ID population
-

~~Beth~~ Angela - "Dennis wants EPA to provide tribes & WA guidance on these things"

- "Dennis thinks the OR outcome was the right outcome"
- Regionally "want to explore that position"

...ribes & Ecology, EPA
April 25

Lisa ♦ March 29 mtg w/ ID
Kurt France
Barry Burnell

Regional Guidance – Don't want it – already doing [illegible]

"e.g. general survey or 'regional guidance'"

EPA "early judgments" – don't limit our options or public process discussion by trying to make policy calls that have always belonged to the state, or by trying to change our public process.

General population data and relevance to HHC development:

- General population and high-consumer population data (and the frequency distribution that represents these combined data) are both relevant to the HH criteria development process, and use of either or both are part of the EPA 2000 guidance.

- If the low end of the fish consumption distribution is poorly characterized, due to a focus solely on high end consumers, it is likely the distribution will be skewed high. This will bias high not only the value of a high end FCR, it will mean the percentile associated with it is biased low.

- Idaho has a risk level for the general population of 10^{-6}. This means that for carcinogens the FCR could be a general population value, such as EPA's national recommended 17.5 or a local general population value, and still likely confer adequate protection within EPA's acceptable risk range of 10^{-6} to no-more-than 10^{-4} for the most highly exposed populations (e.g., 17.5 at 10^{-6} = 1,750 at 10^{-4}).

- The national general population recommended value of 17.5 (for which EPA included non-consumers) was disapproved by EPA for ID use. This implies that EPA needs generation of local data in order to find a general population value that is approvable for carcinogens in Idaho. In other words, since Idaho applies their risk level to the general population it logically follows that local general population data are what are needed by EPA. So in this case EPA funding to address their Idaho disapproval seems altogether reasonable. If this was not the basis of the ID disapproval then what, specifically, was?

Not disc.
Would excluding the part of "non-consumers" from the calc have resulted in disapproval?

- Washington has not made a final science- policy decision about whether the national data set can be used to create a general population frequency distribution for Washington state, or whether new data will be needed. Ecology wants a frequency distribution that can represent the full range of consumption in Washington so we can ensure that risk management decisions are based on data representative of all Washington consumers. Washington's risk level applies to the general population, as applied in EPA's NTR. If Washington made the state risk management decision to apply the national recommended FCR of 17.5 to carcinogens, would these standards be disapproved by EPA because they were not based on local data? The answer to this question is relevant to future consideration by Ecology on FCRs and use of the national recommendations. → need to talk w/ toxic. abt.

- General population data (if collected appropriately) could be used with the information from studies of populations with higher FC rates to better describe how all people in Idaho or Washington are protected to levels chosen by the states in their risk management processes. There could be non-surveyed people in Washington or Idaho that consume as much or more than are shown in current FCR studies, which would affect the overall frequency distribution of consumption rates. If a state chooses to pair a specific distribution metric with a specific risk level, having a complete and representative distribution of consumers seems very relevant.

Questions to clarify EPA thoughts on risk:

Does EPA agree that WA risk level applies to the general population? – Angela: EPA can't answer that now.

If not – why?

Would EPA disapprove a standard based on 10^{-6} for general population as long as 10^{-4} is max for highly exposed? Angela: EPA can't answer that now

If not – why?

OGC opinion or guidance?

ID – disapproval questions

"sound scientific rationale"?

"Consideration" vs "use of"?

Does epa mean "use" when they say "consider"? Angela: EPA can't answer that now

What does EPA think of the OR approach?

Angela: "Dennis thinks this is the right approach."

AQ – I told them we disagree w/ some of it – explained dwk scope concern – double counting imported shellfish in the RSC

From: Susewind, Kelly (ECY) [mailto:KSUS461@ECY.WA.GOV]
Sent: Tuesday, March 11, 2014 1:41 PM
To: Opalski, Dan
Cc: Bellon, Maia (ECY)
Subject: Listing and EJ Discussion

Hey Dan

Did a little looking on my own following today's discussion.

Listing:

The 2012 Oregon assessment states that:

- New and revised human health criteria apply to pollutants in the water column except for methyl mercury…..
- Category 5 listings require two or more samples not meeting the most stringent applicable criterion of a specific substance in the water, or
- A fish consumption advisory issued for a specific water body based on pollutants in fish tissue

We acknowledged that Oregon lists based on fish advisories, but that is far different than saying they do listing based on tissue. A quick perusal of Oregon's fish advisories only shows a few advisories generally based on mercury and PCBs.

We've also been contacted by DEQ staff regarding our listing policy because they are getting pressure to list based on tissue "like Washington."

Is there more information that I am missing?

EJ

I have a copy of the document: "EPA Policy on Environmental Justice for Tribes and Indigenous Peoples." It's a pre-decisional working draft dated November 14,2012.

Is that the document Dennis referred to?

The only real pertinent language I could find in that document was:

4. THE EPA ASSESSES THE POTENTIAL FOR DISPROPORTIONATELY HIGH AND ADVERSE HUMAN HEALTH OR ENVIRONMENTAL EFFECTS ON TRIBES OR INDIGENOUS COMMUNITIES.
a. The EPA considers both quantitative and qualitative information about the potential disproportionately high and adverse human health or environmental effects pertaining to, and/or provided by, tribes or indigenous stakeholders.
b. The EPA works to understand Traditional Ecological Knowledge and its role in protecting public health and the environment, and to understand community definitions of health and the environment.

As we discussed, tribal members, and anyone eating high amounts of fish, are at higher risk. They are at a risk exactly proportionate to the consumption rate and will be at the same ratio (proportion) regardless of where the rule lands. Interpreting this section of the policy to mean that they can't be at a higher risk would frustrate the entire system the HHC equations are based on and make it impossible to comply.

Is there a statement somewhere that one in a million risk rate is the baseline to establish environmental justice? Or that a higher risk rate is inherent in the approach, but establishes some criteria to define "disproportionately high and adverse effects?

I’m not trying to be argumentative, but we are getting to the end of a very contentious process, and I really need to understand these concepts in order to advise decision makers.

Thanks

Kelly

From: Fran Wilshusen [mailto:fwilshus@nwifc.org]
Sent: Tuesday, March 18, 2014 12:56 PM
To: van der Lugt, Lisa (GOV)
Cc: Brian Cladoosby; Leonard Forsman; Allen, Ron; Debra Lekanoff; Austin, JT (GOV); Bellon, Maia (ECY)
Subject: Follow-up from Friday Mar 14 Tribal FCR Mtg. with Gov. Inslee

Honorable Governor Inslee:

Thank you for meeting with us and continuing discussions on the issue of establishing revised human health criteria, including a revised fish consumption rate, as part of state water quality standards.

Following up on your request from our meeting last Friday, please find attached a copy of the white paper being developed by tribal technical staff, on compliance tools and implementation. This paper was originally drafted to be submitted to Ecology to support integration of tribal perspectives. Also attached are the tribal comments that were developed regarding the development of human health criteria. The tribal message continues to be clear, well documented and progressive. As we discussed on Friday, this issue is important to tribes and the *175 g/d fcr combined with the 10 -6 risk level represents real compromise and a meaningful step forward in protecting the health of Washington citizens.*

On Friday, we heard you questioning and considering the concept of increasing the cancer risk rate. To be clear, from a tribal perspective, adjusting the cancer risk rate and increasing exposure to known carcinogens is an unacceptable way to address discharger compliance concerns. Tribal people, and other high end fish consumers, will bear a disproportionate burden of that exposure. Flexibility should be created through compliance pathways, not by eroding the standard.

We appreciate your interest and attention on this difficult issue and are available to you for any questions or further discussion necessary as you move forward.

Thank you.

Chairman Ron Allen, Jamestown S'Klallam Tribe
Chairman Brian Cladoosby, Swinomish Tribe
Chairman Leonard Forsman, Suquamish

Northwest Indian Fisheries Commission
6730 Martin Way E., Olympia, Washington 98516-5540
Phone (360) 438-1180 www.nwifc.org FAX # 753-8659

January 31, 2014

Maia Bellon, Director
Washington Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

RE: Follow-up from December Leadership Meeting on Water Quality Standards

Dear Director Bellon:

On behalf of the member tribes of the Northwest Indian Fisheries Commission, I would like to thank you and your staff for meeting with tribal leaders on December 12, 2013 to discuss the status of water quality standards in Washington State. The tribes recognize that this has been a very difficult issue for the state. However, the tribes remain steadfast in their request for revised standards that will protect the health of tribal people from exposure to toxic substances in Washington.

The purpose of this letter is to request an updated timeline for the completion of rule-making on the human health criteria (HHC), and to convey some initial comments on the preliminary options for the HHC. At the December meeting, tribes again asked for the timely completion of revised human health criteria in Washington State's standards that will utilize a new fish consumption rate, without lowering the protective level of other existing variables such as the cancer risk rate. As in previous meetings, tribes also asked for standards that are at least as protective as those approved in Oregon with a fish consumption rate of at least 175 grams per day and maintaining a cancer risk rate of 10^{-6}. Many tribes also stated that the Oregon standards represent a substantial compromise, since tribal studies indicate higher levels of modern and historical consumption. The rule options put forth by the Department of Ecology in November, 2013 include several options that fail to achieve the protective levels of even the Oregon standards in the HHC. The NWIFC staff has prepared a consolidated set of preliminary comments on the options, based on input from NWIFC member tribes, and have attached these for your review and consideration as you move toward preparation of rule language. The tribes also plan to continue discussions with the Department of Ecology and others on proposed implementation options.

During the last two meetings of the Leadership Oversight Group with EPA and tribal leaders, you indicated verbally that a draft rule for the revised water quality standards will be completed this winter, and a final rule will be adopted in 2014. Given that the tribes have experienced numerous delays during the course of this work, they have asked for greater clarity as to the precise timelines for rule development and promulgation, with dates instead of seasonal time frames. The tribes also requested in December that the Department of Ecology reaffirm previous commitments, by indicating a specific timeline that incorporates no further delay.

The tribes look forward to establishing revised human health criteria, so that we may better focus on the important work of toxic reduction in Washington through all available pathways. Once again, the NWIFC thanks you for meeting with tribal leaders in December, and we look forward to continuing to work with you.

Sincerely,

Michael Grayum
Executive Director

Enclosure: Response to Preliminary Options on the Human Health Criteria by NWIFC staff

Cc: Tribal Chairs and NWIFC Commissioners
Dennis McLerran, Regional Administrator; EPA Region 10
Dan Opalski, Director - Office of Water & Watersheds; EPA Region 10
Jim Woods, Senior Tribal Policy Advisor; EPA Region 10
JT Austin, Governor's Policy Advisor for Natural Resources
Phil Rigdon, Deputy Director; Department of Natural Resources; Yakama Nation
Columbia River Intertribal Fisheries Commission

Response to Preliminary Options on the Human Health Criteria
(as presented by the Washington Department of Ecology on November 6, 2013)

Compiled by: Northwest Indian Fisheries Commission staff
January 31, 2014

A. Introduction and Summary

Washington Department of Ecology (Ecology) outlined preliminary options for rule-making for state water quality standards at a public workshop on November 6, 2013. Recognizing that these are preliminary options, and are not yet embedded into state rule-making language, staff from the Northwest Indian Fisheries Commission (NWIFC) met with staff from member tribes in November and December of 2013 to obtain initial tribal input and develop a summary of responses. These do not constitute final comments on rules and may not be representative of the perspectives of individual tribes, but are submitted to the Department of Ecology as input prior to the development of rule language.

In general, tribes agree that Ecology must update state water quality standards to incorporate human health criteria at a protective level that is much higher than what currently exists. Tribes concur that Washington State has enough data to set a fish consumption rate at this time. The tribes also concur that Washington State must use fish consumption rates reflective of tribal consumption; however, the tribes disagree that the selection of "mean" consumption levels for tribes is an adequate standard of protection. Tribes have previously indicated that the fish consumption rate of 175 grams per day adopted by Oregon and approved by EPA, using a fish consumption level at the 90th to 95th percentile of Columbia River tribal studies, is a compromise from historical levels of consumption and is lower than documented consumption by Puget Sound tribes within the last 20 years. Tribes previously indicated that the Oregon standard of 175 gpd was low, but recognized that it would significantly reduce the potential for toxic chemicals to enter state water bodies through discharges, with the assumption that the state would not relax other parameters in the risk equation.

Unfortunately, the Department of Ecology is considering an option of using 10^{-5} as the cancer risk level, and a relative source contribution of 1.0, both of which options are unacceptable to the tribes. The potential improvement in protective standards through a fish consumption rate at or above 175 gpd would be diminished by a higher risk of cancer or by failing to account for human exposure to toxins from other pathways.

The tribes support the preliminary determination by Ecology to include salmon in the fish consumption equation at 100%, i.e., using all species and all sources. The tribes continue to evaluate the "challenging chemicals" highlighted by the Department of Ecology in their presentations, and how the state may address these through compliance tools. Comments on compliance tools, at Ecology's present stage of development of options, will be forthcoming.

B. Use of Tribal Fish Consumption Levels as a Basis for Rate-Setting

Tribes agree that the Department of Ecology must use tribal fish consumption as a basis for reasonable maximum exposure and the FCR parameter in the human health criteria. At the November workshop this decision was characterized as a "big deal" and a policy choice, because it is substantially different from existing standards, which followed a national default rule set in the early 1990's. Tribes do not believe that the Department of Ecology has any other supportable alternative than to use tribal FCR findings, since these are scientifically derived and regionally relevant. Additionally, the guidance of the National Environmental Justice Advisory Committee requires full consideration of the impact of environmental standards, and incorporation of protections, for culturally and racially distinct groups of people. Although some industrial and legislative representatives have called for a study of the fish consumption of the general population in Washington, such information would not be relevant given that Washington has appropriate and technically suitable data on tribal consumption, unless there is evidence that the general population fish consumption is higher.

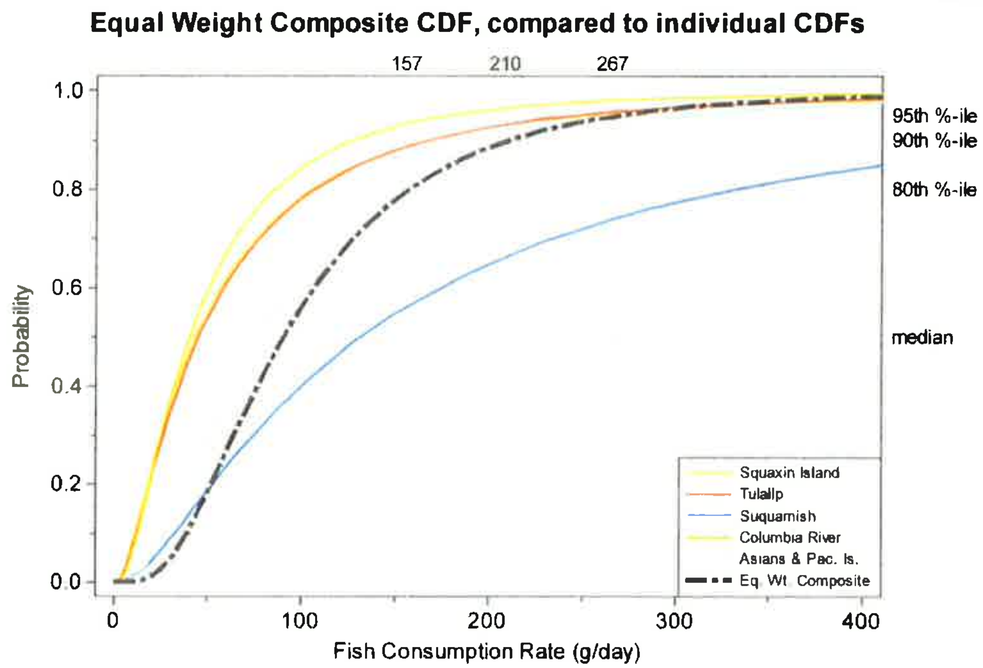
C. Fish Consumption Rate Options

The Department of Ecology presented three options for revising the FCR from the current level of 6.5 grams per day: 125, 175, and 225 grams per day. Tribes question the rationale for the selection of these options based on policy choices made by the Department of Ecology Water Quality Program. In some cases, the mean value is used, leaving a large portion of the tribal population unprotected from exposure to toxic chemicals in fish. Several tribes have commented previously that a fish consumption rate that is lower than the standard adopted by Oregon of 175 g/per day is unacceptable; tribes also note that this rate may not sufficiently protect tribes in light of suppression and other factors affecting consumption.

1. **The rationale for policy choices by the Water Quality Program in the selection of options are unclear and inadequate:** The Technical Support Document on Fish Consumption Rates, Verson 1.0 prepared by the Department of Ecology Toxics Cleanup Program and published in October 2011, used a composite analysis of regional studies of fish consumption by tribes and groups of Asian and Pacific Islander communities to recommend a FCR default range of 157-267 grams per day. (Figure 1) This was based on a logical and transparent analysis, selecting a range encompassing the 80th

to 95th percentiles of most regional studies. The University of Washington School of Public Health commented that the Technical Support Document V 1.0 "represent[ed] a robust, scientific-based assessment that is clear and transparent." The Department of Ecology's presentation on November 6, 2013 explained where the numbers came from that were used for the three proposed FCR options, but not why they were selected. Ecology will need to include a transparent rationale to express their reasoning for the selection of the final FCR option in rule language in the water quality standards, particularly if an option is selected that is less than the range recommended by the Department's own Toxic Cleanup Program in the earlier Technical Support Document.

Figure 1: Composite analysis for Pacific Northwest fish dietary surveys for tribes and Asian and Pacific Islander Communities. (From WA Department of Ecology Technical support Document, version 1.0; October 2011). A FCR range of 157 to 267 grams per day was recommended, based on the composite 80th to 95th percentile.



2. **Use of mean values for the Fish Consumption Rate is unacceptably low:** At the November 6, 2013 workshop, the Department of Ecology staff indicated that the Department is considering an option of 125 grams per day for the fish consumption rate, and that this value was based on the approximate average of averages from three

tribal dietary studies in Puget Sound.[1] Public health standards are not intended to protect only the average person; instead they are intended to set a level that reduces risk for a high percentage of the exposed population—especially where children and women of reproductive age are affected. For example, toxic cleanup programs utilize a reasonable maximum exposure at the 90th percentile. Ecology has made a preliminary determination that the standards should be based on the exposure of tribal populations, but it is unacceptable to tribes that the state would select a fish consumption rate at only an average level of tribal consumption. Tribes want to see the risk of ingesting toxics via fish consumption driven to zero or near zero. Oregon tribes advocated for an FCR at the 99th percentile of Columbia River studies in the Oregon water quality standards, but the state of Oregon ultimately decided to set a rate in the 90th - 95th percentile. The average of FCR values in Washington tribal studies at the 90th to 95th percentile would range from 254 to 385 grams per day, based on consumption surveys of Columbia River and Puget Sound tribes. For Puget Sound tribes only, the 90-95th percentile range would be 296 to 448 gpd.

3. **Additional comment on the compromise FCR in Oregon standards.** In the public workshop on November 6th, the Department of Ecology expressed no indication that the state of Washington supports consistency with the FCR option at the Oregon standard, even though the FCR of 175 gpd was based largely on studies of Columbia River tribes located in Washington. Since the state of Washington sees little need for regulatory consistency between the states, earlier comments from tribes that the Oregon standard could be an acceptable compromise, depending on other aspects of rule-making, may no longer be relevant. Some Washington tribes have informed the NWIFC that they cannot support any option that is less than the 175 grams per day FCR adopted in Oregon, and are likely to advocate for a higher rate than Oregon's to protect their citizens given the higher levels of fish consumption here. The studies of tribal consumption used for the Oregon standards are now 20 years old and occurred at a time when fish consumption was more suppressed due to habitat loss, lack of access to fishing grounds, and contamination of fish species. Tribes will want to reserve the ability to consume fish at unsuppressed levels in the future. Tribes also note that historical levels of fish consumption have been documented to be much higher—in excess of 800 grams per day at treaty times. Some tribes are using historical levels to set tribal standards, and expect the state to follow suit for downstream dischargers.

[1] See Table 33 from the Fish Consumption Rate Technical Support Document Version 2.0 for the referenced data. The average of the mean values for the Tulalip, Squaxin Island and Suquamish Tribes is 126.66 g/day.

4. **The "mean" option of 125 grams per day is inadequate to protect Puget Sound tribes.** As noted above, tribes consider the option of 125 grams per day, to be inadequate as it is based on mean values for three Puget Sound tribal studies. The combined mean (the average of the average consumption for the three Puget Sound tribes) is even lower than the median consumption rate for one of the tribes—thus the FCR would not cover consumption exhibited by over half of the tribe. Moreover, some studies indicate that tribal children have a fish consumption rate nearly three times that of adults, relative to body weight.[2] An inadequate fish consumption rate puts the health of tribal children at particular risk.

D. Cancer Risk Rate

The Department of Ecology indicated that they are considering a cancer risk rate of one-per-million (10^{-6}) or one-per-100,000 (10^{-5}) in the human health criteria. The Department currently uses a standard of 10^{-6} for the calculation of allowable limits for priority pollutants. The option of using 10^{-5} in the HHC would therefore raise the risk of cancer by ten-fold for all Washington fish consumers and is unacceptable to tribes. Tribes will suffer disproportionately from an increase in the risk rate, and the option would largely negate any protective benefit that tribes and other high fish consumers would receive from a higher FCR, if adopted and implemented. Further, the 10^{-5} option fails to consider risks to high consumers from persistent bioaccumulative toxics or exposure based on combinations of toxic chemicals (additive toxicity). Ecology has rejected a cancer risk rate of 10^{-5} in the past and should continue to do so, whether or not other states choose lesser levels of protection. The Environmental Protection Agency has not stated that a 10^{-5} risk level would be approvable given the circumstances in Washington, and the applicability of risk to tribes with treaty-reserved fishing rights.

1. **Any increased risk of cancer is a harm.** The Clean Water Act and other health-based environmental standards that govern the sources or clean-up of pollution generally express goals to reduce the risk of exposure to harmful byproducts to zero. EPA has consistently used a level of 1 per million in national standards and criteria in an effort to drive pollutant sources close to the zero goal. Many tribal leaders view any risk of cancer through pollution as unacceptable; a ten-fold increase in existing rates is a major step in the wrong direction.

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[2] U.S. Environmental Protection Agency (EPA). (2013) Reanalysis of fish and shellfish consumption data for the Tulalip and Squaxin Island Tribes of the Puget Sound Region: Consumption Rates for Consumers Only. National Center for Environmental Assessment, Washington, DC; EPA/600/R-06/080F.
The mean fish consumption rate for Squaxin Island Tribe adults was 1.02 g/kg-day. The mean consumption rate for children less than 6 years of age was almost three times higher at 2.89 g/kg-day.

2. **Tribes will suffer disproportionately from a ten-fold increase in the cancer risk level in Washington.** Arguments for a less protective risk level are based on a premise that everyone is equally likely to bear the higher risk of cancer. However, in Washington State the increase in risk will disproportionately affect tribes as the highest consumers and most exposed. The Department of Ecology has presented data indicating that tribes are the highest consumers of fish, and therefore is knowingly considering action that would shift a greater risk to tribal people, raising questions about ethics and environmental justice.

   Furthermore, harvesting and consuming fish is a lifeway and a right for tribal people; it is not a choice or a voluntarily assumed risk. Business has characterized the risk of getting cancer from eating fish as just one of many health risks, like cigarette smoking or getting an x-ray. In recent presentations, the Department of Ecology offered statistics, purportedly as context for the risk discussion, that the average American male has a 1 in 2 risk of cancer in his lifetime (1 in 3 for females). This discussion fuels misunderstanding by minimizing the perception of harm directed toward tribal people, especially children, from contamination that they have not caused and cannot control.

3. **The combination of a higher risk of cancer with a higher fish consumption rate negates much of the protective value of raising the FCR to a level that reflects tribal fish consumption.**
   The Department of Ecology is considering an option of a FCR of 175 grams per day, or even less, in combination with an option to raise the cancer risk rate to 10^{-5}. We note that 175 grams per day at a cancer risk rate of 10^{-5} is functionally the equivalent of a FCR of 17.5 grams per day at a risk of 10^{-6}, and that this rate has already been rejected by EPA in Oregon and Idaho. If the Department of Ecology adopts the option of a FCR at 125 grams per day and a risk rate of 10^{-5}, the level of protection would only improve to a level of 12.5 grams per day at the existing risk rate.

   In the November 6, 2013 workshop, the Department of Ecology offered a graph comparing the FCR and risk rate alternatives to a hypothetical chemical discharge at existing standards (Figure 2), purportedly to illustrate the drastic reduction in chemical concentrations that will be required of dischargers under any of the proposed options. Instead of illustrating the burden to dischargers from revised standards, the graph should be interpreted to show that existing pollutant concentrations need to be reduced. The existing standards are based on a grossly under-valued estimate of fish consumption and need to be raised to come to a realistic and protective level based on actual fish consumption and existing risk.

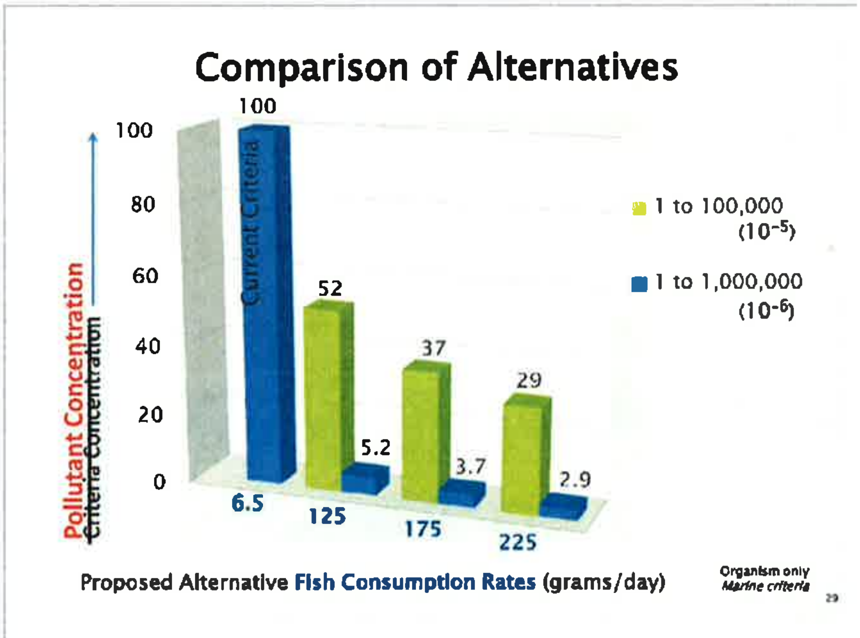

Figure 2: Comparison of FCR and risk rate alternatives to existing allowable pollutant concentration levels.

Tribes have already suffered harm from an inadequate fish consumption rate for years, and changing the risk rate to a less protective level in combination with a higher FCR will largely negate any value from potential remediation of the fish consumption criterion.

4. **Washington State should not reduce the level of protection for its people by making a comparison with the less stringent standards in other states, or assume that such reduction is approvable by EPA.**
The fact that some other states have chosen lesser protection does not answer the question whether Washington should decline to protect its people. Ecology has cited the fact that several other states have selected a less protective risk level, and used this as the basis for a preliminary option for a risk level at 1 in 100,000 (10^{-5}). However, to say that other states have selected this risk level says nothing about why they have done so, or whether it is legally, technically, or ethically appropriate to follow suit. Washington has a disproportionately high level of shorelines, streams and lakes in comparison with many other states, and is renowned for abundant and varied fish and shellfish resources. These resources, and the people who consume them, coexist with industrial users who legally discharge pollutants into Washington water bodies--thus Washington's industrial environment also varies from many other states. As noted above, a less protective cancer risk rate will disproportionately and involuntarily harm tribes and other high consumers of fish. Additionally the state has a legal obligation

to honor the treaty reserved rights held by Washington tribes, and comply with the implementation of trust responsibilities overseen by the Federal Government. These circumstances add to the legal and ethical questions that are relevant to Washington's selection of human health criteria, in contrast with those of other states, and must be considered by EPA in the exercise of their Federal Government trust responsibilities.

EPA has not stated that an increased risk level is approvable for the circumstances present in Washington. EPA has stated that it would need to consider the rigor and representativeness of the process by which a state arrived at its risk level—particularly where the risk level selected was less protective than 1 per million. Additionally the EPA has expressed concern for actual risk to affected individuals, based on a comprehensive look at parameters and circumstances. EPA guidance with respect to "sub-populations" or to diverse and unrelated subsistence fishers, cannot be equated with the risk to treaty fishing tribes and their members in Washington. Further review of the process underway in Washington will show that tribes have consistently opposed a less protective fish consumption rate and higher risk of cancer for years. Tribal members live the circumstances that contribute to compounded risks since they eat large quantities of fish, harvested from usual and accustomed fishing areas affected by Washington standards, and they consume fish from their earliest childhood through old age.

5. **The Department of Ecology has previously gone on record in support of a risk level of 10^{-6}, and should continue to support this level, particularly in light of the potential for Washington people to consume fish with bio-accumulative toxics and the potential for interaction of multiple contaminants.**

   EPA promulgated a rule for 14 states, including Washington, in 1992 to establish numeric criteria for priority toxic pollutants necessary to bring states into compliance with provisions of the Clean Water Act. In the official comments on the proposed rule, the Washington Department of Ecology urged EPA to promulgate human health criteria at 10^{-6}:

   > *"The State of Washington supports adoption of a risk level of one in one million for carcinogens. If EPA decides to promulgate a risk level below one in one million, the rule should specifically address the issue of multiple contaminants so as to better control overall site risks."*[3]

[3] 57 FR 60848 (Full description at *Federal Register*, Volume: 57, Issue: 246, Page: 60848 (Tuesday, December 22, 1992) Page 60868 contains comments by WA Department of Ecology.

The Department of Ecology should apply these comments to their own proposed rule options, specifically by rejecting the option of establishing a general risk rate of 10^{-5}. Currently there are no provisions to address the issue of multiple contaminants in Washington's existing or new rules.

During the 1992 EPA rule-making, EPA also indicated that it was appropriate to adopt a more stringent risk level (one-per-million) for those carcinogens with substantially higher bio-concentration factors. Recognizing that carcinogens that bioaccumulate are of particular concern for exposure by fishermen, EPA further stated that a more protective risk level of 10^{-6} would be appropriate for fish consumers. (ibid.)

The proposed reduction of the protective level of the cancer risk rate to 10^{-5} is inconsistent with Ecology's previous positions expressed to EPA, fails to adequately address the cancer risk from bioaccumulative toxics, and fails to account for the interactions of multiple toxic chemicals. The 10^{-5} option for a risk rate places tribes at a disproportionately higher level of risk, and negates the potential benefit of remediation to the standards that would have accrued through the adoption of a higher fish consumption rate. The option of a ten-fold increase in the risk of cancer for Washington citizens should be rejected.

E. Other Comments Related to the Proposed Options for Human Health Criteria

1. **The Tribes concur with Ecology's tentative decision to include salmon at 100% in the fish consumption rate.** This was an inevitable conclusion in the face of: the high levels of consumption of salmon by tribes and the general population in Washington; fish tissue sampling showing the presence of persistent bioaccumulative toxics in salmon in freshwater and estuarine water bodies at various life stages; and documentation that tribal consumers primarily eat salmon and other seafood that are derived from and harvested in local water bodies. Previous comments from industrial representatives on the Technical Support Document V1.0 relating to salmon attempted to discount salmon on the basis that the "oceanic" portion of their life cycle was outside of Washington's jurisdiction. However, some species of Puget Sound salmon remain resident within the marine waters of Puget Sound, and exhibit higher levels of PCBs than their counterparts in British Columbia or the Columbia River, indicating that substantial uptake of toxic chemicals occur in the estuarine portion of Washington's waters and are influenced by Washington regulatory standards. Tribal salmon harvest is comprised primarily of salmon that are natal to Washington rivers and streams, and the tribes concur with the preliminary conclusion to include all species of salmon and all geographic areas.

2. **Tribes do not concur with Ecology's decision to disregard EPA direction to consider multiple pathways of exposure to toxic chemicals. Ecology's preliminary choice of 1.0 as the relative source contribution (RSC) provides an inadequate level of protection to fish consumers.** Fish consumption is only one of the pathways by which humans absorb toxic chemicals. The EPA has issued guidance calling for states to attribute 20-80% of exposure to toxic chemicals to water-borne sources, and the rest from other sources including air and other foods. The tribes reiterate previous comments relative to carcinogenic risk--that tribes are highly exposed to toxic chemicals in fish, and will suffer disproportionately from the body burden resulting from other chemical loads as part of a human body burden. Tribes have indicated that Ecology should follow EPA guidance on this issue.

3. **The tribes recognize that pervasive chemicals are a substantial concern in Washington, and that dischargers will have difficulty meeting new standards right away for substances including PCBs, arsenic, and mercury.** Tribes are continuing to evaluate the options presented by Ecology for regulatory solutions to these chemicals of concern to facilitate the transition to new standards for dischargers. However, the tribes point out that variances, extended schedules, or other potential compliance tools must be limited, or Washington will not achieve long term goals for water quality—instead engaging in an endless and expensive cycle of pollution discharge, site and species contamination, issuance of health advisories, and site cleanup. Tribes are seeking to attain the highest water quality possible as soon as possible for the protection of tribal health. Tribes also point out that Ecology has stated that pervasive chemicals, such as PCBs, are a state-wide problem, and that some of the chemicals, such as mercury, come from air deposition. These assertions appear to contrast with Ecology's decision to use a relative source contribution of 1.0, since that option assumes 100% of toxic contaminants in the human health criteria come from consuming fish from impaired waters.

In conclusion, tribes concur with Ecology's preliminary decisions on the human health criteria to base fish consumption rates on tribal levels of consumption and to include salmon at 100%. Tribes strongly disagree with Ecology's proposal to increase the risk of cancer by ten-fold, and the use of average values in setting the fish consumption rate. Tribal populations depend on fish consumption for sustenance and livelihood and are disproportionately at risk from toxic chemicals in fish. The tribes retain treaty-reserved rights to harvest, and assume that these fish and shellfish will be healthy to eat throughout a tribal member's life span.

NWIFC and individual tribal staff will continuing to work with Ecology staff to evaluate the options presented for compliance tools. Thank you for your attention to the tribes' concerns on the preliminary options for the human health criteria.

State of Oregon Department of Environmental Quality

Human Health Criteria Issue Paper

Toxics Rulemaking

Prepared by: Andrea Matzke, Debra Sturdevant, and Jennifer Wigal

2008 - 2011

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Human Health Criteria Issue Paper

Toxics Rulemaking

A. Introduction

Purpose of this issue paper

DEQ's currently effective human health toxics criteria are based on a fish consumption rate (FCR) that does not adequately protect Oregonians based on the amount of fish and shellfish they are known to consume. On June 1, 2010, EPA disapproved Oregon's human health toxics criteria that were submitted for approval in 2004 and were based on a fish consumption rate of 17.5 grams per day (g/d). EPA disapproved the human health toxics criteria because the fish consumption rate used to calculate the criteria does not protect Oregonians based on the amount of fish and shellfish they are known to consume. DEQ is addressing EPA's disapproval by proposing to use a higher, more protective fish consumption rate of 175 g/d in its calculation of revised human health toxics criteria. If DEQ does not promulgate revised standards in a timely manner addressing EPA's disapproval, EPA must conduct rulemaking to promulgate human health toxics criteria for Oregon.

This issue paper includes information relevant to DEQ's development of proposed human health toxics criteria based on a higher fish consumption rate. It also describes the human health toxics criteria methodology used to calculate criteria. Proposed changes will affect the criteria values contained in Tables 20, 33A, and 33B, as well as the narrative toxics provision in OAR 340-041-0033 (Toxic Substances).

B. Background

B.1. Brief History of EPA's Recommended Human Health Toxics Criteria

The Clean Water Act requires EPA to publish recommended water quality criteria based upon the most recent science. States typically use these values in developing their own water quality standards regulations. In 1986, EPA published a compilation of these values in the Quality Criteria for Water 1986[1], also known as the "Gold Book." In 1992, EPA promulgated water quality criteria for toxic pollutants for 14 States. These updated criteria became known as the National Toxics Rule[2] and differed substantially from the EPA Gold Book. In 1995, EPA applied the methodology and data used in the Great Lakes Water Quality Initiative[3] to derive new national aquatic life criteria for 15 toxic pollutants in freshwater. In 1999, EPA published the next major update of water quality criteria[4]. In 2000, EPA promulgated water

[1] EPA. Quality Criteria for Water, 1986 (Gold Book). EPA 440/5-86-001

[2] EPA. Federal Register, Volume: 57, Issue: 246, Page: 60848 (57 FR 60848), Tuesday, December 22, 1992.

[3] EPA. Federal Register, Volume: 60, Number 56, Page: 15365, March 23, 1995.

[4] EPA. National Recommended Water Quality Criteria—Correction. EPA 822-Z-99-001.

quality criteria for toxic pollutants for California known as the California Toxics Rule[5] and also in that same year published a revised methodology[6] for deriving human health criteria. EPA did not publish a summary criteria table to accompany the revised methodology. Since 2000, EPA has updated the human health criteria for some individual compounds as well (e.g. cadmium). In late 2002, EPA published another major update[7] of criteria values using the EPA revised human health methodology, which included more extensive criteria revisions for 15 other toxic pollutants.

B.2. Oregon 2004 Submission of Water Quality Standards

In 1999, DEQ initiated a Water Quality Standards Review (triennial review) to update DEQ toxics criteria based on the 1986 EPA Gold Book (contained in Table 20 of Oregon's water quality standards). This review was completed in 2003. During this review, DEQ made significant revisions to both the aquatic life and human health criteria based on the updated EPA methodologies and science for deriving aquatic life and human health criteria (as described above) that had occurred since the Gold Book had been published. DEQ's criteria that it adopted in 2004 reflected an increase in the fish consumption rate from 6.5 g/d to 17.5 g/d, based on the rate used EPA's national criteria recommendations. However, despite being based on this higher fish consumption rate, some of the 2004 criteria were actually less stringent than Oregon's previous criteria due to updated scientific information affecting other factors that go into calculating human health criteria. To be consistent with the federal requirements, DEQ specified that the criteria that were less stringent than the older Table 20 criteria were not effective for Clean Water Act purposes until after EPA approval.

The Environmental Quality Commission (commission) adopted these new and revised water quality standards on May 20, 2004. Upon adoption, DEQ submitted these criteria changes along with revisions to the narrative toxics provision to EPA on July 8, 2004.

EPA did not act on these revised water quality standards, and a lawsuit was filed on April 7, 2006 noting EPA's failure to act on Oregon's revised human health water quality criteria among other revisions. On May 29, 2008, a U.S. District Court in the District of Oregon issued a consent decree setting forth deadlines by which EPA must take action on Oregon's 2004 water quality standards submission, under Section 303(c) of the CWA (*Northwest Environmental Advocates v. U.S. EPA,* No. 06-479-HA (D. Or. 2006)). The court subsequently issued several extensions of the applicable deadlines for action. The consent decree's applicable deadline for EPA action on the human health criteria was ultimately extended to June 1, 2010.

[5] EPA. Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California. Federal Register, Volume: 65, Number 97, Page: 31682, May 18, 2000.
[6] EPA. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). EPA-822-B-00-004, October 2000.
[7] EPA. Revision of National Recommended Water Quality Criteria. Federal Register, Volume: 67, Number 249, Page 79091-79095, December 27, 2002.

B.3. EPA Action on Oregon's 2004 Submission of Human Health Toxics Criteria

B.3.1. Disapproved Human Health Criteria

On June 1, 2010, EPA concluded that human health criteria based on a fish consumption rate of 17.5 g/d were not protective of Oregon's designated use of fishing, and thus, did not protect Oregonians who consume higher levels of fish. Consequently, EPA disapproved the majority of the human health criteria that were based on 17.5 g/d (i.e. 48 non-carcinogens and 55 carcinogens). Accompanying footnotes to the disapproved criteria were subsequently disapproved as well. For specific details on EPA's actions, refer to EPA's Technical Support Document[8] accompanying its action.

Oregon's water quality standards included a provision specifying that if a value in Table 33A was disapproved by EPA, the corresponding value in Table 20 would become effective immediately. Values that were the same in Tables 20 and 33A would remain in effect. Consequently, as a result of EPA's disapproval, DEQ's human health toxics criteria reverted back to Table 20 values which are largely based on a fish consumption rate of 6.5 g/d. The few exceptions where EPA did approve criteria from DEQ's 2004 adoption are noted below in the "Approved Human Health Criteria" section.

Under CWA Section 303(c)(3) and EPA's regulations at 40 CFR Parts 131.21 and 131.22, if EPA disapproves a state's new or revised water quality standards, it must "specify the changes" necessary to meet the applicable requirements of the Act and EPA's regulations. If the state does not adopt necessary changes, EPA must propose and promulgate appropriate changes. In the EPA letter[9] disapproving DEQ's 2004 submission, EPA indicated that revising the human health toxics criteria based on a higher fish consumption rate of 175 g/d will address the EPA's disapproval. This rate represents the value that DEQ recommended to the commissioners at the October 23, 2008 Environmental Quality Commission meeting and that they subsequently directed DEQ to use in its revisions. For more information on DEQ's recommended fish consumption rate, see section C.

B.3.2. Approved Human Health Criteria

The human health criteria identified in this section that EPA approved on June 1, 2010, will be included in the new Table 40 along with the proposed human health criteria.

1. **Human health criteria for copper and asbestos**

   Copper
   The "water + organism" criterion of 1300 ug/L is consistent with EPA's 304(a) recommendation and was therefore approved by EPA. Since human health risks from copper are primarily from

[8] EPA. Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Revisions to Narrative Toxics Provisions Submitted on July 8, 2004. June 1, 2010.
[9] EPA. Mike Bussell, EPA Region 10 Division Director to Neil Mullane, DEQ Water Quality Division Administrator. EPA's Action on New and Revised Human Health Water Quality Criteria for Toxics and Revisions to Narrative Toxics Provisions in Oregon's Water Quality Standards. June 1, 2010

drinking water and not fish consumption, the lower fish consumption rate of 17.5 g/d was not relevant to EPA's decision.

Asbestos
The "water + organism" criterion of 7,000,000 fibers/L is consistent with EPA's 304(a) recommendation and was therefore approved by EPA. Since human health risks from copper are primarily from drinking water and not fish consumption, the lower fish consumption rate of 17.5 g/d was not relevant to EPA's decision.

2. Footnote K insofar as it applies to the "water + organism" human health criteria for iron and manganese

Footnote K states: "Human Health criterion is for "dissolved" concentration based on the 1976 EPA Red Book conclusion that adverse effects from exposure at this level are aesthetic rather than toxic." EPA approved this footnote for the "water + organism" criteria for both iron and manganese, but disapproved the footnote for the manganese "organism only" criterion because EPA could not ensure the protectiveness of using the dissolved form of manganese. In a separate rulemaking for manganese, DEQ therefore, expressed the criterion as an "organism only" total manganese criterion for marine waters. The criterion is based on human health toxicity endpoints related to the consumption of marine mollusks.

In same rulemaking, DEQ withdrew the "water + organism" iron and manganese human health criteria and the "organism only" manganese criterion for fresh waters. The criteria were not based on levels needed to protect human health. Rather, the primary effects considered were aesthetic (e.g., taste and laundry staining). Iron and manganese are a naturally occurring earth metals that sometimes exceeded the previous criteria due to natural background levels.

The Environmental Quality Commission adopted the revisions to the iron and manganese criteria on December 9, 2010. The revisions are reflected in the new Table 40 and will become applicable upon EPA approval.

3. Withdrawal of the human health criteria for eight toxic pollutants

Consistent with EPA's action under the National Toxics Rule, Oregon withdrew its human health criteria for the following toxic pollutants and was approved by EPA:

- Beryllium
- Cadmium
- Chromium III
- Chromium VI
- Lead
- Mercury
- Silver

- Trichloroethane 1, 1, 1

4. **Revisions to the narrative toxic provisions at OAR 340-041-0033(1) and (2).**

   Revisions to OAR 340-041-0033(1) were approved by EPA as minor editorial changes. Revisions to (2) describe effective dates for human health and aquatic life toxics criteria in Tables 20, 33A and 33B.

B.4. Applicability of EPA's June 2010 Action to 2011 Proposed Human Health Criteria Revisions

In the current effort to develop the human health criteria proposed revisions, DEQ generally relied on the scientific information, policy decisions, and subsequent recommendations from the 1999 triennial review and 2004 submission as the basis for these human health criteria revisions. The major difference between criteria that were submitted in 2004 and the proposed 2011 criteria is the fish consumption rate (i.e. 175 g/d versus 17.5 g/d). In addition, DEQ is not proposing any revisions to the aquatic life criteria. These criteria were adopted and submitted to EPA in 2004 and are still undergoing Endangered Species Act consultation by EPA, the U.S. Fish and Wildlife Service, and NOAA's National Marine Fisheries Service and are not the subject of this review.

C. Development of a Fish Consumption Rate

C.1. Background

DEQ's water quality standards play an important role in maintaining and restoring the environmental quality and quality of life that Oregonians value. Human health criteria are used to limit the amount of toxic pollutants that enter Oregon's waterways and accumulate in the fish and shellfish consumed by many Oregonians as a traditional and/or healthful lifestyle. Human health criteria help to ensure that people may eat fish and shellfish (from here forward referred to as "fish") from local waters without incurring unacceptable health risks.

In 2004, the commission, at DEQ's recommendation, adopted water quality criteria based on EPA's 2002 recommended toxic pollutants criteria for aquatic life and for human health. The human health criteria were based on a fish consumption rate of 17.5 g/d, which represents the 90th percentile of consumption among consumers and non-consumers of fish nationwide. Prior to adopting the 2004 revisions, DEQ's human health criteria were based on EPA's 1986 recommended criteria and a fish consumption rate of 6.5 g/d. A fish consumption rate of 17.5 g/d equals about 0.6 ounces per day or three 6-ounce meals per month. Based on concerns that the fish consumption rate used in the EPA criteria may not accurately represent Oregonian's consumption patterns, the commission requested that DEQ seek resources to conduct a fish consumption rates study in Oregon.

Following DEQ's 2004 adoption of EPA's recommended criteria, concerns about Oregon's human health criteria heightened. Native American tribal governments objected to the criteria, stating that the criteria did not protect tribal members who eat much greater amounts of fish and for whom fish consumption is a critical part of their cultural tradition and religion. Tribes have rights to catch fish in Oregon waters and EPA has a trust responsibility to protect the interests of the tribes. The Oregon tribes who were most involved in the fish consumption rate workshops and discussions and the subsequent rulemaking process include the Umatilla, Warm Springs, Klamath, Siletz and Grand Ronde tribes.

Although DEQ's 2004 human health criteria reflected EPA's guidance contained in the Human Health Methodology including use of 17.5 g/d as a default value, the guidance also recommends using local fish consumption data when it is available. In this circumstance, local data was available from a study conducted by the Columbia River Inter-Tribal Fish Commission [10] or "CRITFC Study", which included surveys of four Columbia River Tribes, two of whom reside in Oregon, the Confederated Tribes of the Umatilla Indian Reservation (CTUIR) and the Confederated Tribes of the Warms Springs Reservation.

C.2. Fish Consumption Rate Review Project

For the above reasons and with the recognition that many Oregonians eat more than 17.5 g/d of fish and shellfish, DEQ embarked on a project to review the fish consumption rate and subsequently revise the human health water quality criteria for Oregon. DEQ was not able to obtain funding for a study of Oregon fish consumption rates, so the review was based on available literature and data.

DEQ launched the fish consumption rate review project in the fall of 2006 and conducted seven workshops in cooperation with the EPA and the Confederated Tribes of the Umatilla Indian Reservation. The objective for these workshops was to allow any member of the public to receive and provide input on the information being gathered and evaluated, and express views on the policy issues inherent in choosing a fish consumption rate.

DEQ also formed two workgroups, the Human Health Focus Group (HHFG), to assist with gathering and evaluating relevant information. The Human Health Focus Group, made up of public health professionals and toxicologists, reviewed the available data on fish consumption patterns in the Pacific Northwest and elsewhere. The group wrote a report[11] summarizing the science and made recommendations about the quality and appropriate use of the available information. DEQ considered the HHFG's analysis in its selection of a fish consumption rate. The report, materials and agendas from the HHFG process, are contained on DEQ's website.

C.3. Choosing an Appropriate Fish Consumption Rate

Oregon's existing human health criteria are based either on a defined acceptable level of cancer risk (1 in 1,000,000 additional incidents of cancer) or a reference dose beyond which effects in test populations begin to be observed. People who eat more fish have a greater probability of incurring a health effect

[10] Columbia River Inter-Tribal Fish Commission. October 1994. A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin. Technical Report 94.3.

[11] Human Health Focus Group Report. Oregon Fish and Shellfish Consumption Rate Project. June 2008.

from this exposure to contaminants and those who eat less fish will have less risk. As the fish consumption rate increases, the water quality criteria values will decrease and the costs to meet requirements associated with the revised criteria may rise. How much the criterion for any given pollutant will change with a change in the fish consumption rate also depends on the degree to which that pollutant accumulates in fish tissue. Therefore, a ten-fold increase in the fish consumption rate will not necessarily result in a ten-fold decrease for all criteria; the change in the criteria will vary by pollutant.

A major policy decision inherent in developing human health criteria is whether to base the criteria on a fish consumption rate that includes Oregonians who eat large amounts of fish and shellfish for cultural, economic, health or other reasons, or whether to use a fish consumption rate reflective of Oregon's total population, including people who do not eat fish or eat it rarely. A related decision is what proportion or percentile of the population(s) to base the fish consumption rate on. Within any group, whether Native-Americans, Asian-Americans or commercial fishermen, there will be some individuals who eat more than any chosen rate and some who eat less than that rate.

An additional issue discussed during this process was whether to include salmon (an anadromous fish) and/or marine fish in the consumption rate. The Human Health Focus Group recommended that DEQ include salmon and marine fish in the fish consumption rate because these fish are an important part of the fish diet in the Northwest and represent a potential source of exposure to contaminants. In addition, they found that for non-carcinogens, given the status of the relative source contribution (RSC) approach and values, it would be more accurate to account for the consumption of marine fish in the consumption rate than to use the RSCs in deriving criteria for non-carcinogens. Counter arguments to including (or fully counting) salmon and marine fish in the fish consumption rate assert that these fish accumulate most of their contaminant body burden in ocean waters, outside the influence of Oregon's water quality standards and pollution controls. In addition, salmon tend to contain lower levels of contaminants than resident fish. DEQ ultimately recommended that salmon be included in the rate given the large number of Oregonians who traditionally consume large amounts of salmon and noted that they represent a potential path of exposure to toxic pollutants. Consequently, the recommended rate reflects consumption of salmon and lamprey relative to rates documented in the CRITFC study (to protect at least 95% of fish consumers in Oregon), as well as marine fish and shellfish relative to the rates documented in the Puget Sound studies (to protect at least 90% of fish consumers in Oregon).

C.4. DEQ Recommendation on Selecting a Fish Consumption Rate

DEQ determined that a fish consumption rate of 175 g/d is a reasonable and protective fish consumption rate to use as the basis for Oregon's human health criteria. A fish consumption rate of 175 g/d equals approximately 6.2 ounces per day (or approximately 23 8-oz fish or shellfish meals per month). This rate represents the 95th percentile value from the Columbia River Inter-Tribal Fish Commission study and is within the range of the 90th percentile values from various studies from the Northwest assembled by the HHFG. The 175 g/d rate is consistent with the HHFG recommendation to use 90th or 95th percentile values to represent the proportion of the population the criteria should be designed to protect. It is also consistent with HHFG recommendations to use a fish consumption rate that represents fish consumers only, rather than a rate derived from the overall population including both consumers and non-consumers of fish, and to include salmon and other marine species in the rate.

Another question raised during the 2004 water quality standards review was whether Oregon should use different fish consumption rates for basins or water bodies that reflect consumption patterns in those areas. Although the Technical Advisory Committee proposed applying different consumption rates for different geographic areas within the state, DEQ did not recommend this option based on the following considerations:

- While there is data only for the Umatilla and Warm Springs Tribes in Oregon, studies from the Pacific Northwest and elsewhere show that many Tribes and other groups (e.g. Asian Americans) eat moderate to large amounts of fish. Input at public workshops indicates that there may be other groups that eat large amounts of fish as well, such as commercial or sport fishermen.
- Nearly all the major river basins in Oregon are usual and accustomed fishing areas for an Oregon Tribe.
- People may catch fish in many locations around the state, not just in the river basin in which they live.
- Having different criteria in different basins would create complexities in the regulations and their implementation.

The EPA, CTUIR, and DEQ collaborated on this project throughout the process and issued a joint recommendation[12] to the Environmental Quality Commission on October 23, 2008, to revise Oregon's toxics criteria for human health based on a FCR of 175 g/d. The commission agreed with this recommendation and directed DEQ to proceed with this fish consumption rate as a basis for revising human health criteria.

D. New and Revised Human Health Water Quality Criteria

D.1. Technical Review Process for 2004 Submission

During the development of the 2004 water quality standards revisions, the Technical Advisory Committee (TAC) reviewed EPA's 2000 Methodology in comparison to the 1980 methodology used to derive Table 20 toxics criteria.

The formulae in the 2000 EPA Methodology used to calculate the criteria values differed from those in the 1980 EPA methodology by:

[12] DEQ. October 6, 2008 Memo from Dick Peterson, Director DEQ, to the Environmental Quality Commission. Agenda Item G, Action Item: Oregon's Fish Consumption Rate – For Use in Setting Water Quality Standards for Toxic Pollutants October 23, 2008 commission Meeting.

1) the addition of a new formula to calculate criteria for compounds where the mode of carcinogenicity shows a non-linear relationship between dose and effect;
2) the use of a bioaccumulation factor rather than bioconcentration factor (bioconcentration refers to the uptake and retention of a chemical from the water only; bioaccumulation refers to the uptake and retention of a chemical from all the surrounding environment, e.g. water, food, and sediment); and
3) the use of a new fish consumption rate.

Unless otherwise specified, DEQ relied on the review and decisions made during the development of the 2004 water quality standards to form the technical basis of revising criteria for this rulemaking. The major difference is the use of a higher fish consumption rate of 175 g/d.

D.2. Applicability of "water + organism" and "organism only" Criteria

The criteria calculations for both carcinogens and non-carcinogens differ depending upon the exposure scenario for which the criteria are derived. Oregon's criteria were developed to protect human health from long term exposure to toxic pollutants in drinking water and through eating fish and shellfish contaminated with toxics. The "water + organism" criteria refer to values that if met, ensure exposure through the consumption of drinking water and fish, including shellfish does not result in adverse health effects. The "organism only" criteria refer to values that if met, ensure exposure through the consumption of fish and shellfish only does not result in adverse health effects. These criteria apply where Oregon has designated waters as either a public or private domestic water supply, or as a fishing beneficial use. Generally, the majority of Oregon's waterbodies have been designated as both a domestic or private domestic water supply and as a fishing beneficial use. Therefore, human health toxics criteria will be widely applicable across the state. Table 1 indicates where the "organism only" criteria are the only human health criteria applicable, since a drinking water use has not been designated in these waters (e.g. non-potable estuarine waters).

TABLE 1: Waters Where "Organism Only" Criteria are Solely Applicable: Waters designated as having a fishing use, but not a domestic or private water supply

Table Reference Number	Basin	Segment Name
140A	Goose and Summer Lakes Basin	Goose Lake; and Highly Alkaline and Saline Lakes
190A	Malheur Lake Basin	Natural Lakes
220A	Mid Coast Basin	Estuaries and Adjacent Marine Waters
230A	North Coast Basin	Estuaries and Adjacent Marine Waters
271A	Rogue Basin	Rogue River Estuary and Adjacent Marine Waters; and Bear Creek Main Stem
286A	Sandy Basin	Streams Forming Waterfalls Near Columbia River Highway
300A	South Coast Basin	Estuaries and Adjacent Marine Waters
320A	Umpqua Basin	Umpqua River Estuary to Head of Tidewater and Adjacent Marine Waters

D.3. Criteria Derivation

The methodology for calculating human health toxics criteria takes into consideration three major factors: risk assessment, exposure, and to what degree the pollutant accumulates in fish tissue. Risk assessment includes the potency of the compound to cause a toxic effect that is either cancerous or noncancerous, and for cancer causing compounds, the level of risk that is acceptable for society (e.g. one additional cancer per million people). Exposure includes consideration of body weight, water intake, and fish intake. Bioconcentration is the degree to which an organism accumulates the contaminant from water only, while bioaccumulation describes the net accumulation of a contaminant from all sources.

D.3.1. Non-Carcinogens

DEQ utilized the 2000 Methodology to derive ambient water quality criteria for pollutants. This section describes how DEQ used the methodology as it applies to non-carcinogens.

Equation for Non-Carcinogens:

$$AWQC = RfD \times RSC \times \frac{(BW)}{[DI + (FCR \times BAF)]}$$

where:

AWQC = Ambient Water Quality Criterion (mg/L)

RfD = Reference dose for noncancer effects (mg/kg-day)

RSC = Relative source contribution factor to account for non-water sources of exposure

BW = Human body weight (kg) =70 kg

DI = Drinking water intake (L/day) = 2 L/day

FCR = Fish consumption rate (kg/d) = 175 g/d

BAF = Bioaccumulation factor (L/kg)

Body Weight and Drinking Water Intake

DEQ used EPA's national default values for body weight (70 kilograms or 154 lbs) and drinking water intake (2 L/day). DEQ also relied on EPA's reference doses used as part of its nationally recommended criteria[13]. A reference dose is defined[14] as an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime.

[13] EPA. 2002. Nationally Recommended Water Quality Criteria 2002 – Human Health Criteria Calculation Matrix. USEPA, Office of Water, Washington, DC. EPA 822-R-02012.

[14] EPA. 1993. Reference Dose (RfD): Description and Use in Health Risk Assessments. Integrated Risk Information System (IRIS). Intra-Agency Reference Dose (RfD) Work Group, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, USEPA, Cincinnati, OH.

Bioconcentration Factors (BCF) Versus Bioaccumulation Factors (BAF)

Water quality criteria for the protection of human health are derived, in part, by considering human exposure to pollutants that have been stored within fish after that fish has been exposed to a toxic pollutant. A BCF accounts for the uptake of a pollutant by a fish from the surrounding water, while a BAF accounts for the uptake of a pollutant from all sources (including the surrounding water, food, and sediment). While the consideration of a BAF in EPA's 2000 Methodology was considered an improvement over BCFs, developing BAFs is a complex process and can vary from site to site. EPA has not yet developed a national list of BAFs for its nationally recommended criteria. Consequently, EPA recommends criteria be developed using BCFs until such time local or regional BAFs that would be applicable to Oregon are developed. As a result, proposed criteria for this rulemaking reflect EPA recommended BCF values.

Reference Dose (RfD)

A reference dose is an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime[15]. Proposed criteria for this rulemaking reflect EPA recommended RfD values. Reference Dose values are based on real studies that reflect health effects from these pollutants at specific levels.

Relative Source Contribution

Criteria for pollutants that are non-carcinogens are based on a total cumulative dose over time that causes an observable effect. Because the human health water quality criteria address exposure only through drinking water and eating fish, a relative source contribution (RSC) factor is used to calculate the criteria. The RSC identifies or estimates the portion of total exposure attributed to water and fish consumption, and therefore, accounts for potential exposure from other sources, such as skin absorption, inhalation, other foods and occupational exposures. The RSC value is either multiplied by the reference dose or subtracted from the reference dose, depending on the chemical and known exposure sources of contaminants. Table 2 identifies the pollutants for which DEQ applied RSC values to the revised human health water quality criteria. For all of the pollutants but Endrin, DEQ used EPA's recommended RSC value. The other non-carcinogen pollutants used a RSC of 1, which indicates that all of the exposure to that pollutant is assumed to come from water and fish ingestion. In some cases, EPA does not have enough data to establish RSC values for other chemicals.

TABLE 2: Criteria Where Relative Source Contribution Values Were Applied

1) Antimony (40%)	9) Thallium (20%)
2) Chlorobenzene (20%)	10) Toluene (20%)
3) Chlorodibromomethane (80%)	11) 1,1,2-Trichloroethane (20%)

[15] EPA. Reference dose (RfD): Description and use in health risk assessments. Integrated Risk Information System (IRIS). Online. Intra-Agency Reference Dose (RfD) Work Group, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office. Cincinnati, OH. March 15, 1993.

4) Cyanide (20%)	12) 1,1-Dichloroethylene (20%)
5) Endrin (80%)	13) 1,2,4-Trichlorobenzene (20%)
6) Ethylbenzene (20%)	14) 1,2-Dichlorobenzene(o) (20%)
7) gamma-BHC (Lindane) (20%)	15) 1,2-trans-Dichloroethylene (20%)
8) Hexachlorocyclopentadiene (20%)	16) 1,4-Dichlorobenzene(p) (20%)

RSC for Methylmercury

EPA established a RSC value that is subtracted from the reference dose to derive the tissue based methyl mercury criterion. EPA's recommended criterion uses a RSC because EPA's national default fish consumption rate does not include the consumption of marine species of fish (including Pacific salmon), which are a significant potential exposure route for methylmercury. Because the primary human route of exposure to methylmercury comes from ingestion of fish and shellfish, and because DEQ included marine species in the development of its fish consumption rate, it would be "double counting" the exposure if DEQ incorporated the same RSC value used in EPA's recommended methylmercury criterion. Methylmercury is unique in that it is a fish tissue criterion and the primary route of exposure to humans is through the consumption of fish and shellfish. The other criteria where RSC values have been established have other contributing sources of pollutant (e.g., consumption of food or other exposure routes), so removing the RSC would not be appropriate in those circumstances.

RSC for Endrin

EPA used a default RSC value of 20% for Endrin based on a recommendation from EPA's drinking water program. DEQ's final proposed criteria for Endrin use a RSC value of 80%. The primary reason DEQ proposes using an alternate default value is because DEQ does not anticipate exposure to this chemical outside of water and fish ingestion. This is consistent with EPA guidance for use of default RSC values:

Default RSC Percentage Values: Floor of 20%, Ceiling of 80% (65 FR 66472)

- EPA has recommended using the 20% RSC default when routes of water exposures other than oral or sources of exposure other than fish and water are anticipated, but adequate data are lacking to quantify those exposures.
- Utilize local data to quantify exposures from other routes where available: When data are adequate to quantify exposures to other sources (oral or exposure to fish and water), EPA recommends that they be used instead of the default 20% RSC value.
- If it can be demonstrated that other sources and routes of exposure are not anticipated for the chemical in question (based on information about its known/anticipated uses and chemical/physical properties), then the 80% ceiling is recommended. This 80% ceiling is a way to provide adequate protection for those who experience exposures (from any or several sources) higher than available data may indicate.

Due to the properties of this chemical and the fact that it has not been in use for about 25 years, it is highly unlikely that people in Oregon would gain only 20% of their exposure to Endrin from water and fish and 80% of their exposure from other sources. Endrin bioconcentrates in aquatic organisms, but is not very soluble in water. The bioconcentration factor used to derive the human health criteria is 3970, resulting in the same criteria value (when rounded to significant digits) for water + organism and for organism only ingestion.

The following information from the US Department of Health and Human Services Toxicological Profile for Endrin (1996, Chapter 5) supports DEQ's decision to use an RSC of 80% rather than 20% to derive Oregon's water quality criteria:

- The use of Endrin ended in the mid-1980s and "consequently, there are no longer any significant releases of Endrin to the environment in the United States."
- "Information on current levels of Endrin in the environment is limited; however, the available data indicate that concentrations in all environmental media are generally negligible or below levels of concern. "
- "The FDA has concluded that Endrin is no longer present in the environment to the extent that it may be contaminating food or feed at levels of regulatory concern (USDA 1995)."
- Endrin tends to persist in the environment mainly in forms sorbed to sediments and soil particles. A conservative estimate of its half-disappearance time in sandy loam soils is approximately 14 years. "Therefore, the exposure risks from Endrin to the general population of the United States are likely to steadily decrease over time."
- Limited information on the physical and/or chemical properties of Endrin aldehyde indicates that it is highly insoluble in water (EPA 1981a), highly immobile in soil, and will not volatilize significantly from water or soil.
- Endrin has been found to volatilize significantly (20-30%) from soils within days after application (Nash 1983). Because Endrin has not been in use for many years, this exposure route no longer occurs in Oregon.
- The main sources for potential human exposure to Endrin are residues on imported food items, unused stocks, unregistered use, inappropriate disposal, and hazardous waste sites; however, there is no current evidence of significant exposures from any of these sources. Furthermore, it should be noted that in environmental media, especially in contaminated soils and sediments, the amount of Endrin chemically identified by analysis is not necessarily the amount that is toxicologically available.
- Endrin was identified at 102 and Endrin ketone was identified at 37 of 1430 current or former hazardous waste sites in the United States. None of these sites were in Oregon (Figures 5-1 and 5-2).

D.3.2. Carcinogens

DEQ utilized the 2000 Methodology to derive ambient water quality criteria for pollutants that are carcinogens.

Equation for linear dose-response carcinogens:

$$AWQC = \frac{(\text{Risk Level} \times BW)}{[CSF \times (DI + (FCR \times BAF))]}$$

where:

AWQC = Ambient Water Quality Criterion (mg/L)

Risk Level = Risk Level (unitless)

CSF = Cancer slope factor (mg/kg-day)

BW = Human body weight (kg) =70 kg

DI = Drinking water intake (L/day) = 2 L/day

FCR = Fish consumption rate (kg/d) = 175 g/d

BAF = Bioaccumulation factor (L/kg)

The equation to derive ambient water quality criteria for pollutants that are carcinogens (i.e. cancer-causing pollutants) uses many of the same variables as the equation for non-carcinogens (i.e. body weight, drinking water intake, fish consumption rate, and bioaccumulation factor). The main difference is that a risk level and a cancer slope factor are used, and a relative source concentration is not used.

Cancer Slope Factor and Risk Level

The cancer slope factor is a measure of chemical potency. For most cancer-causing chemicals there is no toxicity threshold or reference dose. Because carcinogenic chemicals are thought to initiate the cancer process at almost any concentration, a dose-response parameter referred to as the cancer slope factor is used for chemicals that display toxic behavior such that the carcinogenic risk increases linearly as the chemical dose increases. Cancer slope factors are specific to individual pollutants. DEQ utilized EPA's nationally recommended slope factors to calculate criteria for carcinogens. Cancer slope factors are based on real studies that reflect health effects from carcinogenic pollutants at specific levels.

Risk estimates for carcinogens are expressed as the incremental probability of developing cancer (e.g., an additional one in one million chance of developing cancer) over a lifetime of exposure to potential carcinogens. EPA has identified a risk level range of 1×10^{-6} (1 in 1,000,000) to 1×10^{-5} (1 in 100,000) to be an appropriate risk management goal for the general population, as long as the most sensitive population is protected at 1×10^{-4} (1 in 10,000). As a matter of policy, DEQ has historically chosen to protect Oregonians at a risk level of 1×10^{-6} and will continue with this recommendation for the proposed human health toxics criteria. As a result, the proposed criteria will protect highly exposed populations in Oregon consuming up to 175 g/d of fish at a risk level of 1×10^{-6}.

D.3.3. Criteria Not Dependent on a Fish Consumption Rate

Although the majority of DEQ's proposed human health criteria are affected by the fish consumption rate, several of Oregon's existing criteria are not based on a fish consumption rate. For these criteria, human health risks are primarily from drinking water and the existing criteria are based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act. Therefore, DEQ has not developed any "organism only" criteria. As a result, DEQ is not proposing to change the existing human health criteria identified in Table 3.

TABLE 3: Human health toxics criteria not dependent on a fish consumption rate

Asbestos	Methoxychlor
Barium	Nitrates
Chlorophenoxy Herbicide (2,4,5,-TP)	Copper
Chlorophenoxy Herbicide (2,4,-D)	Manganese

D.3.4. Toxics Criteria DEQ is Proposing to Withdraw

The following toxics pollutants have currently effective human health criteria, however, there are no longer EPA criteria for these pollutants. In some cases, like PAHs, the revised criteria include individual species of the more toxic forms of PAH, rather than a single criterion for a chemical family. Therefore, DEQ's proposed final rule withdraws the human health criteria for these pollutants.

TABLE 4: Pollutants for which DEQ Proposes to Withdraw Criteria

Dinitrotoluene
Dinitro-o-Cresol 2,4
Diphenylhydrazine
Halomethanes
Monochlorobenzene
Polynuclear Aromatic Hydrocarbons (PAHs)
Endosulfan

Based on information gathered during the public comment period, DEQ learned it had inadvertently included a "benzene range" as part of Table 40. In addition, DEQ included revisions to the "benzene" criteria that are single values. In investigating the basis for the "benzene range" DEQ identified that EPA does not have any recommended criteria for a "benzene range" and noted that DEQ has no precedent for expressing criteria as a range of values. Further investigations show there is a range of values presented in EPA's IRIS database for the cancer slope factor associated with benzene associated with the use of different modeling methods for the data. The cancer slope factor used for the development of the benzene criteria is consistent with the factor EPA used in deriving the national benzene criterion. Given this information, including both the "benzene range" criteria in addition to the benzene criteria is duplicative. As a result, DEQ removed the benzene range criteria from Table 40.

D.3.5. Proposed Toxics Criteria Additions

DEQ's final proposed rules add criteria for 39 toxic pollutants to the human health criteria table. DEQ included criteria for these pollutants in its 2004 water quality standards based on updated EPA criteria, but EPA subsequently disapproved those criteria on June 1, 2010, because of an inadequate fish consumption rate. Revised criteria for these pollutants now reflect a fish consumption rate of 175 g/d.

TABLE 5: Pollutants for Which DEQ Proposes to Add Criteria

Acenapthene	Dimethyl phenol 2,4
Anthracene	Dinitrophenol 2,4
Benzene [represents range]	Dinitrophenols
Benz(a)anthracene	Diphenylhydrazine 1,2
Benzo(a)pyrene	Endosulfan alpha
Benzo(b)fluoranthene 3,4	Endosulfan beta
Benzo(k)fluoranthene	Endosulfan sulfate
Bromoform	Endrin aldehyde
Butylbenzyl phthalate	Fluorene
Chlorodibromomethane	Heptachlor epoxide
Chloronaphthalene 2	Indeno(1,2,3-cd)pyrene
Chlorophenol 2	Methyl bromide
Chrysene	Methyl-4,6-dinitrophenol 2
DDD 4, 4’	Methylene chloride
DDE 4, 4’	Methylmercury (mg/kg)
Dibenz(a,h)anthracene	Nitrosodi-n-propylamine, n
Dichlorobenzene(p) 1,4	Pyrene
Dichlorobromomethane	Trichlorobenzene 1,2,4
Dichloroethylene trans 1,2	Zinc
Dichloropropane	

D.3.6. Less Stringent Toxics Criteria

Although the majority of proposed toxics criteria are more stringent than the currently effective values based on a higher fish consumption rate, several of the criteria values became less stringent. As new risk-based data and studies become available, EPA updates risk values (e.g. cancer slopes, reference doses, bioconcentration factors) associated with exposure to environmental contaminants in EPA’s IRIS (Integrated Risk Information System) database. DEQ, unless otherwise specified, used EPA’s default values in IRIS as the basis for revising criteria. For the pollutants identified in Table 6, changes to values other than the fish consumption rate resulted in proposed criteria that were less stringent than current criteria despite utilizing a higher fish consumption rate.

TABLE 6: Less Stringent Toxics Criteria

Chloroform
Nickel
Phenol
Selenium

E. New, Revised, and Removed Footnotes

DEQ included new or removed footnotes for some human health criteria in Table 40. The majority of these footnotes clarify the source of information upon which the proposed criteria are based. Several of these footnotes with similar language were proposed as part of the 2004 water quality standards submittal, but were subsequently disapproved in conjunction with EPA's disapproval of the associated criteria.

TABLE 7: New Footnotes

Toxic Pollutant	New Footnote
1. Arsenic	This footnote was not included as part of the separate rulemaking for arsenic which was adopted by the EQC on April 21, 2011. A new footnote is now proposed to clarify how arsenic is expressed, as well as the associated risk level the criteria are based upon. *The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately of 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1 x 10^{-4}*
2. Asbestos	*The human health risks from asbestos are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
3. Barium	*The human health criterion for barium is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
4. Chlorophenoxy Herbicide (2,4,5,-TP)	*The Chlorophenoxy Herbicide (2,4,5,-TP) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
5. Chlorophenoxy Herbicide (2,4-D)	*The Chlorophenoxy Herbicide (2,4-D) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also*

Toxic Pollutant	New Footnote
	published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.
6. Cyanide	*The cyanide criterion is expressed as total cyanide (CN)/L.*
7. Di-2-ethylhexyl Phthalate	*Di-2-ethylhexyl Phthalate was previously known as Bis-2-ethylhexyl phthalate*
8. Methoxychlor	*The human health criterion for methoxychlor is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
9. Methylmercury	*This value is expressed as the fish tissue concentration of methylmercury. Contaminated fish and shellfish is the primary human route of exposure to methylmercury*
10. PCBs	*This criterion applies to total PCBs (e.g. determined by Aroclors or congeners)*

TABLE 5: Revised Footnotes

Toxic Pollutant	Current Footnote	Revised Footnote
1. Copper	*This value is based on a Drinking Water regulation.*	*Human health risks from copper are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*

Toxic Pollutant	Current Footnote	Revised Footnote
2. Nitrates	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*	*The human health criterion for nitrates is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*

TABLE 6: Footnotes Removed

Bioconcentration factors for the three toxic pollutants in Table 6 are now available and were used to calculate criteria. For this reason, DEQ removed the footnotes because they are no longer applicable.

Toxic Pollutant	Current Footnote To Be Removed
1. Hexachlorocyclo-hexane-Technical	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*
2. Nitrosamines	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*
3. N-Nitrosodiethylamine	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*

F. Proposed Redline/Strikethrough Revisions to the Toxic Substances Rule

DEQ proposed several changes to 340-041-0033 in the rules DEQ published for public comment. The proposed revisions addressed the separation of the aquatic life criteria and the human health criteria in different tables. In addition, DEQ proposed a "Background Pollutant Allowance" for public comment.

In the revisions shown below, DEQ reorganized provisions relating to the aquatic life criteria and the human health criteria as separate sections. In addition, DEQ added a new section (1) specifying that the 112 toxics human health criteria revised by this rule are not applicable for purposes of the Clean Water Act until they are approved by EPA. This section also applies to the revised iron, manganese, and arsenic criteria the commission adopted in December 2010 and April 2011, respectively.

The provisions addressing background pollutants (now termed "Site-Specific Background Pollutant Criteria") remain in OAR 340-041-0033(6). These revisions are discussed in the *Implementing Water*

Quality Standards in NPDES Permits issue paper, and therefore, are not included in the revisions shown below.

In April 2011, EQC also adopted the arsenic reduction policy as OAR 340-041-0033(3). To accommodate revisions associated with this rulemaking, DEQ reorganized the rule to move the arsenic reduction policy section further back in this rule to OAR 340-041-0033(7), but did not revise any of the rule as adopted by the commission.

340-041-0033

Toxic Substances

(1) Amendments to sections (4) and (6) of this rule (OAR 340-041-0033) and associated revisions to Tables 20, 33A, 33B and 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until they are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

(~~1~~2) Toxic substances may not be introduced above natural background levels in waters of the state in amounts, concentrations, or combinations that may be harmful, may chemically change to harmful forms in the environment, or may accumulate in sediments or bioaccumulate in aquatic life or wildlife to levels that adversely affect public health, safety, or welfare or aquatic life, wildlife, or other designated beneficial uses.

(~~2~~3) Aquatic Life Criteria. Levels of toxic substances in waters of the state may not exceed the applicable aquatic life criteria listed in Tables 20, 33A, and 33B. Tables 33A and 33B, adopted on May 20, 2004, update Table 20 as described in this section.

> *(a) Each value for criteria in Table 20 is effective until the corresponding value in Tables 33A or 33B becomes effective.*
>
> > *(A) Each value in Table 33A is effective on February 15, 2005, unless EPA has disapproved the value before that date. If a value is subsequently disapproved, any corresponding value in Table 20 becomes effective immediately. Values that are the same in Tables 20 and 33A remain in effect.*
> >
> > *(B) Each value in Table 33B is effective upon EPA approval.*
>
> *~~(b) The arsenic criteria in Table 20 established by this rule do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until they are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).~~*
>
> *(~~c~~b) The department will note the effective date for each value in Tables 20, 33A, and 33B as described in this section.*

~~(3) To establish permit or other regulatory limits for toxic substances for which criteria are not included in Tables 20, 33A, or 33B, the department may use the guidance values in Table 33C, public health advisories, and other published scientific literature. The department may also require or conduct bio-~~

~~*assessment studies to monitor the toxicity to aquatic life of complex effluents, other suspected discharges, or chemical substances without numeric criteria.*~~

~~*(4) Arsenic Reduction Policy: The inorganic arsenic criterion for the protection of human health from the combined consumption of organisms and drinking water is 2.1 micrograms per liter. While this criterion is protective of human health and more stringent than the federal maximum contaminant level (MCL) for arsenic in drinking water, which is 10 micrograms per liter, it nonetheless is based on a higher risk level than the Commission has used to establish other human health criteria. This higher risk level recognizes that much of the risk is due to naturally high levels of inorganic arsenic in Oregon's waterbodies. In order to maintain the lowest human health risk from inorganic arsenic in drinking water, the Commission has determined that it is appropriate to adopt the following policy to limit the human contribution to that risk.*~~

~~*(a) The arsenic reduction policy established by this rule section does not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until the numeric arsenic criteria established by this rule are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).*~~

~~*(b) It is the policy of the Commission that the addition of inorganic arsenic from new or existing anthropogenic sources to waters of the state within a surface water drinking water protection area be reduced the maximum amount feasible. The requirements of this rule section [OAR 340-041-0033(4)] apply to sources that discharge to surface waters of the state with an ambient inorganic arsenic concentration equal to or lower than the applicable numeric inorganic arsenic criteria for the protection of human health.*~~

~~*(c) The following definitions apply to this section [OAR 340-041-0033(4)]:*~~

~~*(A) "Add inorganic arsenic" means to discharge a net mass of inorganic arsenic from a point source (the mass of inorganic arsenic discharged minus the mass of inorganic arsenic taken into the facility from a surface water source).*~~

~~*(B) A "surface water drinking water protection area," for the purpose of this section, means an area delineated as such by DEQ under the source water assessment program of the federal Safe Drinking Water Act, 42 U.S.C. § 300j-13. The areas are delineated for the purpose of protecting public or community drinking water supplies that use surface water sources. These delineations can be found at DEQ's drinking water program website.*~~

~~*(C) "Potential to significantly increase inorganic arsenic concentrations in the public drinking water supply source water" means:*~~

~~*(i) to increase the concentration of inorganic arsenic in the receiving water for a discharge by 10 percent or more after mixing with the harmonic mean flow of the receiving water; or*~~

~~*(ii) as an alternative, if sufficient data are available, the discharge will increase the concentration of inorganic arsenic in the surface water intake water of a public water system by 0.021 micrograms per liter or more based on a mass balance calculation.*~~

~~(d) Following the effective date of this rule, applications for an individual NPDES permit or permit renewal received from industrial dischargers located in a surface water drinking water protection area and identified by DEQ as likely to add inorganic arsenic to the receiving water must include sufficient data to enable DEQ to determine whether:~~

~~(A) The discharge in fact adds inorganic arsenic; and~~

~~(B) The discharge has the potential to significantly increase inorganic arsenic concentrations in the public drinking water supply source water.~~

~~(e) Where DEQ determines that both conditions in subsection (d) of this section (4) are true, the industrial discharger must develop an inorganic arsenic reduction plan and propose all feasible measures to reduce its inorganic arsenic loading to the receiving water. The proposed plan, including proposed measures, monitoring and reporting requirements, and a schedule for those actions, will be described in the fact sheet and incorporated into the source's NPDES permit after public comment and DEQ review and approval. In developing the plan, the source must:~~

~~(A) Identify how much it can minimize its inorganic arsenic discharge through pollution prevention measures, process changes, wastewater treatment, alternative water supply (for groundwater users) or other possible pollution prevention and/or control measures;~~

~~(B) Evaluate the costs, feasibility and environmental impacts of the potential inorganic arsenic reduction and control measures;~~

~~(C) Estimate the predicted reduction in inorganic arsenic and the reduced human health risk expected to result from the control measures;~~

~~(D) Propose specific inorganic arsenic reduction or control measures, if feasible, and an implementation schedule; and~~

~~(E) Propose monitoring and reporting requirements to document progress in plan implementation and the inorganic arsenic load reductions.~~

~~(f) In order to implement this section, DEQ will develop the following information and guidance within 120 days of the effective date of this rule and periodically update it as warranted by new information:~~

~~(A) A list of industrial sources or source categories, including industrial stormwater and sources covered by general permits, that are likely to add inorganic arsenic to surface waters of the State.~~

~~(i) For industrial sources or source categories permitted under a general permit that have been identified by DEQ as likely sources of inorganic arsenic, DEQ will evaluate options for reducing inorganic arsenic during permit renewal or evaluation of Stormwater Pollution Control Plans.~~

~~(B) Quantitation limits for monitoring inorganic arsenic concentrations.~~

~~(C) Information and guidance to assist sources in estimating, pursuant to paragraph (d) (C) of this section, the reduced human health risk expected to result from inorganic arsenic control measures based on the most current EPA risk assessment.~~

~~(g) It is the policy of the Commission that landowners engaged in agricultural or development practices on land where pesticides, fertilizers, or soil amendments containing arsenic are currently being or have previously been applied, implement conservation practices to minimize the erosion and runoff of inorganic arsenic to waters of the State or to a location where such material could readily migrate into waters of the State.~~

(4) Human Health Criteria. The criteria for waters of the state listed in Table 40 are established to protect Oregonians from potential adverse health effects associated with long-term exposure to toxic substances associated with consumption of fish, shellfish, and water.

(~~3~~5) To establish permit or other regulatory limits for toxic substances for which criteria are not included in Tables 20, 33A, or 33B, the department may use the guidance values in Table 33C, public health advisories, and other published scientific literature. The department may also require or conduct bio-assessment studies to monitor the toxicity to aquatic life of complex effluents, other suspected discharges, or chemical substances without numeric criteria.

(6) Establishing Site-Specific Background Pollutant Criteria: ….

(~~4~~7) Arsenic Reduction Policy: …

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 468.020, 468B.030, 468B.035 & 468B.048
Stats. Implemented: ORS 468B.030, 468B.035 & 468B.048
Hist.: DEQ 17-2003, f. & cert. ef. 12-9-03; DEQ 3-2004, f. & cert. ef. 5-28-04; DEQ 17-2010, f. & cert. ef. 12-21-10

G. Implementation

G.1. Effective Dates

DEQ is proposing that the human health criteria revisions established by OAR 340-041-0033 and shown in Table 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act until approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

In contrast, for DEQ's 2004 water quality standards submission, the revised toxics criteria became effective for NPDES purposes nine months following the date of commission adoption. DEQ also specified that if the values were subsequently disapproved after that date, any corresponding value in Table 20 would become effective. EPA disapproved the majority of DEQ's 2004 human health criteria on June 1, 2010, nearly six years after the effective date. As a result, many of the criteria adopted in 2004 that had become effective subsequently reverted back to human health criteria based on a FCR of 6.5 g/day. Given the potential ramifications of criteria becoming effective in advance of EPA's action, DEQ is proposing that the human health criteria only become applicable for CWA programs upon EPA approval, rather than at the time of commission adoption.

G.2. NPDES Compliance

Dischargers will not need to modify existing permits to immediately incorporate new limits or requirements associated with the revised criteria at the time of EPA approval if that approval occurs during their permit cycle. However, at the time of permit renewal, permits will be evaluated and water quality-based effluent limitations (WQBELs) will be developed or revised in the renewed permit, if needed, to meet revised water quality criteria.

G.3. Methylmercury

In January 2001, EPA published a new water quality criterion for methylmercury that, for the first time, expresses a human health criterion as a concentration in fish and shellfish tissue rather than in the water. In 2004, the EQC adopted a tissue-based methylmercury criterion to replace its previous mercury water column criteria, but it was subsequently disapproved by EPA based on a fish consumption rate that was too low (i.e. 17.5 g/day). DEQ's final proposed rules includes a revised methylmercury fish tissue criterion based on a fish consumption rate of 175 g/day. Because the adoption of tissue-based criteria can pose challenges in implementing the criteria, DEQ has begun exploring options for incorporating the new criteria into various DEQ programs. Generally, DEQ intends to develop implementation procedures similar to EPA's *Guidance for Implementing the January 2001 Methylmercury Criterion*.

G.3.1. NPDES Permitting

DEQ intends to develop implementation procedures based on EPA's *Guidance for Implementing the January 2001 Methylmercury Criterion*. A variety of situations exist throughout Oregon that are addressed in EPA's implementation guidance, including waterbodies with mercury TMDLs, waters listed as impaired without TMDLs, and other waters with insufficient methylmercury data. DEQ will use the options as described in EPA's guidance to develop additional detail regarding how DEQ will implement the new criterion in various circumstances, once adopted by the Environmental Quality Commission and approved by EPA.

G.3.1.2. TMDLs

DEQ intends to make use of EPA's guidance in developing TMDLs and notes that it is fairly flexible and provides DEQ with several options. However, the guidance is written to address waterbodies that are dominated by direct air deposition of mercury, as found in the mid-west and east coast states. In contrast, Oregon is not dominated by direct air deposition of mercury.

In addition to EPA's Guidance, DEQ may also utilize EPA Region 10's Mercury Reduction Strategy in implementing a methylmercury criterion of which DEQ was a key stakeholder in the development of this strategy. Additionally, implementation may include the results of Region 10's *"Development of a Monitoring Guide to Support Water-Resource Assessments for Mercury within EPA Region X"*. This work may help answer questions related to mercury methylation and bioaccumulation in fish tissue.

Oregon's methylmercury criterion implementation strategy from a TMDL perspective would:

- Utilize an environmentally relevant analytical approach that could be conducted on a seasonal basis and include general water and sediment quality parameters that are known to methylate mercury, which could allow for a spatially appropriate bioaccumulation factor to be calculated.
- Focus either on a regional or grouped (likely basin scale) spatial approach that would evaluate both mercury loading and methylmercury methylation.
- Spatially detailed models could be used that are dynamic for modeling fate and transport of both mercury and methylmercury, or a simplified regression model depending on the amount of data available for the analytical area.
- A linked model approach may be likely, especially in data rich areas such as the Willamette Basin. This method would include the use of EPA models: GBMM, WASP, and / or BASS
- Fish tissue could be monitored at a frequency of every 5 years at a minimum(DEQ is already developing a statewide baseline with the Toxics Monitoring Program).
- Relative source contribution analysis would include REMSAD air modeling from EPA for both far field (Asia) and near-field (in-basin sources) analysis.

Further discussion with EPA and DEQ staff in implementing the methylmercury criterion will occur following the commission's adoption of the rules.

G.4. Quantitation Limits

Approximately 48 percent of the proposed human health criteria have Quantification Limits (QLs) that are higher than the criterion. For that reason, pollutants may occur in Oregon's waterbodies at concentrations greater than the proposed criteria that cannot be measured given limitations in analytical methods. As a point of reference, approximately 40 percent of the currently effective criteria have QLs that are higher than the criterion. For permitting purposes, the QL becomes the compliance point for dischargers. Consequently, if the criterion for a particular pollutant becomes more stringent, but the QL remains higher than the criterion, there would be no effective change in the point of compliance until and unless analytical methods improve. Historically, the pace of change in laboratory methods has not been rapid. However, when methods do improve, there will likely be additional toxics impairment listings and more stringent water quality based effluent limits (WQBELs) for permit holders.

G.5. Effective Toxics Criteria Tables

DEQ is proposing a new Table 40 which will only contain criteria applicable to human health. Human health criteria will be deleted from Table 20, Table 33A, and Table 33B. These tables will remain a part of Oregon's water quality standards and only contain the aquatic life criteria. Once EPA takes action on the aquatic life criteria, DEQ will take action to combine the aquatic life criteria in Tables 20, 33A, and Table 33B into one table containing all of the aquatic life criteria.

Appendix A. Table 20 Redline/Strikethrough

TABLE 20

AQUATIC LIFE WATER QUALITY CRITERIA SUMMARY[1]

The concentration for each compound listed in Table 20 is a criterion not to be exceeded in waters of the state in order to protect aquatic life ~~and human health~~. All values are expressed as micrograms per liter (µg/L) except where noted. Compounds are listed in alphabetical order with the corresponding designations as to whether EPA has identified it as a priority pollutant and a carcinogen, aquatic life freshwater acute and chronic criteria, and aquatic life marine acute and chronic criteria, ~~human health water & organism and fish consumption only criteria, and Drinking Water Maximum Contaminant Level (MCL)~~. The acute criteria refer to the average concentration for one (1) hour and the chronic criteria refer to the average concentration for 96 hours (4 days), and that these criteria should not be exceeded more than once every three (3) years.

			Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
ACENAPTHENE	Y	~~N~~							
ACROLEIN	Y	~~N~~					~~320ug~~	~~780ug~~	

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
ACRYLONITRILE	Y	~~Y~~					~~0.058ug**~~	~~0.65ug**~~	
ALDRIN	Y	~~Y~~	3		1.3		~~0.074ng**~~	~~0.079ng**~~	
ALKALINITY	N	~~N~~		20,000					
AMMONIA	N	~~N~~	CRITERIA ARE pH AND TEMPERATURE DEPENDENT—SEE DOCUMENT USEPA JANUARY 1985 (Fresh Water) CRITERIA ARE pH AND TEMPERATURE DEPENDENT—SEE DOCUMENT USEPA APRIL 1989 (Marine Water)						
ANTIMONY	Y	~~N~~					~~146ug~~	~~45,000ug~~	
ARSENIC	Y	~~Y~~					~~2.2ng**~~	~~17.5ng**~~	~~0.05mg~~
ARSENIC (PENT)	Y	~~Y~~							
ARSENIC (TRI)	Y	~~Y~~	360	190	69	36			
ASBESTOS	Y	~~Y~~					~~30K f/L**~~		
BARIUM	N	~~N~~					~~1mg~~		~~1.0mg~~
BENZENE	Y	~~Y~~					~~0.66ug**~~	~~40 ug**~~	
BENZIDINE	Y	~~Y~~					~~0.12ng~~	~~0.53ng**~~	
BERYLLIUM	Y	~~Y~~					~~6.8ng**~~	~~117ng**~~	
BHC	Y	~~N~~							

			Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
Compound Name (or Class)	**Priority Pollutant**	~~**Carcinogen**~~	**Fresh Acute Criteria**	**Fresh Chronic Criteria**	**Marine Acute Criteria**	**Marine Chronic Criteria**	~~**Water and Fish Ingestion**~~	~~**Fish Consumption Only**~~	~~**Drinking Water M.C.L.**~~
CADMIUM	Y	~~N~~	3.9+	1.1+	43	9.3	~~10ug~~		~~0.010mg~~
CARBON TETRACHLORIDE	Y	~~Y~~					~~0.4ug**~~	~~6.94ug**~~	
CHLORDANE	Y	~~Y~~	2.4	0.0043	0.09	0.004	~~0.46ng**~~	~~0.48ng**~~	
CHLORIDE	N	~~N~~	860 mg/L	230 mg/L					
CHLORINATED BENZENES	Y	~~Y~~					~~488 ug~~		
CHLORINATED NAPHTHALENES	Y	~~N~~							
CHLORINE	N	~~N~~	19	11	13	7.5			
CHLOROALKYL ETHERS	Y	~~N~~							
CHLOROETHYL ETHER (BIS-2)	Y	~~Y~~					~~0.03 ug~~	~~1.36 ug**~~	
CHLOROFORM	Y	~~Y~~					~~0.19ug**~~	~~15.7ug**~~	
CHLOROISOPROPYL ETHER (BIS-2)	Y	~~N~~					~~34.7ug~~	~~4.36mg~~	
CHLOROMETHYL ETHER (BIS)	N	~~Y~~					~~0.00000376ng**~~	~~0.00184ug**~~	
CHLOROPHENOL 2	Y	~~N~~							
CHLOROPHENOL 4	N	~~N~~							

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
CHLOROPHENOXY HERBICIDES (2,4,5,-TP)	N	~~N~~					~~10ug~~		
CHLOROPHENOXY HERBICIDES (2,4-D)	N	~~N~~					~~100ug~~		
CHLORPYRIFOS	N	~~N~~	0.083	0.041	0.011	0.0056			
CHLORO-4 METHYL-3 PHENOL	N	~~N~~							
CHROMIUM (HEX)	Y	~~N~~	16	11	1,100	50	~~50ug~~		~~0.05mg~~
CHROMIUM (TRI)	N	~~N~~	1,700.+	210.+			~~170mg~~	~~3,433mg~~	~~0.05mg~~
COPPER	Y	~~N~~	18.+	12.+	2.9	2.9			
CYANIDE	Y	~~N~~	22	5.2	1	1	~~200ug~~		
DDT	Y	~~Y~~	1.1	0.001	0.13	0.001	~~0.024ng**~~	~~0.024ng**~~	
(TDE) DDT METABOLITE	Y	~~Y~~							
(DDE) DDT METABOLITE	Y	~~Y~~							
DEMETON	Y	~~N~~		0.1		0.1			
DIBUTYLPHTHALATE	Y	~~N~~					~~35mg~~	~~154mg~~	

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
DICHLOROBENZENES	Y	~~N~~					~~400ug~~	~~2.6mg~~	
DICHLOROBENZIDINE	Y	~~Y~~					~~0.01ug**~~	~~0.020ug**~~	
DICHLOROETHANE 1,2	Y	~~Y~~					~~0.94ug**~~	~~243ug**~~	
DICHLOROETHYLENES	Y	~~Y~~					~~0.033ug**~~	~~1.85ug**~~	
DICHLOROPHENOL 2,4	N	~~N~~					~~3.09mg~~		
DICHLOROPROPANE	Y	~~N~~							
DICHLOROPROPENE	Y	~~N~~					~~87ug~~	~~14.1mg~~	
DIELDRIN	Y	~~Y~~	2.5	0.0019	0.71	0.0019	~~0.071ng**~~	~~0.076ng**~~	
DIETHYLPHTHALATE	Y	~~N~~					~~350mg~~	~~1.8g~~	
DIMETHYL PHENOL 2,4	Y	~~N~~							
DIMETHYL PHTHALATE	Y	~~N~~					~~313mg~~	~~2.9g~~	
DINITROTOLUENE 2,4	N	~~Y~~					~~0.11ug**~~	~~9.1ug**~~	
DINITROTOLUENE	Y	~~N~~					~~70ug~~	~~14.3mg~~	
DINITROTOLUENE	N	~~Y~~							
DINITRO-O-CRESOL 2,4	Y	~~N~~					~~13.4~~	~~765ug~~	
DIOXIN (2,3,7,8-TCDD)	Y	~~Y~~					~~0.000013ng**~~	~~0.000014ng**~~	

			Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
Compound Name (or Class)	**Priority Pollutant**	~~**Carcinogen**~~	**Fresh Acute Criteria**	**Fresh Chronic Criteria**	**Marine Acute Criteria**	**Marine Chronic Criteria**	~~**Water and Fish Ingestion**~~	~~**Fish Consumption Only**~~	~~**Drinking Water M.C.L.**~~
DIPHENYLHYDRAZINE	Y	~~N~~					~~42ng**~~	~~0.56ug**~~	
DIPHENYLHYDRAZINE 1,2	Y	~~N~~							
DI-2-ETHYLHEXYL PHTHALATE	Y	~~N~~					~~15mg~~	~~50mg~~	
ENDOSULFAN	Y	~~N~~	0.22	0.056	0.034	0.0087	~~74ug~~	~~159ug~~	
ENDRIN	Y	~~N~~	0.18	0.0023	0.037	0.0023	~~1ug~~		~~0.0002mg~~
ETHYLBENZENE	Y	~~N~~					~~1.4mg~~	~~3.28mg~~	
FLUORANTHENE	Y	~~N~~					~~42ug~~	~~54ug~~	
GUTHION	N	~~N~~		0.01		0.01			
HALOETHERS	Y	~~N~~							
HALOMETHANES	Y	~~Y~~					~~0.19ug**~~	~~15.7ug**~~	
HEPTACHLOR	Y	~~Y~~	0.52	0.0038	0.053	0.0036	~~0.28ng**~~	~~0.29ng**~~	
HEXACHLOROETHANE	N	~~Y~~					~~1.9ug~~	~~8.74ug~~	
HEXACHLOROBENZENE	Y	~~N~~					~~0.72ng**~~	~~0.74ng**~~	
HEXACHLOROBUTADIENE	Y	~~Y~~					~~0.45ug**~~	~~50ug**~~	
HEXACHLOROCYCLOHEXANE (LINDANE)	Y	~~Y~~	2	0.08	0.16				~~0.004mg~~

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life: Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Concentration in Units Per Liter for Protection of Human Health~~: ~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
HEXACHLOROCYCLOHEXANE-ALPHA	Y	~~Y~~					~~9.2ng**~~	~~31ng**~~	
HEXACHLOROCYCLOHEXANE-BETA	Y	~~Y~~					~~16.3ng**~~	~~54.7ng**~~	
HEXACHLOROCYCLOHEXANE-GAMA	Y	~~Y~~					~~18.6ng**~~	~~62.5ng**~~	
HEXACHLOROCYCLOHEXANE-TECHNICAL	Y	~~Y~~					~~12.3ng**~~	~~41.4ng**~~	
HEXACHLOROCYCLOPENTADIENE	Y	~~N~~					~~206ug~~		
IRON	N	~~N~~		1,000			~~0.3mg~~		
ISOPHORONE	Y	~~N~~					~~5.2mg~~	~~520mg~~	
LEAD	Y	~~N~~	82.+	3.2+	140	5.6	~~50ug~~		~~0.05mg~~
MALATHION	N	~~N~~		0.1		0.1			
MANGANESE	N	~~N~~					~~50ug~~	~~100ug~~	
MERCURY	Y	~~N~~	2.4	0.012	2.1	0.025	~~144ng~~	~~146ng~~	~~0.002mg~~
METHOXYCHLOR	N	~~N~~		0.03		0.03	~~100ug~~		~~0.1mg~~
MIREX	N	~~N~~		0.001		0.001			
MONOCHLOROBENZENE	Y	~~N~~					~~488ug~~		
NAPHTHALENE	Y	~~N~~							

			Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
NICKEL	Y	~~N~~	1,400.+	160+	75	8.3	~~13.4ug~~	~~100ug~~	
NITRATES	N	~~N~~					~~10mg~~		~~10mg~~
NITROBENZENE	Y	~~N~~					~~19.8mg~~		
NITROPHENOLS	Y	~~N~~							
NITROSAMINES	Y	~~Y~~					~~0.8ng**~~	~~1,240ng**~~	
NITROSODIBUTYLAMINE N	Y	~~Y~~					~~6.4ng**~~	~~587ng**~~	
NITROSODIETHYLAMINE N	Y	~~Y~~					~~0.8ng**~~	~~1,240ng**~~	
NITROSODIMETHYLAMINE N	Y	~~Y~~					~~1.4ng**~~	~~16,000ng**~~	
NITROSODIPHENYLAMINE N	Y	~~Y~~					~~4,900ng**~~	~~16,100ng**~~	
NITROSOPYRROLIDINE N	Y	~~Y~~					~~16ng**~~	~~91,900ng**~~	
PARATHION	N	~~N~~	0.065	0.013					
PCB's	Y	~~Y~~	2	0.014	10	0.03	~~0.079ng**~~	~~0.079ng**~~	
PENTACHLORINATED ETHANES	N	~~N~~							
PENTACHLOROBENZENE	N	~~N~~					~~74ug~~	~~85ug~~	
PENTACHLOROPHENOL	Y	~~N~~	***20	***13	13		~~1.01mg~~		

			Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
Compound Name (or Class)	**Priority Pollutant**	~~**Carcinogen**~~	**Fresh Acute Criteria**	**Fresh Chronic Criteria**	**Marine Acute Criteria**	**Marine Chronic Criteria**	~~**Water and Fish Ingestion**~~	~~**Fish Consumption Only**~~	~~**Drinking Water M.C.L.**~~
PHENOL	Y	~~N~~					~~3.5mg~~		
PHOSPHORUS ELEMENTAL	N	~~N~~				0.1			
PHTHALATE ESTERS	Y	~~N~~							
POLYNUCLEAR AROMATIC HYDROCARBONS	Y	~~Y~~					~~2.8ng**~~	~~31.1ng**~~	
SELENIUM	Y	~~N~~	260	35	410	54	~~10ug~~		~~0.01mg~~
SILVER	Y	~~N~~	4.1+	0.12	2.3		~~50ug~~		~~0.05mg~~
SULFIDE HYDROGEN SULFIDE	N	~~N~~		2		2			
TETRACHLORINATED ETHANES	Y	~~N~~							
TETRACHLOROBENZENE 1,2,4,5	Y	~~N~~					~~38ug~~	~~48ug~~	
TETRACHLOROETHANE 1,1,2,2	Y	~~Y~~					~~0.17ug**~~	~~10.7ug**~~	
TETRACHLOROETHANES	Y	~~N~~							
TETRACHLOROETHYLENE	Y	~~Y~~					~~0.8ug**~~	~~8.85ug**~~	
TETRACHLOROPHENOL 2,3,5,6	Y	~~N~~							
THALLIUM	Y	~~N~~					~~13ug~~	~~48ug~~	
TOLUENE	Y	~~N~~					~~14.3mg~~	~~424mg~~	

Compound Name (or Class)	Priority Pollutant	~~Carcinogen~~	Concentration in Micrograms Per Liter for Protection of Aquatic Life				~~Concentration in Units Per Liter for Protection of Human Health~~		
			Fresh Acute Criteria	Fresh Chronic Criteria	Marine Acute Criteria	Marine Chronic Criteria	~~Water and Fish Ingestion~~	~~Fish Consumption Only~~	~~Drinking Water M.C.L.~~
TOXAPHENE	Y	~~Y~~	0.73	0.0002	0.21	0.0002	~~0.71ng**~~	~~0.73ng**~~	~~0.005mg~~
TRICHLORINATED EtHANES	Y	~~Y~~							
TRICHLOROETHANE 1,1,1	Y	~~N~~					~~18.4mg~~	~~1.03g~~	
TRICHLOROETHANE 1,1,2	Y	~~Y~~					~~0.6ug**~~	~~41.8ug**~~	
TRICHLOROETHYLENE	Y	~~Y~~					~~2.7ug**~~	~~80.7ug**~~	
TRICHLOROPHENOL 2,4,5	N	~~N~~					~~2,600ug~~		
TRICHLOROPHENOL 2,4,6	Y	~~Y~~					~~1.2ug**~~	~~3.6ug**~~	
VINYL CHLORIDE	Y	~~Y~~					~~2ug**~~	~~525ug**~~	
ZINC	Y	~~N~~	120+	110+	95	86			

MEANING OF SYMBOLS:

g = grams ~~M.C.L = Maximum Contaminant Level~~

mg = milligrams + = Hardness Dependent Criteria (100 mg/L used).

The freshwater criterion for this metal is expressed as a function of hardness (mg/L) in the water column. Criteria values for hardness may be calculated from the following formulae (CMC refers to Acute Criteria; CCC refers to Chronic Criteria):

CMC = $(\exp(m_A * [\ln(\text{hardness})] + b_A)) * CF$

CCC = $(\exp(m_C * [\ln(\text{hardness})] + b_C)) * CF$

Chemical	m_A	b_A	m_C	b_C
Cadmium	1.128	-3.828	0.7852	-3.49
Chromium III	0.819	3.688	0.819	1.561
Copper	0.9422	-1.464	0.8545	-1.465
Lead	1.273	-1.46	1.273	-4.705
Nickel	0.846	3.3612	0.846	1.1645
Silver	1.72	-6.52		
Zinc	0.8473	0.8604	0.8473	0.7614

ug = micrograms

* = Insufficient data to develop criteria; value presented is the L.O.E.L – Lower Observed Effect Level.

ng	=	nanograms	~~**~~	~~=~~	~~Human health criteria for carcinogens reported for three risk levels. Value presented is the 10-6 risk level, which means the probability of one concern case per million people at the stated concentration.~~
pg	=	picograms	***	=	pH Dependent Criteria (7.8 pH used).
f	=	fibers			
Y	=	Yes			
N	=	No			

1 = Values in Table 20 are applicable to all basins.

~~Water and Fish Ingestion~~

~~Values represent the maximum ambient water concentration for consumption of both contaminated water and fish or other aquatic organisms.~~

~~Fish Ingestion~~

~~Values represent the maximum ambient water concentrations for consumption of fish or other aquatic organisms~~

Appendix B. Table 33A Redline/Strikethrough

TABLE 33A

Note: The Environmental Quality Commission adopted the following criteria on May 20, 2004 to become effective February 15, 2005. However, EPA has not yet (as of June 2006) approved the criteria. Thus, Table 33A criteria may be used in NPDES permits, but not for the section 303(d) list of impaired waters.

AQUATIC LIFE WATER QUALITY CRITERIA SUMMARY[A]

The concentration for each compound listed in Table 33A is a criterion not to be exceeded in waters of the state in order to protect aquatic life~~ and human health~~. All values are expressed as micrograms per liter (µg/L) except where noted. Compounds are listed in alphabetical order with the corresponding EPA number (from National Recommended Water Quality Criteria: 2002, EPA-822-R-02-047), the Chemical Abstract Service (CAS) number, aquatic life freshwater acute and chronic criteria, aquatic life saltwater acute and chronic criteria~~, human health water & organism and organism only criteria~~, and Drinking Water Maximum Contaminant Level (MCL). The acute criteria refer to the average concentration for one (1) hour and the chronic criteria refer to the average concentration for 96 hours (4 days), and that these criteria should not be exceeded more than once every three (3) years.

					Freshwater				Saltwater				~~Human Health For Consumption of:~~				
EPA NO.	Compound			CAS Number	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	~~Water + Organism B~~	~~Effective~~	~~Organism only B~~	~~Effective~~	~~Drinking Water M.C.L.~~
56	Acenaphthene			83329									~~670~~		~~990~~		
57	Acenaphthylene			208968													

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of:~~ ~~Water + Organism[B]~~	~~Effective~~	~~Organism only[B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
17	Acrolein			107028									~~190~~		~~290~~		
18	Acrylonitrile			107131									~~0.051~~		~~0.250~~		
102	Aldrin			309002	3 O	X			1.3 O	X			~~0.000049~~		~~0.000050~~		
1 N	Alkalinity						20,000 P										
2 N	Aluminum (pH 6.5 - 9.0)			7429905													
3 N	Ammonia			7664417					D	X	D	X					
58	Anthracene			120127									~~8300~~		~~40000~~		
1	Antimony			7440360									~~5.6~~		~~640~~		
2	Arsenic			7440382													~~0.05mg~~
15	Asbestos			1332214													

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	~~Water + Organism B~~	~~Effective~~	~~Organism only B~~	~~Effective~~	~~Drinking Water M.C.L.~~
6 N	Barium			7440393									~~1000~~				~~1.0mg~~
19	Benzene			71432													
59	Benzidine			92875									~~0.000086~~		~~0.00020~~		
60	Benzo(a)Anthracene			56553									~~0.0038~~		~~0.018~~		
61	Benzo(a)Pyrene			50328									~~0.0038~~		~~0.018~~		
62	Benzo(b)Fluoranthene			205992									~~0.0038~~		~~0.018~~		
63	Benzo(g,h,i)Perylene			191242													
64	Benzo(k)Fluoranthene			207089									~~0.0038~~		~~0.018~~		
3	Beryllium			7440417													
103	BHC alpha-			319846									~~0.0026~~		~~0.0049~~		
104	BHC beta-			319857									~~0.0091~~		~~0.017~~		
106	BHC delta-			319868													
105	BHC gamma- (Lindane)			58899	0.95		0.08	X	0.16 O								~~0.004mg~~
7 N	Boron			7440428													

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of: Water + Organism [8]~~	~~Effective~~	~~Organism only[8]~~	~~Effective~~	~~Drinking Water M.C.L.~~
20	Bromoform			75252									~~4.3~~		~~140~~		
69	Bromophenyl Phenyl Ether 4-																
70	Butylbenzyl Phthalate			85687									~~1500~~		~~1900~~		
4	Cadmium			7440439													~~0.010mg~~
21	Carbon Tetrachloride			56235									~~0.23~~		~~1.6~~		
107	Chlordane			57749	2.4 O	X	0.0043 O	X	0.09 O	X	0.004 O	X					
8 N	Chloride			16887006	860000		230000										
9 N	Chlorine			7782505	19	X	11	X	13	X	7.5	X					
22	Chlorobenzene			108907									~~130~~		~~1600~~		
23	Chlorodibromomethane			124481									~~0.40~~		~~13~~		
24	Chloroethane			75003													

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective	~~Water + Organism B~~	~~Effective~~	~~Organism only B~~	~~Effective~~	~~Drinking Water M.C.L.~~
65	ChloroethoxyMethane Bis2-			111911													
66	ChloroethylEther Bis2-			111444									~~0.030~~		~~0.53~~		
25	Chloroethylvinyl Ether 2-			110758													
26	Chloroform			67663													
67	ChloroisopropylEther Bis2-			108601													
15 N	ChloromethylEther, Bis			542881											~~0.00029~~		
71	Chloronaphthalene 2-			91587									~~1000~~		~~1600~~		
45	Chlorophenol 2-			95578									~~81~~		~~150~~		
10 N	Chlorophenoxy Herbicide (2,4,5,-TP)			93721									~~10 H~~				
11 N	Chlorophenoxy Herbicide (2,4-D)			94757									~~100 H~~				
72	Chlorophenyl Phenyl Ether 4-			7005723													
12 N	Chloropyrifos			2921882	0.083	X	0.041	X	0.011	X	0.0056	X					

					Freshwater				Saltwater				~~Human Health For Consumption of:~~				
EPA NO.	Compound			CAS Number	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	~~Water + Organism~~ [B]	~~Effective~~	~~Organism only~~ [B]	~~Effective~~	~~Drinking Water M.C.L.~~
																	~~0.05mg~~
5a	Chromium (III)																~~0.05mg~~
5b	Chromium (VI)			18540299													~~0.05mg~~
73	Chrysene			218019									~~0.0038~~		~~0.018~~		
6	Copper			7440508									~~1300 H~~				
14	Cyanide			57125	22 S	X	5.2 S	X	1 S	X	1 S	X	~~140~~		~~140~~		
108	DDT 4,4'-			50293	1.1 O,T	X	0.001 O,T	X	0.13 O,T	X	0.001 O,T	X					
109	DDE 4,4'-			72559									~~0.00022~~		~~0.00022~~		
110	DDD 4,4'-			72548									~~0.00031~~		~~0.00031~~		
14 N	Demeton			8065483			0.1	X			0.1	X					
74	Dibenzo(a,h)Anthracene			53703									~~0.0038~~		~~0.018~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	~~Water + Organism [B]~~	~~Effective~~	~~Organism only[B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
75	Dichlorobenzene 1,2-			95501									~~420~~		~~1300~~		
76	Dichlorobenzene 1,3-			541731									~~320~~		~~960~~		
77	Dichlorobenzene 1,4-			106467									~~63~~		~~190~~		
78	Dichlorobenzidine 3,3'-			91941									~~0.021~~		~~0.028~~		
27	Dichlorobromomethane			75274									~~0.55~~		~~17~~		
28	Dichloroethane 1,1-			75343													
29	Dichloroethane 1,2-			107062									~~0.38~~		~~37~~		
30	Dichloroethylene 1,1-			75354									~~330~~		~~7100~~		
46	Dichlorophenol 2,4-			120832									~~77~~		~~290~~		
31	Dichloropropane 1,2-			78875									~~0.50~~		~~15~~		
32	Dichloropropene 1,3-			542756									~~0.34~~		~~21~~		
111	Dieldrin			60571	0.24				0.71 O	X	0.0019 O	X	~~0.000052~~		~~0.000054~~		
79	DiethylPhthalate			84662									~~17000~~		~~44000~~		
47	Dimethylphenol 2,4-			105679									~~380~~		~~850~~		

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of:~~ ~~Water + Organism B~~	~~Effective~~	~~Organism only B~~	~~Effective~~	~~Drinking Water M.C.L.~~
80	DimethylPhthalate			131113									~~270000~~		~~1100000~~		
81	Di-n-Butyl Phthalate			84742									~~2000~~		~~4500~~		
49	Dinitrophenol 2,4-			51285									~~69~~		~~5300~~		
27 N	Dinitrophenols			25550587									~~69~~		~~5300~~		
82	Dinitrotoluene 2,4-			121142									~~0.11~~		~~3.4~~		
83	Dinitrotoluene 2,6-			606202													
84	Di-n-Octyl Phthalate			117840													
16	Dioxin (2,3,7,8-TCDD)			1746016									~~5.0E-09~~		~~5.1E-09~~		
85	Diphenylhydrazine 1,2-			122667									~~0.036~~		~~0.20~~		
68	EthylhexylPhthalate Bis2-			117817									~~1.2~~		~~2.2~~		

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Freshwater Effective Date	Freshwater Chronic (CCC)	Freshwater Effective Date	Saltwater Acute (CMC)	Saltwater Effective Date	Saltwater Chronic (CCC)	Saltwater Effective Date	~~Human Health For Consumption of: Water + Organism [8]~~	~~Effective~~	~~Organism only [8]~~	~~Effective~~	~~Drinking Water M.C.L.~~
	Endosulfan				0.22 I,P	X	0.056 I,P	X	0.034 I,P	X	0.0087 I,P	X	~~62 I~~		~~89 I~~		
112	Endosulfan alpha-			959988	0.22 O		0.056 O		0.034 O		0.0087 O		~~62~~		~~89~~		
113	Endosulfan beta-			33213659	0.22 O		0.056 O		0.034 O		0.0087 O		~~62~~		~~89~~		
114	Endosulfan Sulfate			1031078									~~62~~		~~89~~		
115	Endrin			72208	0.086				0.037 O		0.0023 O		~~0.059~~		~~0.060~~		~~0.0002 mg~~
116	Endrin Aldehyde			7421934									~~0.29~~		~~0.30~~		
33	Ethylbenzene			100414									~~530~~		~~2100~~		
86	Fluoranthene			206440													
87	Fluorene			86737									~~1100~~		~~5300~~		
17 N	Guthion			86500			0.01	X			0.01	X					

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EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of: Water + Organism [B]~~	~~Effective~~	~~Organism only [B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
117	Heptachlor			76448	0.52 O	X	0.0038 O	X	0.053 O	X	0.0036 O	X	~~0.000079~~		~~0.000079~~		
118	Heptachlor Epoxide			1024573	0.52 O		0.0038 O		0.053 O		0.0036 O		~~0.000039~~		~~0.000039~~		
88	Hexachlorobenzene			118741									~~0.00028~~		~~0.00029~~		
89	Hexachlorobutadiene			87683									~~0.44~~		~~18~~		
91	Hexachloroethane			67721									~~1.4~~		~~3.3~~		
19 N	Hexachlorocyclo-hexane-Technical			319868									~~0.0123 J~~		~~0.0414 J~~		
90	Hexachlorocyclopentadiene			77474									~~40~~		~~1100~~		
92	Ideno1,2,3-(cd)Pyrene			193395									~~0.0038~~		~~0.018~~		

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of: Water + Organism~~ [B]	~~Effective~~	~~Organism only~~ [B]	~~Effective~~	~~Drinking Water M.C.L.~~
20 N	Iron			7439896			1,000	X									
93	Isophorone			78591									~~35~~		~~960~~		
7	Lead			7439921													~~0.05mg~~
21 N	Malathion			121755			0.1	X			0.1	X					
22 N	Manganese			7439965													
8a	Mercury			7439976	2.4	X	0.012	X	2.1	X	0.025	X					~~0.002mg~~
23 N	Methoxychlor			72435			0.03	X			0.03	X	~~100 J~~				~~0.1mg~~
34	Methyl Bromide			74839									~~47~~		~~1500~~		
35	Methyl Chloride			74873													
48	Methyl-4,6-Dinitrophenol 2-			534521									~~13~~		~~280~~		
52	Methyl-4-Chlorophenol 3-			59507													
36	Methylene Chloride			75092									~~4.6~~		~~590~~		
8b	Methylmercury			22967926											~~300ug/kg L~~		

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of:~~ ~~Water + Organism B~~	~~Effective~~	~~Organism only B~~	~~Effective~~	~~Drinking Water M.C.L.~~
24 N	Mirex			2385855			0.001	X			0.001	X					
94	Naphthalene			91203													
9	Nickel			7440020													
25 N	Nitrates			14797558									~~10000 J~~				~~10mg~~
95	Nitrobenzene			98953									~~17~~		~~690~~		
50	Nitrophenol 2-			88755													
51	Nitrophenol 4-			100027													
26 N	Nitrosamines			35576911									~~0.0008 J~~		~~1.24 J~~		
28 N	Nitrosodibutylamine,N			924163									~~0.0063~~		~~0.22~~		
29 N	Nitrosodiethylamine,N			55185									~~0.0008 J~~		~~1.24 J~~		
96	N-Nitrosodimethylamine			62759									~~0.00069~~		~~3.0~~		

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Freshwater Effective Date	Freshwater Chronic (CCC)	Freshwater Effective Date	Saltwater Acute (CMC)	Saltwater Effective Date	Saltwater Chronic (CCC)	Saltwater Effective Date	~~Human Health For Consumption of:~~ ~~Water + Organism[B]~~	~~Effective~~	~~Organism only[B]~~	~~Effective~~	~~Drinking Water M.C.L.~~
98	N-Nitrosodiphenylamine			86306									~~3.3~~		~~6.0~~		
30 N	Nitrosopyrrolidine,N			930552									~~0.016~~		~~34~~		
97	N-Nitrosodi-n-Propylamine			621647									~~0.0050~~		~~0.51~~		
32 N	Oxygen, Dissolved			7782447													
33 N	Parathion			56382	0.065	X	0.013	X									
119	Polychlorinated Biphenyls PCBs:			1336363	2 U	X	0.014 U	X	10 U	X	0.03 U	X	~~0.000064 U~~		~~0.000064 U~~		
34 N	Pentachlorobenzene			608935									~~1.4~~		~~1.5~~		
53	Pentachlorophenol			87865	M				13		7.9		~~0.27~~		~~3.0~~		
99	Phenanthrene			85018													
54	Phenol			108952											~~1700000~~		
36 N	Phosphorus Elemental			7723140							0.1						

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of: Water + Organism~~ [B]	~~Effective~~	~~Organism only~~ [B]	~~Effective~~	~~Drinking Water M.C.L.~~
100	Pyrene			129000									~~830~~		~~4000~~		
10	Selenium			7782492											~~4200~~		~~0.01mg~~
11	Silver			7440224													~~0.05mg~~
40 N	Sulfide-Hydrogen Sulfide			7783064			2	X			2	X					
43 N	Tetrachlorobenzene,1,2,4,5			95943									~~0.97~~		~~1.1~~		
37	Tetrachloroethane 1,1,2,2-			79345									~~0.17~~		~~4.0~~		
38	Tetrachloroethylene			127184									~~0.69~~		~~3.3~~		
12	Thallium			7440280									~~0.24~~		~~0.47~~		
39	Toluene			108883									~~1300~~		~~15000~~		

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	~~Water + Organism~~ [8]	~~Effective~~	~~Organism only~~[8]	~~Effective~~	~~Drinking Water M.C.L.~~
120	Toxaphene			8001352	0.73	X	0.0002	X	0.21	X	0.0002	X	~~0.00028~~		~~0.00028~~		~~0.005mg~~
40	Trans-Dichloroethylene 1,2-			156605									~~140~~		~~10000~~		
44 N	Tributyltin (TBT)			688733													
101	Trichlorobenzene 1,2,4-			120821									~~35~~		~~70~~		
41	Trichloroethane 1,1,1-			71556													
42	Trichloroethane 1,1,2-			79005									~~0.59~~		~~16~~		
43	Trichloroethylene			79016									~~2.5~~		~~30~~		
45 N	Trichlorophenol 2,4,5			95954									~~1800~~		~~3600~~		
55	Trichlorophenol 2,4,6-			88062											~~2.4~~		
44	Vinyl Chloride			75014									~~0.025~~		~~2.4~~		
13	Zinc			7440666									~~7400~~		~~26000~~		

Footnotes for Tables 33A and 33B:

A Values in Table 20 are applicable to all basins.

~~B Human Health criteria values were calculated using a fish consumption rate of 17.5 grams per day (0.6 ounces/day) unless otherwise noted.~~

C Ammonia criteria for freshwater may depend on pH, temperature, and the presence of salmonids or other fish with ammonia-sensitive early life stages. Values for freshwater criteria (of total ammonia nitrogen in mg N/L) can be calculated using the formulae specified in *1999 Update of Ambient Water Quality Criteria for Ammonia* (EPA-822-R-99-014; http://www.epa.gov/ost/standards/ammonia/99update.pdf):

Freshwater Acute:

salmonids present….CMC = $\frac{0.275}{1+10^{7.204-pH}}+\frac{39.0}{1+10^{pH-7.204}}$

salmonids not present…CMC= $\frac{0.411}{1+10^{7.204-pH}}+\frac{58.4}{1+10^{pH-7.204}}$

Freshwater Chronic:

fish early life stages present

$$CCC = \left(\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}\right) * MIN(2.85, 1.45*10^{0.028*(25-T)})$$

fish early life stages not present

$$CCC = \left(\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}\right) * 1.45*10^{0.028*(25-MAX(T,7))}$$

Note: these chronic criteria formulae would be applied to calculate the 30-day average concentration limit; in addition, the highest 4-day average within the 30-day period should not exceed 2.5 times the CCC.

D Ammonia criteria for saltwater may depend on pH and temperature. Values for saltwater criteria (total ammonia) can be calculated from the tables specified in *Ambient Water Quality Criteria for Ammonia (Saltwater)--1989* (EPA 440/5-88-004; http://www.epa.gov/ost/pc/ambientwqc/ammoniasalt1989.pdf).

E Freshwater and saltwater criteria for metals are expressed in terms of "dissolved" concentrations in the water column, except where otherwise noted (e.g. aluminum).

F The freshwater criterion for this metal is expressed as a function of hardness (mg/L) in the water column. Criteria values for hardness may be calculated from the following formulae (CMC refers to Acute Criteria; CCC refers to Chronic Criteria):

$$CMC = (\exp(m_A*[\ln(hardness)] + b_A))*CF$$

$$CCC = (\exp(m_C*[\ln(hardness)] + b_C))*CF$$

where CF is the conversion factor used for converting a metal criterion expressed as the total recoverable fraction in the water column to a criterion expressed as the dissolved fraction in the water column.

Chemical	m_A	b_A	m_C	b_C
Cadmium	1.0166	-3.924	0.7409	-4.719
Chromium III	0.8190	3.7256	0.8190	0.6848
Copper	0.9422	-1.700	0.8545	-1.702
Lead	1.273	-1.460	1.273	-4.705
Nickel	0.8460	2.255	0.8460	0.0584
Silver	1.72	-6.59		
Zinc	0.8473	0.884	0.8473	0.884

Conversion factors (CF) for dissolved metals (the values for total recoverable metals criteria were multiplied by the appropriate conversion factors shown below to calculate the dissolved metals criteria):

Chemical	Freshwater		Saltwater	
	Acute	Chronic	Acute	Chronic
Arsenic	1.000	1.000	1.000	1.000
Cadmium	1.136672-[(ln hardness)(0.041838)]	1.101672-[(ln hardness)(0.041838)]	0.994	0.994
Chromium III	0.316	0.860	--	--
Chromium VI	0.982	0.962	0.993	0.993
Copper	0.960	0.960	0.83	0.83
Lead	1.46203-[(ln hardness)(0.145712)]	1.46203-[(ln hardness)(0.145712)]	0.951	0.951
Nickel	0.998	0.997	0.990	0.990
Selenium	0.996	0.922	0.998	0.998
Silver	0.85	0.85	0.85	--
Zinc	0.978	0.986	0.946	0.946

~~G Human Health criterion is the same as originally published in the 1976 EPA Red Book (Quality Criteria for Water, EPA-440/9-76-023) which predates the 1980 methodology and did not use the fish ingestion BCF approach.~~

~~H This value is based on a Drinking Water regulation.~~

I This value is based on criterion published in Ambient Water Quality Criteria for Endosulfan (EPA 440/5-80-046) and should be applied as the sum of alpha- and beta-endosulfan.

~~J No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.~~

~~K Human Health criterion is for “dissolved” concentration based on the 1976 EPA Red Book conclusion that adverse effects from exposure at this level are aesthetic rather than toxic.~~

~~L This value is expressed as the fish tissue concentration of methylmercury.~~

M Freshwater aquatic life values for pentachlorophenol are expressed as a function of pH, and are calculated as follows: CMC=(exp(1.005(pH)-4.869); CCC=exp(1.005(pH)-5.134).

N This number was assigned to the list of non-priority pollutants in National Recommended Water Quality Criteria: 2002 (EPA-822-R-02-047).

O This criterion is based on EPA recommendations issued in 1980 that were derived using guidelines that differed from EPA's 1985 Guidelines for minimum data requirements and derivation procedures. For example, a "CMC" derived using the 1980 Guidelines was derived to be used as an instantaneous maximum. If assessment is to be done using an averaging period, the values given should be divided by 2 to obtain a value that is more comparable to a CMC derived using the 1985 Guidelines.

P Criterion shown is the minimum (i.e. CCC in water should not be below this value in order to protect aquatic life).

Q Criterion is applied as total arsenic (i.e. arsenic (III) + arsenic (V)).

R Arsenic criterion refers to the inorganic form only.

S This criterion is expressed as µg free cyanide (CN)/L.

T This criterion applies to DDT and its metabolites (i.e. the total concentration of DDT and its metabolites should not exceed this value).

U This criterion applies to total PCBs (e.g. the sum of all congener or all isomer or homolog or Arochlor analyses).

V The CMC=1/[(f1/CMC1)+(f2/CMC2)] where f1 and f2 are the fractions of total selenium that are treated as selenite and selenate, respectively, and CMC1 and CMC2 are 185.9 µg/L and 12.82 µg/L, respectively.

W The acute and chronic criteria for aluminum are 750 µg/L and 87 µg/L, respectively. These values for aluminum are expressed in terms of “total recoverable” concentration of metal in the water column. The criterion applies at pH<6.6 and hardness<12 mg/L (as $CaCO_3$).

X The effective date for the criterion in the column immediately to the left is 1991.

Y No criterion.

Appendix C. Table 33B Redline/Strikethrough

TABLE 33B

Note: The Environmental Quality Commission adopted the following criteria on May 20, 2004 to become effective on EPA approval. EPA has not yet (as of June 2006) approved these criteria. The Table 33B criteria may not be used until they are approved by EPA.

AQUATIC LIFE WATER QUALITY CRITERIA SUMMARY[A]

The concentration for each compound listed in Table 33A is a criterion not to be exceeded in waters of the state in order to protect aquatic life ~~and human health~~. All values are expressed as micrograms per liter (µg/L) except where noted. Compounds are listed in alphabetical order with the corresponding EPA number (from National Recommended Water Quality Criteria: 2002, EPA-822-R-02-047), the Chemical Abstract Service (CAS) number, aquatic life freshwater acute and chronic criteria, aquatic life saltwater acute and chronic criteria, ~~human health water & organism and organism only criteria~~, and Drinking Water Maximum Contaminant Level (MCL). The acute criteria refer to the average concentration for one (1) hour and the chronic criteria refer to the average concentration for 96 hours (4 days), and that these criteria should not be exceeded more than once every three (3) years.

					Freshwater				Saltwater				~~Human Health For Consumption of:~~				
EPA No.	Compound			CAS Number	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	~~Water + Organism B~~	~~Effective~~	~~Organism only B~~	~~Effective~~	
2 N	Aluminum (pH 6.5 - 9.0)			7429905	W		W										
3 N	Ammonia			7664417	C		C										
2	Arsenic			7440382									~~0.018 R~~		~~0.14 R~~		
15	Asbestos			1332214									~~7.0E+06 fibers/Liter~~				

EPA NO.	Compound			CAS Number	Freshwater				Saltwater				~~Human Health For Consumption of:~~				
					Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	Acute (CMC)	Effective Date	Chronic (CCC)	Effective Date	~~Water + Organism~~ [8]	~~Effective~~	~~Organism only~~ [8]	~~Effective~~	
19	Benzene			71432									~~2.2~~		~~51~~		
3	Beryllium			7440417									¥		¥		
105	BHC gamma- (Lindane)			58899									~~0.98~~		~~1.8~~		
4	Cadmium			7440439	E,F		E,F		40 E		8.8 E		¥				
107	Chlordane			57749									~~0.00080~~		~~0.00081~~		
	CHLORINATED BENZENES												¥		¥		
26	Chloroform			67663									~~5.7~~		~~470~~		
67	ChloroisopropylEther Bis2-			108601									~~1400~~		~~65000~~		
15N	ChloromethylEther, Bis			542881									~~0.00010~~				
5a	Chromium (III)				E,F		E,F						¥				
5b	Chromium (VI)			18540299	16 E		11 E						¥		¥		
6	Copper			7440508	E,F		E,F		4.8 E		3.1 E						
108	DDT 4,4'-			50293									~~0.00022~~		~~0.00022~~		
	DIBUTYLPHTHALATE												¥		¥		

00537

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of:~~ ~~Water + Organism B~~	~~Effective~~	~~Organism only B~~	~~Effective~~	
	DICHLOROBENZENES												¥		¥		
	DICHLOROBENZIDINE												¥		¥		
	DICHLOROETHYLENES												¥		¥		
	DICHLOROPROPENE												¥		¥		
111	Dieldrin			60571			0.056										
	DINITROTOLUENE												¥		¥		
	DIPHENYLHYDRAZINE												¥		¥		
115	Endrin			72208			0.036										
86	Fluoranthene			206440									~~130~~		~~140~~		
	HALOMETHANES												¥		¥		
20 N	Iron			7439896									~~300 K~~				
7	Lead			7439921	E,F		E,F		210 E		8.1 E		¥				
22 N	Manganese			7439965									~~50 K~~		~~100 K~~		
8a	Mercury			7439976									¥		¥		

EPA NO.	Compound			CAS Number	Freshwater Acute (CMC)	Effective Date	Freshwater Chronic (CCC)	Effective Date	Saltwater Acute (CMC)	Effective Date	Saltwater Chronic (CCC)	Effective Date	~~Human Health For Consumption of:~~ ~~Water + Organism B~~	~~Effective~~	~~Organism only B~~	~~Effective~~	
	MONOCHLOROBENZENE												¥		¥		
9	Nickel			7440020	E,F		E,F		74 E		8.2 E		~~610~~		~~4600~~		
53	Pentachlorophenol			87865			M										
54	Phenol			108952									~~21000~~				
	POLYNUCLEAR AROMATIC HYRDOCARBONS												¥		¥		
10	Selenium			7782492	E,V		5 E		290 E		71 E		~~170~~				
11	Silver			7440224	E,F,P		0.10 E		1.9 E,P				¥				
44 N	Tributyltin (TBT)			688733	0.46		0.063		0.37		0.01						
41	Trichloroethane 1,1,1-			71556									¥		¥		
55	Trichlorophenol 2,4,6-			88062									~~1.4~~				
13	Zinc			7440666	E,F		E,F		90 E		81 E						

Footnotes for Tables 33A and 33B:

A Values in Table 20 are applicable to all basins.

~~B Human Health criteria values were calculated using a fish consumption rate of 17.5 grams per day (0.6 ounces/day) unless otherwise noted.~~

C Ammonia criteria for freshwater may depend on pH, temperature, and the presence of salmonids or other fish with ammonia-sensitive early life stages. Values for freshwater criteria (of total ammonia nitrogen in mg N/L) can be calculated using the formulae specified in *1999 Update of Ambient Water Quality Criteria for Ammonia* (EPA-822-R-99-014; http://www.epa.gov/ost/standards/ammonia/99update.pdf):

Freshwater Acute:

salmonids present....CMC = $\frac{0.275}{1+10^{7.204-pH}}+\frac{39.0}{1+10^{pH-7.204}}$

salmonids not present...CMC= $\frac{0.411}{1+10^{7.204-pH}}+\frac{58.4}{1+10^{pH-7.204}}$

Freshwater Chronic:

fish early life stages present

$$\text{CCC} = \left(\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}\right) * MIN(2.85, 1.45*10^{0.028*(25-T)})$$

fish early life stages not present

$$\text{CCC} = \left(\frac{0.0577}{1+10^{7.688-pH}}+\frac{2.487}{1+10^{pH-7.688}}\right) * 1.45*10^{0.028*(25-MAX(T,7))}$$

Note: these chronic criteria formulae would be applied to calculate the 30-day average concentration limit; in addition, the highest 4-day average within the 30-day period should not exceed 2.5 times the CCC.

D Ammonia criteria for saltwater may depend on pH and temperature. Values for saltwater criteria (total ammonia) can be calculated from the tables specified in *Ambient Water Quality Criteria for Ammonia (Saltwater)--1989* (EPA 440/5-88-004; http://www.epa.gov/ost/pc/ambientwqc/ammoniasalt1989.pdf).

E Freshwater and saltwater criteria for metals are expressed in terms of "dissolved" concentrations in the water column, except where otherwise noted (e.g. aluminum).

F The freshwater criterion for this metal is expressed as a function of hardness (mg/L) in the water column. Criteria values for hardness may be calculated from the following formulae (CMC refers to Acute Criteria; CCC refers to Chronic Criteria):

$$CMC = (\exp(m_A*[\ln(\text{hardness})] + b_A))*CF$$

$$CCC = (\exp(m_C*[\ln(\text{hardness})] + b_C))*CF$$

where CF is the conversion factor used for converting a metal criterion expressed as the total recoverable fraction in the water column to a criterion expressed as the dissolved fraction in the water column.

Chemical	**m_A**	**b_A**	**m_C**	**b_C**
Cadmium	1.0166	-3.924	0.7409	-4.719
Chromium III	0.8190	3.7256	0.8190	0.6848
Copper	0.9422	-1.700	0.8545	-1.702
Lead	1.273	-1.460	1.273	-4.705
Nickel	0.8460	2.255	0.8460	0.0584
Silver	1.72	-6.59		
Zinc	0.8473	0.884	0.8473	0.884

Conversion factors (CF) for dissolved metals (the values for total recoverable metals criteria were multiplied by the appropriate conversion factors shown below to calculate the dissolved metals criteria):

Chemical	Freshwater		Saltwater	
	Acute	Chronic	Acute	Chronic
Arsenic	1.000	1.000	1.000	1.000
Cadmium	1.136672-[(ln hardness)(0.041838)]	1.101672-[(ln hardness)(0.041838)]	0.994	0.994
Chromium III	0.316	0.860	--	--
Chromium VI	0.982	0.962	0.993	0.993
Copper	0.960	0.960	0.83	0.83
Lead	1.46203-[(ln hardness)(0.145712)]	1.46203-[(ln hardness)(0.145712)]	0.951	0.951
Nickel	0.998	0.997	0.990	0.990
Selenium	0.996	0.922	0.998	0.998
Silver	0.85	0.85	0.85	--
Zinc	0.978	0.986	0.946	0.946

~~G Human Health criterion is the same as originally published in the 1976 EPA Red Book (Quality Criteria for Water, EPA-440/9-76-023) which predates the 1980 methodology and did not use the fish ingestion BCF approach.~~

~~H This value is based on a Drinking Water regulation.~~

I This value is based on criterion published in Ambient Water Quality Criteria for Endosulfan (EPA 440/5-80-046) and should be applied as the sum of alpha- and beta-endosulfan.

~~J No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.~~

~~K Human Health criterion is for "dissolved" concentration based on the 1976 EPA Red Book conclusion that adverse effects from exposure at this level are aesthetic rather than toxic.~~

~~L This value is expressed as the fish tissue concentration of methylmercury.~~

M Freshwater aquatic life values for pentachlorophenol are expressed as a function of pH, and are calculated as follows: CMC=(exp(1.005(pH)-4.869); CCC=exp(1.005(pH)-5.134).

N This number was assigned to the list of non-priority pollutants in National Recommended Water Quality Criteria: 2002 (EPA-822-R-02-047).

O This criterion is based on EPA recommendations issued in 1980 that were derived using guidelines that differed from EPA's 1985 Guidelines for minimum data requirements and derivation procedures. For example, a "CMC" derived using the 1980 Guidelines was derived to be used as an instantaneous maximum. If assessment is to be done using an averaging period, the values given should be divided by 2 to obtain a value that is more comparable to a CMC derived using the 1985 Guidelines.

P Criterion shown is the minimum (i.e. CCC in water should not be below this value in order to protect aquatic life).

Q Criterion is applied as total arsenic (i.e. arsenic (III) + arsenic (V)).

R Arsenic criterion refers to the inorganic form only.

S This criterion is expressed as µg free cyanide (CN)/L.

T This criterion applies to DDT and its metabolites (i.e. the total concentration of DDT and its metabolites should not exceed this value).

U This criterion applies to total PCBs (e.g. the sum of all congener or all isomer or homolog or Arochlor analyses).

V The CMC=1/[(f1/CMC1)+(f2/CMC2)] where f1 and f2 are the fractions of total selenium that are treated as selenite and selenate, respectively, and CMC1 and CMC2 are 185.9 µg/L and 12.82 µg/L, respectively.

W The acute and chronic criteria for aluminum are 750 µg/L and 87 µg/L, respectively. These values for aluminum are expressed in terms of "total recoverable" concentration of metal in the water column. The criterion applies at pH<6.6 and hardness<12 mg/L (as $CaCO_3$).

X The effective date for the criterion in the column immediately to the left is 1991.

Y No criterion.

Appendix D. Crosswalk Between Effective Human Health Criteria and Proposed Criteria

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
ACENAPTHENE	Y	N	--	--	95	99
ACROLEIN	Y	N	320	780	0.88	0.93
ACRYLONITRILE	Y	Y	0.058	0.65	0.018	0.025
ALDRIN	Y	Y	0.000074	0.000079	0.0000050	0.0000050
ANTHRACENE	N	N	--	--	2900	4000
ANTIMONY	Y	N	146	45,000	5.1	64
ARSENIC	Y	Y	2.1	2.1 (freshwater) 1.0 (saltwater)	2.1	2.1 (freshwater) 1.0 (saltwater)
ASBESTOS	Y	Y	7,000,000 fibers/L	--	7,000,000 fibers/L	--
BARIUM	N	N	1000	--	1000	--
BENZENE	N	Y	0.66	40	0.44	1.4
BENZIDINE	N	Y	0.00012	0.00053	0.000018	0.000020

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
BENZ(A) ANTHRACENE	N	Y	--	--	0.0013	0.0018
BENZO(A)PYRENE	N	Y	--	--	0.0013	0.0018
BENZO(B)FLUORANTHENE 3,4	N	Y	--	--	0.0013	0.0018
BENZO(K)FLUORANTHENE	N	Y	--	--	0.0013	0.0018
BROMOFORM	N	Y	--	--	3.3	14
BUTYLBENZYL PHTHALATE	N	N	--	--	190	190
CARBON TETRACHLORIDE	Y	Y	0.4	6.94	0.10	0.16
CHLORDANE	Y	Y	0.00046	0.00048	0.000081	0.000081
CHLORINATED BENZENES [CHLOROBENZENE]	Y	Y	488	--	74	160
CHLORODIBROMOMETHANE	N	Y	--	--	0.31	1.3
CHLOROETHYL ETHER (BIS-2)	Y	Y	0.03	1.36	0.020	0.05
CHLOROFORM	Y	Y	0.19	15.7	260	1100
CHLOROISOPROPYL ETHER (BIS-2)	Y	N	34.7	4360	1200	6500
CHLOROMETHYL ETHER (BIS)	N	Y	0.00000376	0.00184	0.000024	0.000029

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
CHLORONAPHTHALENE 2	N	N	--	--	150	160
CHLOROPHENOL 2	Y	N	--	--	14	15
CHLOROPHENOXY HERBICIDES (2,4,5,-TP)	N	N	10	--	10	--
CHLOROPHENOXY HERBICIDES (2,4-D)	N	N	100	--	100	--
CHRYSENE	N	Y	--	--	0.0013	0.0018
COPPER	Y	N	1300	--	1300	--
CYANIDE	Y	N	200	--	130	130
DDT [DDT 4,4']	Y	Y	0.000024	0.000024	0.000022	0.000022
DDD 4, 4'	Y	Y	--	--	0.000031	0.000031
DDE 4, 4'	Y	Y	--	--	0.000022	0.000022
DIBENZO(A,H)ANTHRACENE	N	Y	--	--	0.0013	0.0018
DIBUTYLPHTHALATE [DI-N-BUTYL PHTHALATE]	Y	N	35,000	154,000	400	450

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
DICHLOROBENZENES [DICHLOROBENZENE(O)1,2]	Y	N	400	2,600	110	130
DICHLOROBENZENE(P) 1,4	N	N	--	--	16	19
DICHLOROBENZIDINE [DICHLOROBENZIDINE 3,3']	Y	Y	0.01	0.020	0.0027	0.0028
DICHLOROBROMOMETHANE	N	Y	--	--	0.42	1.7
DICHLOROETHANE 1,2	Y	Y	0.94	243	0.35	3.7
DICHLOROETHYLENES [DICHLOROETHYLENE 1,1]	Y	Y	0.033	1.85	230	710
DICHLOROETHYLENE TRANS 1,2	N	N	--	--	120	1000
DICHLOROPHENOL 2,4	N	N	3,090	--	23	29
DICHLOROPROPANE [DICHLOROPROPANE 1,2]	Y	N	--	--	0.38	1.5
DICHLOROPROPENE [DICHLOROPROPENE 1,3]	Y	N	87	14,100	0.30	2.1
DIELDRIN	Y	Y	0.000071	0.000076	0.0000053	0.0000054

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
DIETHYLPHTHALATE	Y	N	350,000	1,800,000	3800	4400
DIMETHYL PHENOL 2,4	Y	N	--	--	76	85
DIMETHYL PHTHALATE	Y	N	313,000	2,900,000	84,000	110,000
DINITROPHENOL 2,4	Y	N	--	--	62	530
DINITROPHENOLS	Y	N	--	--	62	530
DINITROTOLUENE 2,4	N	Y	0.11	9.1	0.084	0.34
DINITROTOLUENE	Y	N	70	14,300	No criteria	No criteria
DINITRO-O-CRESOL 2,4	Y	N	13.4	765	No criteria	No criteria
DIOXIN (2,3,7,8-TCDD)	Y	Y	0.000000013	0.000000014	0.00000000051	0.00000000051
DIPHENYLHYDRAZINE	Y	N	0.042	0.56	No criteria	No criteria
DIPHENYLHYDRAZINE 1,2	Y	N	--	--	0.014	0.02
DI-2-ETHYLHEXYL PHTHALATE [BIS-2-ETHYLHEXYL PHTHALATE]	Y	N	15,000	50,000	0.20	0.22
ENDOSULFAN	Y	N	74	159	--	--
ENDOSULFAN ALPHA	Y	N	--	--	8.5	8.9

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
ENDOSULFAN BETA	Y	N	--	--	8.5	8.9
ENDOSULFAN SULFATE	Y	N	--	--	8.5	8.9
ENDRIN	Y	N	1	--	0.024	0.024
ENDRIN ALDEHYDE	Y	N	--	--	0.03	0.03
ETHYLBENZENE	Y	N	1,400	3,280	160	210
FLUORANTHENE	Y	N	42	54	14	14
FLUORENE	Y	N	--	--	390	530
HALOMETHANES	Y	Y	0.19	15.7	No criteria	No criteria
HEPTACHLOR	Y	Y	0.00028	0.00029	0.0000079	0.0000079
HEPTACHLOR EPOXIDE	Y	Y	--	--	0.0000039	0.0000039
HEXACHLOROETHANE	N	Y	1.9	8.74	0.29	0.33
HEXACHLOROBENZENE	Y	N	0.00072	0.00074	0.000029	0.000029
HEXACHLOROBUTADIENE	Y	Y	0.45	50	0.36	1.8

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
HEXACHLOROCYCLOHEXANE-ALPHA [BHC ALPHA]	Y	Y	0.0092	0.031	0.00045	0.00049
HEXACHLOROCYCLOHEXANE-BETA [BHC BETA]	Y	Y	0.0163	0.0547	0.0016	0.0017
HEXACHLOROCYCLOHEXANE-GAMA [BHC GAMMA (LINDANE)]	Y	Y	0.0186	0.0625	0.17	0.18
HEXACHLOROCYCLOHEXANE-TECHNICAL	Y	Y	0.0123	0.0414	0.0014	0.0015
HEXACHLOROCYCLOPENTADIENE	Y	N	206	--	30	110
INDENO(1,2,3-CD)PYRENE	Y	Y	--	--	0.0013	0.0018
ISOPHORONE	Y	N	5,200	520,000	27	96
MANGANESE	N	N	--	100	--	100
METHOXYCHLOR	N	N	100	--	100	--
METHYL BROMIDE	Y	N	--	--	37	150

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	**Priority Pollutant**	**Carcinogen**	**Concentration in Units Per Liter for Protection of Human Health CURRENT**		**Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40**	
			Water and Fish Ingestion (µg/L)	**Fish Consumption Only (µg/L)**	**Water and Fish Ingestion (µg/L)**	**Fish Consumption Only (µg/L)**
METHYL-4,6-DINITROPHENOL 2	Y	N	--	--	9.2	28
METHYLENE CHLORIDE	Y	Y	--	--	4.3	59
METHYLMERCURY (MG/KG)	Y	N	--	--	--	0.040
MONOCHLOROBENZENE	Y	N	488	--	No criteria	No criteria
NICKEL	Y	N	13.4	100	140	170
NITRATES	N	N	10,000	--	10,000	--
NITROBENZENE	Y	N	19,800	--	14	69
NITROSAMINES	Y	Y	0.0008	1.24	0.00079	0.046
NITROSODIBUTYLAMINE N	Y	Y	0.0064	0.587	0.0050	0.02
NITROSODIETHYLAMINE N	Y	Y	0.0008	1.24	0.00079	0.046
NITROSODIMETHYLAMINE N	Y	Y	0.0014	16	0.00068	0.30
NITROSODI-N-PROPYLAMINE, N	Y	Y	--	--	0.0046	0.051
NITROSODIPHENYLAMINE N	Y	Y	4.9	16.1	0.55	0.60
NITROSOPYRROLIDINE N	Y	Y	0.016	91.9	0.016	3.4

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
PCBS	Y	Y	0.000079	0.000079	0.0000064	0.0000064
PENTACHLOROBENZENE	N	N	74	85	0.15	0.15
PENTACHLOROPHENOL	Y	N	1,010	--	0.15	0.30
PHENOL	Y	N	3,500	--	9,400	86,000
POLYNUCLEAR AROMATIC HYDROCARBONS	Y	Y	0.0028	0.0311	No criteria	No criteria
PYRENE	Y	N	--	--	290	400
SELENIUM	Y	N	10	--	120	420
TETRACHLOROBENZENE 1,2,4,5	Y	N	38	48	0.11	0.11
TETRACHLOROETHANE 1,1,2,2	Y	Y	0.17	10.7	0.12	0.40
TETRACHLOROETHYLENE	Y	Y	0.8	8.85	0.24	0.33
THALLIUM	Y	N	13	48	0.043	0.047
TOLUENE	Y	N	14,300	424,000	720	1500
TOXAPHENE	Y	Y	0.00071	0.00073	0.000028	0.000028
TRICHLOROBENZENE 1,2,4	Y	N	--	--	6.4	7.0

Compound Name or Class [Table 40 Name, if different] *Criteria denoted in red indicate proposed additions to the human health criteria*	Priority Pollutant	Carcinogen	Concentration in Units Per Liter for Protection of Human Health CURRENT		Concentration in Units Per Liter for Protection of Human Health PROPOSED TABLE 40	
			Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)	Water and Fish Ingestion (µg/L)	Fish Consumption Only (µg/L)
TRICHLOROETHANE 1,1,2	Y	Y	0.6	41.8	0.44	1.6
TRICHLOROETHYLENE	Y	Y	2.7	80.7	1.4	3.0
TRICHLOROPHENOL 2,4,5	N	N	2,600	--	330	360
TRICHLOROPHENOL 2,4,6	Y	Y	1.2	3.6	0.23	0.24
VINYL CHLORIDE	Y	Y	2	525	0.02	0.24
ZINC	Y	N	--	--	2100	2600

Appendix E. TABLE 40: Human Health Water Quality Criteria for Toxic Pollutants

DRAFT

Human Health Criteria Summary

The concentration for each pollutant listed in Table 40 was derived to protect Oregonians from potential adverse health impacts associated with long-term exposure to toxic substances associated with consumption of fish, shellfish, and water. The "organism only" criteria are established to protect fish and shellfish consumption and apply to waters of the state designated for fishing. The "water + organism" criteria are established to protect the consumption of drinking water, fish, and shellfish, and apply where both fishing and domestic water supply (public and private) are designated uses. All criteria are expressed as micrograms per liter (µg/L), unless otherwise noted. Pollutants are listed in alphabetical order. Additional information includes the Chemical Abstract Service (CAS) number, whether the criterion is based on carcinogenic effects (can cause cancer in humans), and whether there is an aquatic life criterion for the pollutant (i.e. "y"= yes, "n" = no). All the human health criteria were calculated using a fish consumption rate of 175 grams per day unless otherwise noted. A fish consumption rate of 175 grams per day is approximately equal to 23 8-ounce fish meals per month. For pollutants categorized as carcinogens, values represent a cancer risk of one additional case of cancer in one million people (i.e. 10^{-6}), unless otherwise noted. All metals criteria are for total metal concentration, unless otherwise noted. Italicized pollutants represent non-priority pollutants. The human health criteria revisions established by OAR 340-041-0033 and shown in Table 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act until approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

No.	Pollutant	CAS No.	Carcinogen	Aquatic Life Criterion	Human Health Criteria for the Consumption of: Water + Organism (µg/L)	Organism Only (µg/L)
1	Acenaphthene	83329	n	n	95	99
2	Acrolein	107028	n	n	0.88	0.93
3	Acrylonitrile	107131	y	n	0.018	0.025
4	Aldrin	309002	y	y	0.0000050	0.0000050
5	Anthracene	120127	n	n	2900	4000
6	Antimony	7440360	n	n	5.1	64
7	Arsenic (inorganic)[A]	7440382	y	n	2.1	2.1(freshwater) 1.0 (saltwater)
	[A] The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately of 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1 x 10^{-4}					
8	Asbestos[B]	1332214	y	n	7,000,000 fibers/L	--
	[B]The human health risks from asbestos are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.					
9	*Barium* [C]	7440393	n	n	1000	--
	[C] The human health criterion for barium is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.					
10	Benzene	71432	y	n	0.44	1.4
11	Benzidine	92875	y	n	0.000018	0.000020
12	Benz(a)anthracene	56553	y	n	0.0013	0.0018
13	Benzo(a)pyrene	50328	y	n	0.0013	0.0018
14	Benzo(b)fluoranthene 3,4	205992	y	n	0.0013	0.0018
15	Benzo(k)fluoranthene	207089	y	n	0.0013	0.0018
16	BHC Alpha	319846	y	n	0.00045	0.00049
17	BHC Beta	319857	y	n	0.0016	0.0017
18	BHC Gamma (Lindane)	58899	n	y	0.17	0.18
19	Bromoform	75252	y	n	3.3	14
20	Butylbenzyl Phthalate	85687	n	n	190	190
21	Carbon Tetrachloride	56235	y	n	0.10	0.16
22	Chlordane	57749	y	y	0.000081	0.000081
23	Chlorobenzene	108907	n	n	74	160
24	Chlorodibromomethane	124481	y	n	0.31	1.3
25	Chloroethyl Ether bis 2	111444	y	n	0.020	0.05
26	Chloroform	67663	n	n	260	1100
27	Chloroisopropyl Ether bis 2	108601	n	n	1200	6500
28	*Chloromethyl ether, bis*	542881	y	n	0.000024	0.000029
29	Chloronaphthalene 2	91587	n	n	150	160
30	Chlorophenol 2	95578	n	n	14	15
31	*Chlorophenoxy Herbicide (2,4,5,-TP)* [D]	93721	n	n	10	--
	[D] The Chlorophenoxy Herbicide (2,4,5,-TP) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established					

No.	Pollutant	CAS No.	Carcinogen	Aquatic Life Criterion	Human Health Criteria for the Consumption of: Water + Organism (µg/L)	Organism Only (µg/L)
	under the Safe Drinking Water Act.					
32	*Chlorophenoxy Herbicide (2,4-D)* [E]	94757	n	n	100	--
	[E] The Chlorophenoxy Herbicide (2,4-D) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.					
33	Chrysene	218019	y	n	0.0013	0.0018
34	Copper [F]	7440508	n	y	1300	--
	[F] Human health risks from copper are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.					
35	Cyanide [G]	57125	n	y	130	130
	[G] The cyanide criterion is expressed as total cyanide (CN)/L.					
36	DDD 4,4'	72548	y	n	0.000031	0.000031
37	DDE 4,4'	72559	y	n	0.000022	0.000022
38	DDT 4,4'	50293	y	y	0.000022	0.000022
39	Dibenz(a,h)anthracene	53703	y	n	0.0013	0.0018
40	Dichlorobenzene(m) 1,3	541731	n	n	80	96
41	Dichlorobenzene(o) 1,2	95501	n	n	110	130
42	Dichlorobenzene(p) 1,4	106467	n	n	16	19
43	Dichlorobenzidine 3,3'	91941	y	n	0.0027	0.0028
44	Dichlorobromomethane	75274	y	n	0.42	1.7
45	Dichloroethane 1,2	107062	y	n	0.35	3.7
46	Dichloroethylene 1,1	75354	n	n	230	710
47	Dichloroethylene trans 1,2	156605	n	n	120	1000
48	Dichlorophenol 2,4	120832	n	n	23	29
49	Dichloropropane 1,2	78875	y	n	0.38	1.5
50	Dichloropropene 1,3	542756	y	n	0.30	2.1
51	Dieldrin	60571	y	y	0.0000053	0.0000054
52	Diethyl Phthalate	84662	n	n	3800	4400
53	Dimethyl Phthalate	131113	n	n	84000	110000
54	Dimethylphenol 2,4	105679	n	n	76	85
55	Di-n-butyl Phthalate	84742	n	n	400	450
56	Dinitrophenol 2,4	51285	n	n	62	530
57	*Dinitrophenols*	25550587	n	n	62	530
58	Dinitrotoluene 2,4	121142	y	n	0.084	0.34
59	Dioxin (2,3,7,8-TCDD)	1746016	y	n	0.00000000051	0.00000000051
60	Diphenylhydrazine 1,2	122667	y	n	0.014	0.020
61	Endosulfan Alpha	959988	n	y	8.5	8.9
62	Endosulfan Beta	33213659	n	y	8.5	8.9
63	Endosulfan Sulfate	1031078	n	n	8.5	8.9
64	Endrin	72208	n	y	0.024	0.024
65	Endrin Aldehyde	7421934	n	n	0.030	0.030

No.	Pollutant	CAS No.	Carcinogen	Aquatic Life Criterion	Human Health Criteria for the Consumption of:	
					Water + Organism (µg/L)	Organism Only (µg/L)
66	Ethylbenzene	100414	n	n	160	210
67	Ethylhexyl Phthalate bis 2	117817	y	n	0.20	0.22
68	Fluoranthene	206440	n	n	14	14
69	Fluorene	86737	n	n	390	530
70	Heptachlor	76448	y	y	0.0000079	0.0000079
71	Heptachlor Epoxide	1024573	y	y	0.0000039	0.0000039
72	Hexachlorobenzene	118741	y	n	0.000029	0.000029
73	Hexachlorobutadiene	87683	y	n	0.36	1.8
74	*Hexachlorocyclo-hexane-Technical*	608731	y	n	0.0014	0.0015
75	Hexachlorocyclopentadiene	77474	n	n	30	110
76	Hexachloroethane	67721	y	n	0.29	0.33
77	Indeno(1,2,3-cd)pyrene	193395	y	n	0.0013	0.0018
78	Isophorone	78591	y	n	27	96
79	*Manganese* [H]	7439965	n	n	--	100
	[H] The "fish consumption only" criterion for manganese applies only to salt water and is for total manganese. This EPA recommended criterion predates the 1980 human health methodology and does not utilize the fish ingestion BCF calculation method or a fish consumption rate.					
80	*Methoxychlor* [I]	72435	n	y	100	--
	[I]The human health criterion for methoxychlor is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.					
81	Methyl Bromide	74839	n	n	37	150
82	Methyl-4,6-dinitrophenol 2	534521	n	n	9.2	28
83	Methylene Chloride	75092	y	n	4.3	59
84	Methylmercury (mg/kg) [J]	22967926	n	n	--	0.040 mg/kg
	[J]This value is expressed as the fish tissue concentration of methylmercury. Contaminated fish and shellfish is the primary human route of exposure to methylmercury					
85	Nickel	7440020	n	n	140	170
86	*Nitrates* [K]	14797558	n	n	10000	--
	[K]The human health criterion for nitrates is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.					
87	Nitrobenzene	98953	n	n	14	69
88	*Nitrosamines*	35576911	y	n	0.00079	0.046
89	*Nitrosodibutylamine, N*	924163	y	n	0.0050	0.022
90	*Nitrosodiethylamine, N*	55185	y	n	0.00079	0.046
91	Nitrosodimethylamine, N	62759	y	n	0.00068	0.30
92	Nitrosodi-n-propylamine, N	621647	y	n	0.0046	0.051
93	Nitrosodiphenylamine, N	86306	y	n	0.55	0.60
94	*Nitrosopyrrolidine, N*	930552	y	n	0.016	3.4
95	*Pentachlorobenzene*	608935	n	n	0.15	0.15
96	Pentachlorophenol	87865	y	y	0.15	0.30

No.	Pollutant	CAS No.	Carcinogen	Aquatic Life Criterion	Human Health Criteria for the Consumption of: Water + Organism (µg/L)	Organism Only (µg/L)
97	Phenol	108952	n	n	9400	86000
98	Polychlorinated Biphenyls (PCBs) [L]	NA	y	y	0.0000064	0.0000064
	[L] *This criterion applies to total PCBs (e.g. determined as Aroclors or congeners).*					
99	Pyrene	129000	n	n	290	400
100	Selenium	7782492	n	n	120	420
101	*Tetrachlorobenzene, 1,2,4,5-*	95943	n	n	0.11	0.11
102	Tetrachloroethane 1,1,2,2	79345	y	n	0.12	0.40
103	Tetrachloroethylene	127184	y	n	0.24	0.33
104	Thallium	7440280	n	n	0.043	0.047
105	Toluene	108883	n	n	720	1500
106	Toxaphene	8001352	y	y	0.000028	0.000028
107	Trichlorobenzene 1,2,4	120821	n	n	6.4	7.0
108	Trichloroethane 1,1,2	79005	y	y	0.44	1.6
109	Trichloroethylene	79016	y	n	1.4	3.0
110	Trichlorophenol 2,4,6	88062	y	n	0.23	0.24
111	*Trichlorophenol, 2, 4, 5-*	95954	n	n	330	360
112	Vinyl Chloride	75014	y	n	0.023	0.24
113	Zinc	7440666	n	n	2100	2600

DEQ Water Quality Division - Standards and Assessments

State of Oregon
Department of Environmental Quality

Human Health Focus Group Report
Oregon Fish and Shellfish Consumption Rate Project

June 2008

Questions or comments about this document should be directed to:

Water Quality Standards Program
Department of Environmental Quality
811 SW Sixth Avenue
Portland, OR 97204
(503) 229-6691

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For printed copies please contact the DEQ Headquarters Office in Portland at (503) 229-6490.

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HUMAN HEALTH FOCUS GROUP MEMBERS:

Patricia Cirone, PhD
Retired Federal Scientist
Affiliate of University of Washington

Elaine M. Faustman, Ph.D. DABT
Professor and Director
Institute for Risk Analysis and Risk Communication
Department of Environmental and Occupational Health Sciences
University of Washington

Ken Kauffman
Environmental Health Specialist
DHS Public Health Environmental Toxicology
Oregon Department of Human Services

Susan MacMillan
Senior Risk Assessor
URS Corporation

Dave McBride
Toxicologist
Office of Environmental Health Assessments
Division of Environmental Health
Washington State Department of Health

Joan Rothlein, PhD
Senior Research Associate
Center for Research on Occupational and Environmental Toxicology (CROET)
Oregon Health & Science University

FOCUS GROUP SUPPORT

Jordan Palmeri, Project Lead, Contributing Author
Water Quality Standards Specialist
Water Quality Division
Oregon Department of Environmental Quality

Debra Sturdevant
Water Quality Standards Coordinator
Water Quality Division
Oregon Department of Environmental Quality

Bruce Hope
Environmental Toxicologist
Air Quality Division
Oregon Department of Environmental Quality

Tonya Dombrowski
Environmental Chemist
Water Quality Division
Oregon Department of Environmental Quality

Becky Chu
Water Quality Standards Coordinator
Office of Water and Watersheds
Water Quality Standards Unit
U.S. Environmental Protection Agency, Region 10

Kathleen Feehan
Senior Policy Analyst, Environmental Planning / Rights Protection
Department of Natural Resources
Confederated Tribes of the Umatilla Indian Reservation

Patti Howard
Water Quality Coordinator
Columbia River Inner Tribal Fish Commission

Donna Silverberg
Facilitation Team
DS Consulting

Robin Harkless
Facilitation Team
DS Consulting

Erin Halton
Facilitation Team
DS Consulting

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1. INTRODUCTION

Oregon has over 110,000 miles of rivers and streams, more than 6,000 lakes and ponds, and 362 miles of coastal waters (ODEQ 2000). These waters support fish and shellfish species that are consumed by a broad range of Oregonians. Potentially toxic chemicals are found in some Oregon waters (ODEQ 2008). Over time, fish and shellfish may accumulate these pollutants, resulting in a potential risk to the health of people who consume them. The magnitude of health risks depends on the amount of fish or shellfish consumed, the level of contamination in the fish and shellfish, and a person's susceptibility to a particular contaminant. The Oregon Department of Human Services (ODHS) has issued numerous fish advisories throughout the state's rivers and reservoirs (ODHS 2007) to protect the health of people who may consume contaminated fish.

For purposes of its regulatory programs, the Oregon Department of Environmental Quality (ODEQ) is responsible for establishing the level of human health protection for Oregonians who consume fish and shellfish from state water bodies. In order to provide adequate protection for Oregonians, ODEQ needs to accurately assess how much fish Oregonians consume and adopt an appropriate fish consumption rate. This fish consumption rate is used with other factors such as chemical toxicity to develop human health-based water quality criteria. These criteria are codified into Oregon law as human health water quality standards (OAR 340-41). These human health water quality standards are used in ODEQ's regulatory programs to establish water quality permit limits, etc.

The purpose of this report is to document the discussion and conclusions of the Human Health Focus Group. The Human Health Focus Group includes Pacific Northwest scientists who were convened to advise the Oregon Fish and Shellfish Consumption Rate Project on technical issues surrounding the selection of fish consumption rates in Oregon. The Fish Consumption Rate Project is a collaborative effort of ODEQ, the U.S. Environmental Protection Agency (EPA), and the Confederated Tribes of the Umatilla Indian Reservation (CTUIR). The purpose of this collaborative effort is to revise ODEQ's current fish consumption rate of 17.5 grams per day (g/day). In addition to the three cooperating agencies the Fish Consumption Rate Project includes a Core Team of about 40 individuals and organizations that are either directly affected by or interested in the outcome of this project.

The Human Health Focus Group members are regional experts with experience in the areas of toxicology, risk assessment, public health, biostatistics, and/or epidemiology. The members of the Human Health Focus Group were selected from nominations received from the Fish Consumption Rate Project's Core Team as well as ODEQ, EPA, and CTUIR. A total of 26 nominations were received and the six members were selected by ODEQ, EPA, and the CTUIR.

1.1 MEMBERS OF THE HUMAN HEALTH FOCUS GROUP

- Patricia Cirone, PhD, Retired Federal Scientist – Affiliate of University of Washington

- Elaine M. Faustman, Ph.D. DABT, Professor and Director, Institute for Risk Analysis and Risk Communication – Department of Environmental and Occupational Health Sciences, University of Washington

- Ken Kauffman, Environmental Health Specialist –Public Health Environmental Toxicology, Oregon Department of Human Services (ODHS)

- Susan MacMillan, Senior Risk Assessor – URS Corporation

- Dave McBride, MS, Toxicologist – Office of Environmental Health Assessments, Division of Environmental Health, Washington State Department of Health

- Joan Rothlein, PhD, Senior Research Associate – Center for Research on Occupational and Environmental Toxicology (CROET), Oregon Health & Science University

1.2 OBJECTIVES FOR THE HUMAN HEALTH FOCUS GROUP

In their advisory role to the Fish Consumption Rate Project, the Human Health Focus Group was asked to address the following three questions:

1) Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on when selecting a fish consumption rate to use in setting water quality criteria?
2) How should salmon be considered in selecting a fish consumption rate and/or setting criteria?
3) To what extent are populations who consume more than the current fish consumption rate of 17.5 g/day at a greater risk for adverse health impacts?

The Human Health Focus Group was asked to review the available scientific evidence that would inform the Fish Consumption Rate Project. The scientific evidence was gathered from existing literature and the expertise of the Human Health Focus Group. Many different fish consumption rate studies are available in the literature. The Human Health Focus Group chose a subset of relevant studies to assess more comprehensively as well as provide a manageable summary of information.

The Human Health Focus Group was asked to provide a range of fish consumption rates that the group deems to be credible and representative of various Oregon fish-consuming populations. The Oregon Environmental Quality Commission, ODEQ's governing body, is responsible for choosing a fish consumption rate(s), or alternatively, a range of consumption rates. This risk management decision will specifically consider the people that will be protected by the human health-based water quality criteria (e.g. the general population, tribal populations, children and other sensitive populations), and what percentage of those populations to protect. The Environmental Quality Commission will be responsible for considering whether to include Pacific salmon in the rate, if there should be a single statewide fish consumption rate or various rates for different regions, and how revised human health criteria will be implemented. Overall, the Fish Consumption Rate Project encompasses a complicated mix of science and policy considerations.

The discussion and conclusions presented in this report were generated in one year (May 2007 – May 2008), a relatively short time considering the scope of the questions addressed. This report should be used in conjunction with the wide range of literature on fish consumption data that already exists. Some of this literature can be found in the report's cited references (Chapter VIII), and in the attached bibliography of related literature sources (Chapter IX). This report is not a comprehensive review of all fish consumption surveys. It is a focused review of the fish consumption surveys most relevant to fish consumers in Oregon, a review which was subject to the time constraints of the overall Fish Consumption Rate Project schedule. EPA ambient water quality criteria guidance (USEPA 2000a) recommends that "states use regional or local consumption studies and consumption rates to adequately protect the most highly exposed population when developing state water quality criteria". Other relevant national and world studies on fish consumption patterns were also reviewed by the Human Health Focus Group members during this process, but time constraints prevented in-depth analysis of all of these studies. Additionally, this report represents a brief review and recommendations for how Pacific salmon should be considered in selecting a fish consumption rate, but does not provide a comprehensive review of the life histories or potential sources of contamination for Pacific salmon.

This report is a summary of the Human Health Focus Group discussions, recommendations, and conclusions for each of the three questions posed by ODEQ, EPA, and CTUIR. There are seven chapters in this report. The historical and regulatory background regarding selection of a fish consumption rate(s) for human health-based water quality criteria in Oregon are described in Chapter 2. The results and discussion of the Human Health Focus Group's review of fish consumption surveys relevant to Oregon are presented in Chapter 3. The Human Health Focus Group's discussion of the inclusion of Pacific salmon in the fish consumption rate is given in Chapter 4. The rationale and recommendations of the Human Health Focus Group for fish consumption rate(s) for Oregon are described in Chapter 5. A brief description of human health risk assessment and its application to human health-based water quality criteria is presented in Chapter 6. Finally, the conclusions and recommendations of the Human Health Focus Group for the Fish Consumption Rate Project are presented in Chapter 7.

Detailed Human Health Focus Group meeting minutes and information on the Human Health Focus Group meeting schedule can be obtained from ODEQ or online at (http://www.deq.state.or.us/wq/standards/fishfocus.htm)

2. BACKGROUND

Water quality standards are the foundation of ODEQ's water quality program and influence a variety of other programs within ODEQ. Standards are established to protect the designated uses of Oregon waters, such as fishing, swimming, irrigation, drinking water, and industrial use. Water quality standards consist of three basic elements: 1) designated uses; 2) numeric and narrative water quality criteria; and 3) an anti-degradation policy. In order to restore and maintain the chemical, physical and biological integrity of Oregon waters, ODEQ works with a wide range of public and private entities to administer the regulatory programs of the Clean Water Act (CWA) that are based on water quality standards.

Water quality criteria can be both numeric and narrative and are derived for the protection of aquatic life and human health. Both aquatic life and human health criteria are used to assess water quality monitoring data and identify impaired waters, establish waste load allocations for Total Maximum Daily Loads (TMDLs), evaluate projects seeking a CWA Section 401 water quality certification, control non-point source pollution, establish cleanup targets at hazardous waste sites, and establish permit limits through the National Pollution Discharge Elimination System water quality permits. Any change in water quality criteria would affect all ODEQ programs using those criteria.

The Fish Consumption Rate Project is focused on reviewing and revising the fish consumption rate, which is one variable used to calculate human health-based water quality criteria. These criteria are intended to protect the quality of state waters so that fish and shellfish can be consumed by all Oregonians without unacceptable risk to human health. All of Oregon's waters (except the Bull Run River[1]) are designated for fishing, which makes the importance of protecting those waters relevant to all Oregonians.

Oregon's water quality standards (beneficial uses and criteria) are adopted by the Oregon Environmental Quality Commission through an administrative rule development process. The Fish Consumption Rate Project will provide fish consumption rates that will be used to establish water quality criteria for protection of human health. The application of human health-based water quality criteria in the CWA regulatory programs mentioned previously occurs in all waters of the state. According to Oregon Administrative Rule (OAR) 340-041-0001, *"Waters of the State" means lakes, bays, ponds, impounding reservoirs, springs, wells, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Pacific Ocean within the territorial limits of the State of Oregon, and all other bodies of surface or underground waters, natural or artificial, inland or coastal, fresh or salt, public or private (except those private waters that do not combine or effect a junction with natural surface or underground waters) that are located wholly or partially within or bordering the state or within its jurisdiction.*

Implementing and enforcing human health-based water quality criteria in waters of the state will only have an effect on those fish and shellfish species residing in and exposed to those waters. Thus, the selection of a fish consumption rate to be used in Oregon human health-based water quality criteria may only include those fish and shellfish species directly influenced by waters of the state. The territorial limits of Oregon extend three nautical miles from shore into the Pacific Ocean.

> EPA's nationally recommended fish consumption rates are based on data from United States Department of Agriculture's (USDA) 1994-1996, 1998 Continuing Survey of Food Intake by Individuals (CSFII) and reported in USEPA 2002b.

Oregon's current numeric human health criteria are based on EPA's 2002 recommended CWA Section 304(a) water quality criteria (USEPA 2002a). EPA derived these criteria by considering

[1] The Bull Run River is located inside a watershed that is closed to public access and is therefore not accessible for fishing.

the known toxicity of the regulated chemicals and the likely exposure people have to these chemicals. These criteria are based on a specific set of variables for estimating exposure including fish consumption rate and human body weight. EPA's current recommended CWA Section 304(a) human health-based water quality criteria are calculated using the national fish consumption rate of 17.5 g/day (USEPA 2000a). This nationally recommended rate is roughly equivalent to two, eight-ounce fish meals per month. This rate represents the 90th percentile of all people (fish consumers and non-consumers) who were interviewed from across United States.

ODEQ is considering which fish consumption rates are most appropriate to use in calculating water quality criteria that are protective of human health. These criteria will apply to Oregon waters and will be implemented through CWA regulatory programs such as National Pollution Discharge Elimination System water quality permits, water quality assessments, and Total Maximum Daily Loads. ODEQ is considering raising the fish consumption rate in part because a local study shows that the Columbia River Tribes (CRITFC 1994) eat substantially more fish than the current EPA default rate of 17.5 g/day (USEPA 2000a). EPA, in an August 15, 2005 letter to the Environmental Quality Commission (ODEQ's rulemaking body), suggested that, "Current information indicates that a fish consumption rate in the range of 105 to 113 g/day may be appropriate for some waters in Oregon, Washington, and Idaho including a number of reaches of the Columbia River (based on studies prepared by EPA and the Columbia River Inter-Tribal Fish Commission)" (Kreizenbeck 2005). Other studies identified in this report demonstrate the existence of other high-volume fish consumers in Oregon, in the United States generally and in the world. An increase in the fish consumption rate in Oregon would result in more stringent human health-based water quality criteria.

Until 2003, Oregon's water quality standards were based on a fish consumption rate of 6.5 g/day, consistent with EPA's default fish consumption rate (USEPA 2000a). EPA increased its recommended rates to a nationally-based per capita default level of 17.5 g/day while urging states to rely on local consumption data wherever possible (USEPA 2000a).

From 1999 to 2003, two separate teams reviewed Oregon's water quality standards and considered potential revisions: the ODEQ's Technical Advisory Committee (TAC) and the Policy Advisory Committee (PAC). When reviewing the appropriate fish consumption rates to calculate the human health-based criteria, the TAC proposed a tiered approach for the Oregon criteria:

1) EPA's (USEPA 2000a) default fish consumption rate (17.5 g/day) for low intensity fish consumption,
2) EPA's (USEPA 2000a) recommended subsistence fish consumption rate (142.4 g/day), for medium intensity fish consumption
3) The ninety-ninth percentile of the Columbia River Basin Tribal fish consumption rates (389 g/day, from CRITFC 1994) for high intensity fish consumption.

The PAC, upon reviewing the TAC's recommendations, had concerns about how this tiered system would be implemented, and could not come to consensus on what the appropriate fish consumption rate should be for calculating the human health-based water quality criteria.

Subsequently, ODEQ recommended to the Environmental Quality Commission that it adopt EPA's 2002 recommended CWA Section 304(a) water quality criteria for toxic pollutants, including the human health criteria (USEPA 2002a), with a few exceptions. The Environmental Quality Commission adopted these criteria, and the revised water quality criteria were submitted to the EPA on July 8, 2004 for its review and approval.

The CWA directs EPA to review and either approve or disapprove water quality standards submitted by states and authorized tribes (40CFR Part 131.5). EPA has not yet taken any action on Oregon's revised human health-based water quality criteria that were submitted on July 8, 2004, but has recommended that Oregon consider adopting a rate of 105-113 g/day for some waters in Oregon in order to be more protective of people who eat fish (Kreizenbeck 2005).

3. EVALUATION OF FISH CONSUMPTION SURVEYS

3.1 FISH CONSUMPTION SURVEYS REVIEWED

The purpose of the Human Health Focus Group review of fish consumption surveys was to establish a body of literature that documents the range of fish consumption rates practiced by fish consuming groups in the Pacific Northwest; and from which Oregon can choose a fish consumption rate.

With the help of ODEQ and EPA, the Human Health Focus Group compiled a list of national and international surveys for review. National and international studies (Table 1, located at the end of this document) demonstrate that there are a wide range of populations with diverse cultures, traditions, and practices that result in a very broad range of fish consumption patterns. This variability can be expected in any population of statewide scale and in some cases, similar variability can be seen in much smaller populations.

3.1.1 SELECTION OF RELEVANT FISH CONSUMPTION SURVEYS

Current EPA (USEPA 2000a) ambient water quality criteria guidance for adopting state fish consumption rates recommends the use of local and regional fish consumption data first, the use of national studies second, and recommends reliance on EPA default rates only if no specific regional data are available.

The Human Health Focus Group established an informal set of procedures for determining which surveys were the most relevant for Oregon and the most useful for estimating fish consumption rates. These procedures included but were not limited to the following considerations:

1) Survey design,
2) Survey questionnaire,
3) Population surveyed,
4) Statistical analysis, and
5) Type of fish and shellfish consumed

Of the national and international studies listed in Table 1, eight regional surveys and one national fish consumption survey reviewed by the Human Health Focus Group were found to be relevant for developing fish consumption rate(s) for Oregon Water Quality Criteria. With this guidance and Oregon's population in mind, nine fish consumption surveys (Table 1) were chosen for detailed review. A survey was determined relevant if the people surveyed were from Oregon or their fish consumption patterns are what one might expect from the people of Oregon.

The nine relevant surveys are:

- A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin (CRITFC 1994)
- Fish Consumption, Nutrition, and Potential Exposure to Contaminants Among Columbia River Basin Tribes. – A Masters thesis by Neil A. Sun Rhodes, Oregon Heath Sciences University (Rhodes 2006)
- Columbia Slough and Sauvie Island Fish Consumption Survey, Technical Memorandum on the Results of the 1995 Fish Consumption and Recreational Use Surveys, Amendment No. 1 (Adolfson Associates 1996)
- A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region (Toy *et al.* 1996)
- Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region (Suquamish 2000)
- Asian and Pacific Islander Seafood Consumption Study (Sechena *et al.* 1999)
- Lake Whatcom Residential and Angler Fish Consumption Survey (WDOH 2001)
- Consumption Patterns of Anglers Who Frequently Fish Lake Roosevelt (WDOH 1997)
- Estimated Per Capita Fish Consumption in the United States (USEPA 2002b)

3.1.2 Selection of Surveys Most Useful for Recommending Fish Consumption Rates

In this review, a survey was determined useful if the quantitative results can be relied upon as good estimates of fish consumption rates for the population surveyed. Of the nine fish consumption surveys considered to be relevant by the Human Health Focus Group, the following five surveys were determined to have the most useful data for estimating quantitative fish consumption rates:

- A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin (CRITFC 1994)
- A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region (Toy *et al.* 1996)
- Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region (Suquamish 2000)
- Asian and Pacific Islander Seafood Consumption Study (Sechena *et al.* 1999)
- Estimated Per Capita Fish Consumption in the United States (USEPA 2002b)

Four of the original nine studies were eliminated for further consideration for various reasons. The Lake Whatcom, Lake Roosevelt, Sauvie Island and the Columbia Slough are good studies, but the reported values in each of these studies were not adequate for calculating accurate fish consumption rates. The re-evaluation of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribal (CRITFC 1994) data by Rhodes did not provide any new quantitative data that would change the results of the original survey of the Columbia River Basin Tribes (CRITFC 1994).

3.1.3 RESULTS OF REVIEW OF NINE SURVEYS

The result of the Human Health Focus Group's evaluation of the nine surveys is provided in the following section.

A FISH CONSUMPTION SURVEY OF THE UMATILLA, NEZ PERCE, YAKAMA, AND WARM SPRINGS TRIBES OF THE COLUMBIA RIVER BASIN (CRITFC 1994)

Relevance

The survey of Columbia River Basin Tribes (CRITFC 1994) is regarded as the study most relevant to Oregon fish consumers. The Confederated Tribes of the Umatilla Indian Reservation and the Warm Springs Tribe, two of the four tribes surveyed, are both located in Oregon, which makes the survey a direct measure of an Oregon population. The Yakama Tribe (Washington) and Nez Perce Tribe (Idaho) both fish in parts of the Columbia River Basin in Oregon

The survey reported that 97 percent of the people interviewed eat fish. Other surveys reviewed by the Human Health Focus Group demonstrated that Asian and Pacific Islanders and Eastern European communities also consume fish at levels similar to Oregon Tribes.

The fish species consumed by Columbia Basin Tribes (CRITFC 1994), either spend their entire life in Oregon waters or part of their life in Oregon waters (Appendix A-1). The fish reported as consumed in this survey include trout, northern pike-minnow, sturgeon, suckers, walleye, and whitefish. The study also reported consumption of Pacific salmon, steelhead, lamprey, shad, smelt, and sturgeon. This is significant because all of these fish are affected by the quality of Oregon waters for all or part of their life cycle. Furthermore, 88 percent of the fish consumed by the Columbia Basin River Tribes originated from the Columbia River Basin (CRITFC 1994).

No consumption of any shellfish or open ocean finfish species was reported. The questionnaire used in the interviews did not include specific questions about marine species or shellfish. Since these questions were not asked in the interview, it is not clear how this may have affected the fish consumption rates reported by the Columbia River Tribes. Since the people of Oregon are likely to eat coastal marine seafood, the Columbia River Tribal data may not be relevant with respect to the marine and shellfish consumption patterns of Oregonians.

In summary, with the exception of the marine fish and shellfish component, the survey of Columbia River Basin Tribes (CRITFC 1994) is relevant to Oregon fish consumers because it offers a reliable and direct measurement of fish consumption by an Oregon population.

Utility

The fish consumption data reported in this survey are useful for the purposes of establishing water quality criteria for Oregon. This study was peer-reviewed and represented a random selection of 513 adult survey participants ages 18 and older from four Columbia River Basin Tribes (CRITFC 1994). Survey participants also provided information for 204 children ages five and younger from adult participant's households. The adult participants were interviewed by trained tribal representatives and asked to report 24-hour recall, weekly, monthly, seasonal, and 20-year average fish intake. The weekly estimates of fish consumption and data on serving size were used to determine the grams per day of fish consumed by each respondent. The survey's overall average and distributed rate of consumption were calculated from the individual rates. The survey did not include body weights for individual participants. This did not affect the overall usefulness of these data, since most consumption patterns are based on a measurement of grams per person per day. However, the accuracy of this measurement for individuals is reduced.

Although the raw data were not available for re-analysis, there was good documentation of the summary statistics conducted. The highest fish consumption rates were not categorized using any statistical methods, but rather considered "unreasonably high" and not included in the statistical analysis.

FISH CONSUMPTION, NUTRITION, AND POTENTIAL EXPOSURE TO CONTAMINANTS AMONG COLUMBIA RIVER BASIN TRIBES (RHODES 2006)

Relevance

This study is a re-evaluation of the original survey of the Columbia River Basin Tribes by CRITFC (1994). Thus it is relevant for developing a fish consumption rate for Oregon. There are no changes (no corrections) in the rate of consumption for the Columbia River Basin Tribes.

Utility

This report provides additional multivariate analysis on the correlation between fish consumption rates and factors including breast feeding after most recent births, percent of fish obtained non-commercially for women who recently gave birth, living off the reservation, and fish consumption rates for children and the elderly. This re-evaluation resulted in no changes or corrections to the consumption rates presented in the original Columbia River Basin Tribal survey (CRITFC 1994). Therefore, the data reported in this survey, were not included in the Human Health Focus Group's deliberations.

COLUMBIA SLOUGH AND SAUVIE ISLAND FISH CONSUMPTION SURVEY, TECHNICAL MEMORANDUM ON THE RESULTS OF THE 1995 FISH CONSUMPTION AND RECREATIONAL USE SURVEYS, AMENDMENT NO. 1 (ADOLFSON ASSOCIATES 1996)

Relevance

This study is regarded as being relevant to fish consumers in Oregon as it provides a description of the race, ethnicity, age and gender of the people fishing and the types of fish species caught and consumed in the Portland, Oregon metropolitan area. The study also provides information on various methods of fish preparation by local populations, other fishing frequencies and local fishing locations.

Utility

The data reported in this creel survey are not useful for quantitative assessment of fish consumption rates but provide regional information of subsistence fishers in the Portland metropolitan area. This study was conducted primarily on land and one day on water for 20 randomly selected days over a one month period. Both the days and times selected to conduct the survey utilized a stratified random sampling methodology. The survey team was trained and multi-lingual. A total of 91 interviews were conducted in the Columbia Slough and 55 interviews on Sauvie Island. The species, weight and length of the fish caught on the day of the interview was reported in addition the number of people consuming the catch. This survey has significant limitations for calculating individual fish consumption rates.

The quantitative fish consumption rates were limited by the inconsistencies in how individuals reported their fish consumption. The survey interviewers noted that individuals had difficulties in reporting the quantity of fish they consumed. Additionally, only fish weighed by the surveyors were counted in consumption estimates and of those fish, only 30 percent of the total weight of fish was regarded as edible despite the preparation method reported by the individual. Finally, if the participant reported that other people in the household ate fish, the individual consumption was simply divided by the number of people and individual portion size was disregarded. Overall, there was not sufficient information to calculate reliable fish consumption estimates.

A FISH CONSUMPTION SURVEY OF THE TULALIP AND SQUAXIN ISLAND TRIBES OF THE PUGET SOUND REGION (TOY ET AL. 1996)

Relevance

The Tulalip and Squaxin Island Tribes survey is regarded as being relevant to Oregon fish-consuming populations; although some of the fish and shellfish they consumed may not be found in Oregon waters (Appendix A-2). Oregon does not have a marine body of water comparable to the size and complexity of Puget Sound, which is the fishing ground for the Tulalip and Squaxin Island Tribes. Places in Oregon such as Coos, Tillamook, and Nehalem Bays may provide a proportionally smaller habitat for comparable finfish and shellfish species that are found in Puget Sound. The life histories or habitat classifications of finfish or shellfish species were not included in the report, although they did identify those species that are found in Puget Sound.

Toy *et al.* (1996) states, “if the fish consumption rates in this report are to be used to represent fish consumption in other tribal populations, information should be collected about their species consumption, preparation methods and other relevant factors”. The origin of fish consumed in the Tulalip and Squaxin Island Tribes survey was divided into five categories: a) those caught in Puget Sound, b) those caught outside Puget Sound, c) those eaten in restaurants, d) those purchased from grocery stores, and e) other. Anadromous fish (e.g. Pacific salmon) were the most heavily consumed fish group, of which 72-80 percent was caught in Puget Sound. Seventy-five percent of the shellfish consumed came from Puget Sound. Less than 50 percent of the open ocean fish (e.g. cod, Pollock) consumed by The Tulalip and Squaxin Island Tribes were collected from the Puget Sound.

The rates in this report are specifically relevant to Oregon fish-consuming populations, especially the coastal communities. Since the results are comparable to the fish consumption rates of members of the Columbia River Basin Tribes (CRITFC 1994), it demonstrates a simple relationship between tribal fish-consuming populations in the Pacific Northwest: people eat what’s available to them and what’s culturally preferred. Additionally, there are patterns of high consumption rates in Pacific Northwest Tribes regardless of species consumed or origin of the fish.

<u>Utility</u>

The fish consumption data reported in this survey are useful for the purposes of establishing water quality criteria for Oregon. This study represented a random selection of 190 adult survey participants from the Tulalip and Squaxin Island Tribes in Washington State. Additionally, survey participants provided information on 69 children of age six years and younger. The participants were interviewed by trained tribal representatives and asked to report on the number of fish meals eaten per day, per week, per month or per year over a one-year period and the portion size of each meal. Individual consumption rates were calculated using the portion size reported and the frequency of consumption, which depended upon how the participant reported it (daily, weekly, monthly, yearly). Any participant that did not eat any fish at all (non-consumer) was not included in the survey or data analysis since the survey objective was to ascertain the consumption rates of people who did eat fish.

The participants also reported their own body weight, which allowed for the calculation of consumption rates in grams per kilogram per day (g/kg/day). Including human body weights enhances the accuracy of estimating risk to any given individual. This study presented varied and useful analyses and summary statistics. There were a number of large consumption rates reported for this study. These high rates were considered outliers (an observation that is numerically distant from the rest of the data). The outliers were re-coded "…to the largest reported consumption rate within three standard deviations of the arithmetic mean" (Toy *et al.* 1996). Toy *et al.* 1996 acknowledged that, when calculating central tendencies, there is the potential that excluding outliers in such a manner may add bias in studies specially designed to examine variation and range of fish consumption and such biases would underestimate true fish consumption.

FISH CONSUMPTION SURVEY OF THE SUQUAMISH INDIAN TRIBE OF THE PORT MADISON INDIAN RESERVATION, PUGET SOUND REGION (SUQUAMISH 2000)

<u>Relevance</u>

The Suquamish Tribe survey is regarded as being relevant to Oregon fish-consuming populations. The type of fish caught in Puget Sound varies from those found in Oregon waters (Appendix A-3). While there is not a one hundred percent correlation between Puget Sound and Oregon waters this limitation does not affect the relevance of this study to Oregon populations.

The origin of fish consumed was divided into five categories: a) those caught in Puget Sound, b) those caught outside Puget Sound, c) those eaten in restaurants, d) those purchased from grocery stores, and e) other. The most heavily consumed fish groups in this survey were Pacific salmon (including steelhead) and shellfish. For both of these groups, 80-90 percent of the fish or shellfish consumed was harvested, of which the vast majority was harvested in Puget Sound. All other fish groups exhibited much lower harvest rates (less than 50 percent) and had higher percentages of restaurant or grocery origin. These data show that for certain groups of fish (Pacific salmon and shellfish) the local (Puget Sound) harvest comprises the vast majority of fish consumed.

This study of the Suquamish Tribe follows the same methodology within the same basin (Puget Sound) as the study of the Tulalip and Squaxin Island Tribes. Thus, the rates in this report are specifically relevant to Oregon fish-consuming populations, especially the coastal communities.

Utility

The fish consumption data reported in this survey are useful for the purposes of establishing water quality criteria for Oregon. This study represents a random selection of 92 adult survey participants from the Suquamish Tribe. Additionally, survey participants provided information on 31 children ages six years and younger. The participants were interviewed by trained tribal representatives and asked to report on the number of fish meals eaten per day, per week, per month or per year over a one-year period and the portion size of each meal. Individual consumption rates were calculated using the portion size reported and the frequency of consumption, which depended on how the participant reported it (daily, weekly, monthly, yearly). All 92 survey respondents reported eating some type of fish which meant there were no “non-consumers” among the respondents. The participants also reported respondent body weight, which allowed for the calculation of consumption rates in g/kg/day. Including body weight enhances the accuracy of estimating risk to any given individual or population. Good summary statistics were presented in the report with useful and varied analyses of the data. The analysis did not exclude any data.

The Suquamish staff chose to include high consumption rates because they were familiar with the individuals eating those large quantities and that the consumption rates reported were likely to reflect real consumption (Suquamish 2000). With no adjustments made for the high consumption rates, it was noted that the reported means may be highly influenced by the consumption of just a few individuals.

ASIAN AND PACIFIC ISLANDER SEAFOOD CONSUMPTION STUDY (SECHENA ET AL. 1999)

Relevance

The Asian and Pacific Islander survey is regarded as being relevant to Oregon fish-consuming populations (with some limitations), as there were a significant number of marine finfish and shellfish species consumed by people interviewed in this study that may or may not be found in certain Oregon waters (see Appendix A-4).

The origin of fish consumed was divided into four categories: a) those harvested in King County, b) those caught outside King County, c) those eaten in restaurants, and d) those purchased from grocery stores or street vendors. The most heavily consumed fish group in this survey was shellfish. For all fish groups, 79-97 percent of the seafood consumed came from either groceries/street vendors or restaurants. Seafood known to be harvested locally comprised from three percent to twenty-one percent of their diet. These data show that the vast majority of fish and shellfish consumed by Asian and Pacific Islanders is obtained through groceries/street vendors and restaurants.

The rates in this report are potentially relevant to Oregon fish-consuming populations such as the Asian and Pacific Islander communities in Oregon. The vast majority of seafood consumed was purchased, but it is not known what proportion of purchased fish was locally caught. Despite this limitation, the study is still relevant to the Asian and Pacific Islanders of Oregon as an indicator of their fish consumption patterns.

Utility

The data on fish consumption rates reported in this survey are useful for the purposes of establishing water quality criteria for Oregon. This study represented a selection of 202 adult survey participants from 10 different ethnic communities that comprise the Asian and Pacific Islander community of King County, Washington. The participants were interviewed by trained representatives from each of the ethnic communities represented and asked to report on the number of annual servings and the portion size of the servings. Individual consumption rates were calculated using the portion size reported multiplied by the number of annual servings and then divided by 365 days times the respondent's body weight. Any participant that did not eat any fish was not included in the survey or data analysis since the survey objective was to ascertain the consumption rates of people who did eat fish.

The participants also reported their own body weights, which allowed for the calculation of consumption rates in g/kg/day. Including human body weights enhances the accuracy of estimating risk to any given individual or population.

Summary statistics were presented in the report with useful and varied analyses of the data. The authors (Sechena *et al*. 1999) reported that there were an usually large number of high fish consumption rates. The values that were identified as outliers were those observed values greater than three standard deviations above the mean. These outliers were then given a smaller value equal to the mean plus three standard deviations.

CONSUMPTION PATTERNS OF ANGLERS WHO FREQUENTLY FISH LAKE ROOSEVELT (WDOH 1997)

Relevance

This survey is regarded as being relevant to Oregon fish consumers. The populations surveyed in this study are likely to exist on a comparable lake in Oregon. The species reported in the survey included kokanee, rainbow trout, walleye and bass. Some or all of these species are likely to be found in Oregon lakes as well. Survey participates were primarily vacationing boat anglers returning from fishing trips. No tribal members were surveyed.

Utility

The data reported in this survey are not useful for quantitative assessment of fish consumption rates. This survey was conducted to determine the consumption patterns of anglers who repeatedly fish in Lake Roosevelt. Creel and fish consumption surveys were conducted at boat launches with people returning from their fishing trips at randomly selected locations. The survey was pilot tested and administered by creel clerks over a four to five month period during 1994 and 1995. The survey protocol was slightly altered from one year to the next to collect more accurate and meaningful consumption data. A total of 448 interviews were conducted. Anglers who did not consume fish (total of 57) were not included in the data analysis. Data collected showed that 84 percent of all respondents were members of two adult households.

The fish consumption rates derived from this survey were not useful because of inconsistencies in how the consumption information was reported. Although the frequency of consumption was obtained, there were difficulties in obtaining the portion size consumed at each meal, which led to further difficulties in calculating individual consumption rates. Therefore, actual consumption rates were not reported, but frequency of consumption and number of fillets eaten per meal was reported.

LAKE WHATCOM RESIDENTIAL AND ANGLER FISH CONSUMPTION SURVEY (WDOH 2001)

Relevance

This survey is regarded as being relevant to Oregon fish consumers as populations similar to those surveyed in this study are likely to exist on a comparable lake in Oregon. The species reported in the survey included smallmouth bass, yellow perch, kokanee, cutthroat trout, and signal crayfish. Some or all of these species are likely to be found in Oregon lakes as well. The source of the fish consumed was Lake Whatcom. There was no indication through the survey protocol if those interviewed consumed harvested fish from any other lake, river, or bay. There was, however, a question about the consumption of canned tuna fish since the study was driven originally by concerns of mercury exposure. Nineteen of the 242 respondents consumed tuna an average of 4.2 times over the previous four weeks. This fact may indicate that these respondents are frequent "fish eaters" and may supplement their diets with fish from other sources such as restaurants or grocers stores.

Utility

This study was designed to collect fish consumption information from residents who live on or near the lake or in developments with direct access to the lake, boat anglers accessing the lake at public boat launch facilities, and shore anglers. Although, the data reported in this survey are not useful for quantitative assessment of fish consumption rates, the study provides some information on types of fish collected and eaten, even in the presence of fish advisories. Only average meal sizes were calculated, and an accurate frequency of meals per week or month was not clearly presented. Due to elevated mercury levels in some fish species reported in a screening survey from Lake Whatcom, Washington, fishing was already influenced by perceived contamination as reported in local media. This study also gathered information regarding the respondents' perceptions and likely reactions to a fish consumption advisory. There were trained interviewers who went door-to-door at randomly selected residencies and approached anglers during specified times on the boat launches and the shore. There interviewees included residents (194), boat anglers (38), and shore anglers (10).

The participants were asked to report on how many times over the previous four weeks they had eaten fish from Lake Whatcom, how many fish were eaten per meal, and how many months per year they consumed Lake Whatcom fish. They were also asked to report typical meal size based on a picture of a Pacific salmon fillet. Fish consumption rates were calculated using the number of reported fish eaten per meal multiplied by the average fillet weight of that species, which was obtained from a previous Lake Whatcom fish sampling effort.

The fish consumption rates from this survey were not useful because of inconsistencies on how the interviewees reported their fish consumption. The four-week recall diet limited the ability to fully quantify fish consumption due to the low number of people that consumed fish during that period. Although some limitations exist for the data, they do provide an indication of the amount of fish consumed exclusively from Lake Whatcom, Washington following the media coverage of potential contamination issues.

ESTIMATED PER CAPITA FISH CONSUMPTION IN THE UNITED STATES (USEPA 2002B

Relevance

This large national study is relevant to Oregon and provides context upon which specific, regional data can be based. The methodology used to conduct the survey and analyze the data is useful for analyzing fish consumption trends of the U.S. population via per-capita consumption rates. The study does not report state-specific fish consumer survey results from Oregon alone but was designed as a national study.

There was a wide variety of fish consumed in this survey, some of which may be found in Oregon waters.

Utility

The EPA national estimates of fish consumption (USEPA 2002b) are considered useful for the purposes of establishing water quality criteria for Oregon. The EPA national estimates (USEPA 2002b) were based on combined data from the USDA 1994-1996 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII). The survey of 20,607 people (adults and children) was well designed to be statistically representative of the overall per-capita consumption rates of the U.S. population. The 24-hour dietary recall was administered by an interviewer and was conducted on two non-consecutive days. Data collection from these surveys spanned a period of four years. For this national survey individuals were interviewed in-person on their food intake on two non-consecutive days. Advantages of the survey methodology are that is that it is statistically representative of all 50 states, it has a good design for per-capita consumption estimates, the interviewer administration enhances its accuracy, and it was administered on non-consecutive days, which avoids correlated consumption data.

Because of the extraordinarily large survey population and the fact that individuals were chosen to statistically represent overall US populations this data set provides a valuable context for Pacific Northwest surveys.

Short-term data collection (two day - 24 hour recall) may not be representative of long-term consumption rates that have been averaged over time. However, since large numbers (20,607) of individuals were included in the EPA estimated per capita survey (USEPA 2002b and the survey includes more than one time period and season, there is a greater likelihood of capturing the distribution of consumption rates when compared to smaller surveys.

Since the goal of the USDA CSFII surveys was to represent the diet of all people (per capita) in the United States, the data included people who eat fish (consumers) and those who don't eat fish (non-consumers). Including non-consumer data in a fish consumption rate can result in misleadingly low fish consumption rates. In addition to reporting the per capita fish consumption rates, EPA (2002) considered it appropriate to report the data for consumers only as well as the combined consumer and non-consumer data.

The Human Health Focus Group agreed that exposure assessments and the evaluation of potential risks to fish consumers must consider the consumption rates appropriate for actual consumers. Thus, EPA (USEPA 2002b) "consumer-only" data were examined for their usefulness. The statistical certainty of the USDA CSII Study was quite high because of the large number of participants (20,607). This certainty is reduced when "consumer-only" data for only adults are extracted because of the decrease in the number of people from 20,607 to 2,585. However, the Human Health Focus Group considered these rates to be useful for Oregon with the acknowledgement of decrease in statistical certainty.

3.1.4 General Discussion of Fish Consumption Survey Methodologies

The survey methodologies in the studies reviewed by the Human Health Focus Group include interview questionnaire (CRITFC 1994, Toy *et al.* 1996, Suquamish 2000, Sechena *et al.* 1999, dietary recall (USEPA 2002b) and creel surveys (Adolfson 1996, WDOH 1997, WDOH 2001). Each of these methodologies has individual advantages and disadvantages.

Fish consumption surveys are designed to estimate the fish consumption patterns of a target population. A number of potential biases can influence survey results. Response rates, literacy, and language barriers may affect the quality of data collected in surveys. Other sources of bias in a survey include interviewer bias, differential effort by interviewers or respondents, cultural differences in interpretation, recall bias or memory problems, and over- or under-reporting (OEHHA 2001). Finally, different methods of data analysis can yield very different estimates of consumption from the same dataset.

The four personal interview surveys reviewed by the Human Health Focus Group utilized local interviewers to conduct the interviews for their own groups, to ensure that the people being interviewed felt comfortable answering the survey questions. This approach helps enhance the trust of the interviewee and the effectiveness of communication during the interview. Personal interviews are often pilot-tested to enhance the relevance of the questionnaire.

Personnel interview surveys may suffer from recall bias as individuals lose accuracy as time from an activity increases. This becomes a challenging issue when individuals are asked to recall consumption rates over prior twelve months. An individual may remember that they ate fish a certain number of times but they may not remember the exact amount in each instance.

The Human Health Focus Group reviewed three creel surveys for this report. Creel surveys are field interviews of anglers at the site they are fishing. Many creel surveys include inspection of the angler's catch, which can increase survey accuracy. Creel survey results are limited by the locations, seasons, dates, and times of the interview. Language and literacy may present difficulties during an interview (USEPA 1998). Since interviews are based upon when the interviewer chooses to visit the angling site, interviewees are not prepared for the interview and may be less likely to participate. The interviewee also may not trust the stranger conducting the interview.

The Human Health Focus Group reviewed only one dietary recall survey for this report. Short-term data collection (two day - 24 hour recall) is a well accepted methodology for dietary studies because individuals more accurately recall recent events, such as the food they consumed within the last day). Recall surveys that are administered by a trained interviewer allow for consistency between participants and reduce the errors in reporting that are possible in self reported surveys. Correlated consumption data can occur if a participant cooks and eats fish on one day and then eats that same fish as leftovers the next day. This can be avoided by conducting the survey on non-consecutive days.

Although estimates of consumption from dietary recalls may be reported as g/day, the values may not be representative of long-term consumption rates that have been averaged over time and presented as a daily rate. Other fish consumption study methodologies consider fish consumption over a much longer period of time and are therefore more likely to more closely represent the fish consumption patterns of the population studied.

3.2 CONSUMERS-ONLY DATA

Fish consumption surveys typically include people who eat fish and people who don't eat fish. People who don't eat fish are termed "non-consumers". Those that do eat fish are considered "consumers". The proportion of non-consumers included in the survey will vary depending on the population being interviewed. For instance, of the 500 respondents in *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (CRITFC 1994), 93 percent were fish consumers. It is common among the tribal populations reviewed in this report to have a high percentage of fish consumers in their population. In contrast, EPA (USEPA 2002b) evaluated national data from approximately 20,000 individuals (3 years and older). Approximately 28 percent were fish consumers.

In EPA's *Estimated Per Capita Fish Consumption in the United States* (USEPA 2002b), fish consumption data were collected using a non-consecutive two-day dietary recall. Anyone who didn't eat fish on either of the two recall days was considered a non-consumer. This methodology has the potential to underestimate the number of consumers in a population. Furthermore, anyone who did eat fish on either of the two days would be considered a consumer. The data for an individual consumer were then assumed to be that person's rate of consumption for every day of the year. In this case, a reported value for short-term consumption on two survey days was used to estimate long-term or "usual" intake of fish and shellfish.

Oregon's current fish consumption rate of 17.5 g/day was determined on a per-capita basis for the entire U.S. population (USEPA 2002b) including fish consumers and non-consumers. All non-consumers are recorded as having a consumption rate of zero g/day. When averaging in the zero consumption rates of the non-consumers with the actual rates of the consumers, the resulting rates represent the averages across an entire population, and do not represent the actual fish consumption rate for people who eat fish.

Oregon's human health-based water quality criteria are developed to specifically protect individuals who consume fish, which would make the consumer-only rates most representative of a fish-consuming population. Oregon should base its regulatory consumption rate on data specifically derived from consumers of fish.

3.3 SUPPRESSED RATES

The Human Health Focus Group also discussed some of the factors that may contribute to the suppression of fish consumption rates. Current reported fish consumption rates may be depressed compared to historic rates due to several factors: 1) significant reductions in fish populations, 2) the belief that fish that reside in polluted waters will bio-concentrate pollutants, 3) contaminated fish, and 4) the intended impact of local fish advisories or the unintended consequences of national fish advisories of commercial fish species that are not applicable to local waters

The Human Health Focus Group also noted that three of the five studies presented in Table 3 (in Section 5.2) excluded or discounted high fish consumers by identifying statistical outliers. This would have the effect of underestimating the true range in fish consumption rates. If the rates are already suppressed the elimination of the highest values may be reporting an artificially low fish consumption rate.

3.4 FISH SPECIES CONSUMED

There are a variety of fish and shellfish species represented in the studies reviewed. Fish and shellfish species can be classified as marine, estuarine, or freshwater based upon the habitat in which they are born/hatched, reproduce, grow, and die. Some species of fish or shellfish can spend portions of their life in multiple aquatic environments. Pacific salmon hatch in freshwater, migrate to the ocean and then return to freshwater to spawn and die. Other migratory species commonly consumed in Oregon include sturgeon, lamprey, smelt, and shad. Note that the white sturgeon is landlocked because of dams on the Columbia River.

The seafood species consumed by recreational and subsistence fishers are dependent upon where these people live and fish. The availability of fish and shellfish is a major factor influencing the types of seafood consumed by populations who harvest for consumption purposes. For example, tribal members interviewed in the survey of Columbia River Basin Tribes (CRITFC 1994) reported eating resident trout, northern pike-minnow, sturgeon, suckers, walleye, and whitefish. They also consumed Pacific salmon, lamprey, shad, smelt, and sturgeon. They did not report eating any shellfish or open ocean finfish species. This may be influenced by the fact that the Columbia River Basin Tribes (CRITFC 1994) questionnaire did not include questions about consumption of specific marine fish or shellfish species.

In contrast, the Puget Sound Tribes (Tulalip and Squaxin Island) reported eating a variety of marine and migratory fish species (e.g. cod, sole, Pacific salmon) and shellfish (e.g. clams) (See Appendix A-2). All of these tribes were consuming fish and shellfish that were available to them in their given harvest locations. Although direct comparisons of the fish and shellfish species consumed between the Columbia River Tribes and the Puget Sound Tribes are difficult, an overall comparison of consumption patterns among tribal fishers is relevant.

The surveys reviewed by the Human Health Focus Group (Table 1, located at the end of this document) suggest that fish consumers generally eat a variety of species that are most readily available geographically and seasonally. Additionally, the ranges of consumption rates among fish consumers tend to be comparable regardless of the species that are available at a given location. Thus, it is reasonable to assume that persons who eat fish will change or substitute species based on availability, cost and accessibility.

4. PACIFIC SALMON IN THE FISH CONSUMPTION RATE

EPA's national default fish consumption rates are derived for specific fish habitats (freshwater, estuarine, marine 65 FR 66469, 2000a). The choice of a fish consumption rate to use in calculating water quality criteria can be influenced by what types of fish and shellfish are included in the rate.

Human health water quality criteria are applied to "waters of the state" (as previously defined) and are used to maintain and improve water quality through numerous CWA regulatory programs administered by ODEQ. Implementing and enforcing human health criteria in waters of the state will only affect those fish and shellfish species residing in and exposed to those waters. Since water quality criteria are only protective of Oregon waters, it is important to understand which fish and shellfish species are found in Oregon waters. This is not a simple task since Oregon waters technically extend three nautical miles off the Oregon coast. There are a wide variety of fish and shellfish that live within that nautical boundary for all or part of their life cycle. Complicating matters even further is the presence of migratory fish (e.g., Pacific salmon), which spend part of their life cycle in the freshwaters of Oregon and part of their life cycle in deep ocean waters that are outside Oregon's jurisdiction.

4.1 EPA CLASSIFICATION OF PACIFIC SALMON

For some species their life history involves multiple habitats (e.g. anadromous). EPA designated their habitat as fresh water/estuarine and marine on a case-by-case basis (Table 2 excerpt from USEPA 2002b). EPA classified the habitat of salmon based on commercial-landings data provided by the National Marine Fisheries Service for the period of 1989-1991 (65 FR 66469, 2000b). All landings of Pacific salmon, including Chum, Coho, King, Pink, or Sockeye were assigned to marine habitat. All landlocked Great Lakes salmon and farmed salmon received the classification of freshwater.

Migratory
Fish that move between multiple habitats (freshwater, estuarine, and marine).
Anadromous
Migratory fish that spend most of their lives in the sea and migrate to fresh water to breed (Myers, 1949 as reported in Bond, 1979)

As the landings of Pacific salmon were reported from the marine environment, Pacific salmon were classified as marine (USEPA 2002b) and excluded from the national default fish consumption rates for calculating water quality standards. However, states and authorized tribes can make alternative assumptions to specifically account for the dietary preferences of the specific population (Oregon) of concern.

TABLE 2 EPA HABITAT APPORTIONMENTS (EXCERPT FROM TABLE 2-1 HABITAT APPORTIONMENTS, EPA 2002B)			
		USDA CSFII food survey database	
Species	**Habitat**	**1994-1996**	**1998**
Flatfish	Estuarine (Flounder)	90	84
	Marine (Halibut)	10	16
Clams	Estuarine (softshell)	2	3
	Marine (Ocean Quahog, Quahog, Atlantic Surf, and remaining hardshell species)	98	97
Crab	Estuarine (Blue, Soft, Hard, Peeler, Dungeness)	66	47
	Marine (King, Snow, Jonah, and Other	34	53
Scallop	Estuarine (Bay)	0.6	0.7
	Marine (Calico and Sea)	99	99
Salmon	Freshwater (Great Lakes)	0.06	0.05
	Estuarine (Aquaculture)_	3	5
	Marine (Pacific)	97	95

4.2 PACIFIC SALMON IN OREGON WATERS

Pacific salmon and other migratory species present a rather complicated life history for establishing habitat preferences. Pacific salmon reside and pass through waters of the state. They are spawned and develop in waters of the state, and, after spending time in the ocean, return to Oregon freshwaters to spawn and die. Additionally, local data reviewed by the Human Health Focus Group (CRITFC 1994) indicate that Pacific salmon are caught in waters of the state in addition to the deep marine water landing data that EPA relied upon to classify Pacific salmon.

Different Pacific salmon species have different life histories, and therefore use fresh and estuarine waters for different lengths of time, and at different intensities. For example, Fall Chinook may be more at risk for uptake of toxic contaminants because of their greater use of shallow-water habitats in the estuary, where toxic sediments are most likely to accumulate (Fresh 2005). Spring Chinook enter fresh waters early in the year and do not spawn until late fall or early winter. These varying life histories also affect the exposure patterns in the marine portion of the Pacific salmon life history, where some stocks may spend more time in coastal waters within the regulatory boundaries of Oregon's water quality standards.

The source of the pollutants found in Pacific salmon tissue is not well understood. The Human Health Focus Group did not conduct a comprehensive review of the life histories or potential sources of contamination for Pacific salmon. Johnson *et al.* (2007a, b) studied the tissue residue levels of chemicals in juvenile Chinook salmon in the Columbia River. They detected the following fish tissue chemical residues: PCBs, DDT, and, to a small extent, aromatic hydrocarbons, chlordanes, aldrin, dieldrin and mirex. These data demonstrate exposure to toxic chemicals occurs during the freshwater portion of the Pacific salmon life cycle.

4.3 RELATIVE SOURCE CONTRIBUTION

If Pacific salmon are not included in the fish consumption rate, utilizing the concept of Relative Source Contribution (RSC) is another way to account for some of the potential risk from consuming Pacific salmon in addition to all other marine fish and shellfish. The purpose of the RSC concept is to account for all other sources of exposure other than those associated with consumption of freshwater and estuarine finfish and shellfish, such as skin absorption, inhalation, drinking water, marine fish, other foods, and occupational exposures.

EPA applies the concept of RSC to chemicals with a reference dose to account for exposure through consumption of marine fish, Pacific salmon and other non-fish sources. The RSC value is not applied to carcinogens. EPA's ambient water quality criteria guidance (USEPA 2000a) states that the concept of the RSC does not apply to carcinogens because regulatory agencies are only responsible for assessing incremental risk from exposure to contaminants in fish tissue and water and no other exposures. In addition EPA states that:

> "...health-based criteria values for one medium [water] based on linear low-dose extrapolation [cancer] typically vary from values for other media in terms of the concentration value, and often the associated risk level. …Therefore, the RSC concept could not … apply unless all risk assessments for a particular carcinogen … resulted in the same concentration value and same risk level; that is, an apportionment would need to be based on a single risk value and level." (USEPA 2000a)

The RSC value is applied to chemicals with a reference dose to ensure that exposure to these chemicals, when combined with all other sources will not exceed the reference dose (65 FR 66473, 2000). Details of how the RSC values are incorporated into the equation to calculate human health-based water quality criteria can be found in EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection for Human Health* (USEPA 2000a).

The RSC value could be applied to the 47 chemicals with a references dose within the current list of priority pollutants. Oregon currently applies the RSC values developed by EPA to human health-based water quality criteria for the following pollutants (more details are available in Appendix B):

- Antimony
- Methylmercury
- Thallium
- Cyanide
- Chlorobenzene
- 1,1, Dichloroethylene
- Ethylbenzene
- Toluene
- 1,2 Trans Dichloroethylene
- 1,2 Dichlorobenzene
- 1,4 Dichlorobenzene
- Hexachlorocyclo-pentadiene
- 1,2,4 Trichlorobenzene
- Gamma-BHC
- Endrin

The concept of the RSC is not applied to the other 32 toxicity reference dose-based criteria. This does not necessarily mean that other reference dose-based criteria do not have other routes of exposure. It simply means that there may not be enough data for EPA to establish RSC values for these other 32 chemicals.

At this time the only pollutant whose exposure pathway is known to be primarily from marine fish and Pacific salmon is methylmercury. The primary source of methylmercury is through consumption of marine fish. Oregon's current criterion for methylmercury incorporates an RSC value of 2.7×10^{-5} milligrams per kilogram (mg/kg) of body weight per day that accounts for the consumption of marine fish shellfish and salmon (Appendices B and C). All other water quality criteria for which RSC values have not been developed do not encompass protection of humans through exposure via consumption of marine fish or Pacific salmon.

EPA provides guidance for calculating RSC values outside of its own default values (Appendix D). This process requires robust datasets on sources of exposure for individual chemicals. Data on other sources of exposure do not exist for Oregon. It would be difficult for ODEQ to develop Oregon-specific RSC values without assistance from EPA.

If Oregon-specific RSC values cannot be derived, then states and tribes have the option to rely upon the EPA default RSC value of 20 percent (of the reference dose). In this approach states and tribes could apply an RSC value of 20 percent to the remaining 32 chemicals that have a reference dose. Since there are no data to evaluate whether the 20 percent default option for the remaining criteria satisfactorily accounts for exposure through Pacific salmon consumption and all other non-fish exposures, the Human Health Focus Group cannot evaluate the use of the RSC concept on its technical merits. Therefore, the use of a default RSC value of 20 percent remains a policy decision.

Double Counting
To prevent double counting, exposures considered through the relative source contribution factor should not be included in the fish consumption rate.

4.4 INCLUDING PACIFIC SALMON IN THE FISH CONSUMPTION RATE

Since Pacific salmon are a known part of the diet for fish-consuming populations in Oregon, the human health-based water quality criteria should account for the potential risk incurred from consuming Pacific salmon. The surveys reviewed by the Human Health Focus Group not only reveal that Pacific salmon is being eaten, but also indicate with varying degrees of accuracy how much Pacific salmon is being consumed. Knowing the amount of consumed Pacific salmon allows for measurable and scientifically defensible inclusion of Pacific salmon in the fish consumption rate. Including Pacific salmon in the fish consumption rate can provide more scientific certainty that Pacific salmon consumption is being accurately accounted for when calculating risk-based water quality criteria.

The alternative to including Pacific salmon in the fish consumption rate is using the concept of the RSC to account for Pacific salmon exposure. The concept of the RSC falls short of full protection because of insufficient data to calculate accurate RSC values, and the RSC process does not account for carcinogenic risk. However, there are reliable data available from studies on the consumption of Pacific salmon. Therefore, it is more accurate to account for the total human health risk by including Pacific salmon directly in the fish consumption rate rather than trying to address it through an estimated RSC value.

4.5 INCLUDING MARINE FISH IN THE FISH CONSUMPTION RATE

During discussions about inclusion of Pacific salmon in the fish consumption rate, the Human Health Focus Group also discussed the possibility of including all marine fish in the fish consumption rate. If a deep ocean fish such as tuna is consumed by an Oregonian, there is a potential that the fish may contain contaminants that would add to the health risk of the consumer. So, regardless of the source of the fish, fish consumers face potential risks. Although this is true, Oregon's fish consumption rate and its associated human health-based water quality criteria can only be applied to waters within the regulatory jurisdiction of the State of Oregon (OAR 340-041-0001(1)). The jurisdiction in marine waters is confined to Oregon's waters of the state, which extend three nautical miles into the Pacific Ocean from the Oregon coast.

5. SELECTING FISH CONSUMPTION RATES

5.1 PROCESS FOR SELECTING FISH CONSUMPTION RATES

A variety of quantitative fish consumption estimates were selected from the five surveys considered relevant and useful by the Human Health Focus Group:

- A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin (CRITFC 1994)
- A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region (Toy *et al.* 1996)
- Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region (Suquamish 2000)
- Asian and Pacific Islander Seafood Consumption Study (Sechena *et al.* 1999)
- Estimated Per Capita Fish Consumption in the United States (USEPA 2002b).

The following process was used by the Human Health Focus Group to refine the recommended fish consumption rates:

1) Eliminate fish consumption rates that include non-fish-consuming populations
2) Include all fish consumption estimates regardless of the source of the fish (harvested or purchased)
3) Include fish consumption estimates for all types of seafood (fish and shellfish species) from marine, freshwater, and estuarine habitats.

*1) Eliminate fish consumption rates that include people who don't eat fish***.**

Oregon's human health-based water quality criteria are developed to specifically protect individuals who eat fish. Therefore it seems most appropriate to select those fish consumption estimates for people who eat fish and exclude estimates that include people who don't eat fish. The inclusion of the non-fish consuming population lowers the consumption rate and thus reduces the level of protection for the people who do eat fish.

2) *Include all fish consumption estimates regardless of the source of the fish (harvested or purchased).*

In some surveys, the respondents report on the source of the fish they consume. Sources of fish and shellfish can include self-harvested, or purchased from stores or restaurants. The fish and shellfish that are purchased may be locally caught. The Human Health Focus Group decided that it is more important to capture the fish consumption rate for all fish consumed rather than excluding those estimates for fish that was purchased.

3) *Include fish consumption estimates for all types of seafood (fish and shellfish species) from marine, freshwater, and estuarine habitats***.**

Deep ocean fish that are found beyond three nautical miles off the Oregon coast (tuna, shark, halibut, etc) are not included in the current fish consumption rate in Oregon. ODEQ was not able to provide a list of the exact species that would be considered near-shore marine fish that live within three nautical miles of the coast. Therefore these particular species could not be isolated from the deep ocean fish in the surveys.

In addition to marine species, EPA's national guidance recommends that Pacific salmon and other migratory species be excluded from the fish consumption rates for water quality criteria.

Exposure to chemicals in marine fish and migratory fish including Pacific salmon is accounted for through the concept of the RSC. Thus, people who eat these fish may be protected through an indirect measure of exposure. However, there is only one chemical (methylmercury) where marine species (Pacific salmon and other migratory species), are accounted for using the concept of RSC. Due to EPA's policy regarding the lack of data that prevents the application of the concept of RSC across all other chemicals and endpoints such as carcinogenesis, the Human Health Focus Group chose not to recommend use of the RSC approach.

Oregonians eat a variety of fish species that may be harvested from fresh water, estuarine, or marine habitats. All types of fish and shellfish are included in the fish consumption rates recommended by the Human Health Focus Group. In particular, Pacific salmon is a major component of fish consumption in Oregon. Including Pacific salmon and other migratory species in the fish consumption rate can provide more scientific certainty that these species are accurately accounted for when calculating water quality criteria.

The alternative to including salmon in the fish consumption rate, as explained in the report, is using the concept of the RSC to account for salmon exposure. This will fall short of full protection because sufficient data are not available to calculate accurate RSC values, and the RSC process does not account for carcinogenic risk. Therefore, it is more accurate to account for the total human health risk by including salmon directly in the fish consumption rate itself.

5.2 RECOMMENDED FISH CONSUMPTION RATES

The final fish consumption rates identified by the Human Health Focus Group are presented in Table 3. The range of fish consumption rates presented in Table 3 provides a scientific basis for choosing a fish consumption rate and establishing water quality criteria that are protective of Oregonians that eat fish. A range of statistical values from each of the five studies: the mean, the median, and the 75th, 90th, 95th, and 99th percentiles are listed in Table 3. Note that there are six surveys reported in five studies. The Toy *et al.* report includes surveys of two tribes (Squaxin Island Tribe and Tulalip Tribes).

TABLE 3. ADULT FISH CONSUMPTION RATES (GRAMS PER DAY) RECOMMENDED BY THE HUMAN HEALTH FOCUS GROUP FOR OREGON HUMAN HEALTH-BASED WATER QUALITY CRITERIA.

Group	Species included in consumption rate evaluation	N	Statistic					
			Mean	Median	Percentile			
					75th	90th	95th	99th
Tulalip Tribe	Anadromous and estuarine finfish and shellfish	73	72	45	85	186	244	312
Suquamish Tribe	Anadromous and estuarine finfish and shellfish	284	214	132	NA	489	NA	NA
Squaxin Island Tribe	Anadromous and estuarine finfish and shellfish	117	73	43	NA	193	247	NA
Columbia River Tribes	Freshwater and anadromous finfish	512	63	40	60	113	176	389
Asians & Pacific Islanders	Anadromous and estuarine finfish and shellfish	202	117	78	139	236	306	NA
U.S. General Population	Freshwater, anadromous, estuarine, and marine finfish and shellfish	2585	127	99	NA	248	334	519

N = Number of adults in survey
NA= Statistical value not available.
Adults are 18 years or older for all surveys except Suquamish; Suquamish adults were 16 years or older
All values reported in this table are described in Table 1 (located at the end of this document)
Tulalip Tribes and Squaxin Island Tribe from Toy *et al.* 1996.
Suquamish Tribe from Suquamish. 2000.
Columbia River Treaty Tribes from CRITFC. 1994.
The Columbia River Tribes did not report marine fish consumption;
The 75, 90, 95 and, 99th percentiles are interpolated from percentiles reported in CRITFC 1994
Asian Pacific Islanders from Sechena *et al.* 1999.
US General Population from US EPA. 2002b.

The Human Health Focus Group only included fish consumption rates (Table 3) for adults in their recommended list of fish consumption rates. When fish consumption rates from these surveys are reported as grams per person per day, the consumption for children is lower than that of the adults and thus when expressed as an exposure value of grams per day, the adult levels may be protective of children. At this time the USEPA recommended water quality criteria are derived for adults with an average body weight of 70 kg (USEPA 2000a). With respect to exposure, children are particularly vulnerable compared to adults due to their lower body weight, differing metabolism, and behaviors. Thus it may be appropriate for the State of Oregon to develop water quality criteria for children.

Table 3 does not include the fish consumption rate of 17.5 g/day which is the basis for current Oregon water quality criteria. This number is considerably lower than the estimates recommended by the Human Health Focus Group because it was calculated in part by including people who don't eat fish and excluding Pacific salmon as well as other migratory and marine species. It is not an accurate estimate of long-term fish consumption rates for people who eat fish. For example, the fish consumption rate of 248 g/day for the general population (USEPA 2002b) shown in Table 3 is more than 14 times greater than the current EPA default fish consumption rate (17.5 g/day) and more than double the 90th percentile (113 g/day) fish consumption rate for the Columbia River Basin Tribes (CRITFC 1994). For the U.S. general population, the mean seafood consumption rate for adults who consume fish is 127 g/day (+/- 6 g/day), while five percent of the adult population consumes 334 grams per day or more (+/- 15 g/day). These fish consumption rates are based on a sample of 2,634 adult consumers 18 years and older (USEPA 2002b, Section 5.2.1.1.Table 4.).

All the fish consumption rates in Table 3 are higher than the current 17.5 g/day fish consumption rate used in the current Oregon water quality criteria. The reason for this is that the Human Health Focus Group included only fish consumption rates for people who eat fish; and included all marine and migratory species described in the regional studies. The 90th and 95th percentile consumption rates for US fish consumers shown in Table 3 are consistent with, and are in fact greater than, the corresponding consumption levels documented in the Pacific Northwest regional studies identified by the Human Health Focus Group.

The Human Health Focus Group recommends selecting an Oregon fish consumption rate from a range of values that includes only those data for fish consumers (since this is about people who eat fish) and all types of fish (fresh water, estuarine, marine, and migratory finfish and shellfish). The national survey fish consumption survey (USEPA 2002b), is important to Oregon because the fish consumption rates from the national survey reflect the general U.S. population. Since there is no similar state-wide survey of all fish-consuming populations in Oregon, the national survey remains a relevant contextual piece of information for determining a change in the Oregon fish consumption rate.

The Human Health Focus Group discussed how recommendations for a fish consumption rate should be presented for use by Oregon. Scientists frequently present their scientific results in two ways, one to represent uncertainty and one to represent variability. Scientists present uncertainty information as 95 percent confidence levels around the mean which is based on a standard error calculation.

For the types of issues the Human Health Focus Group considered in this report, variability in fish consumption rates, scientists usually present the 95th percentile which represents the variability of the population at two standard deviations from the mean (Kavloch *et al.* 1995). The majority of scientists on the Human Health Focus Group referred to this value when they discussed approaches for communicating how the fish consumption values could range for the Oregonian populations. One member used the 90th percentile as the point of reference. Both values are presented in Table 3.

Although the survey (cited here) of Japanese and Korean communities was not reviewed by the Human Health Focus Group because the results were not yet published, the results of the survey add to the conclusions made by the Human Health Focus Group about relevant fish consumption rates to recommend for the Oregon population.

> *Mercury Exposure from Fish Consumption within the Japanese and Korean Communities*. Ami Tsuchiya, Thomas A. Hinners, Thomas M. Burbacher, Elaine M. Faustman, Koenraad Mariën. Journal of Toxicology and Environmental Health 2008 (in press).
>
> *Fish intake guidelines: Incorporating n-3 fatty acid intake and contaminant exposure in the Korean and Japanese communities*. Ami Tsuchiya, Joan Hardy, Thomas M. Burbacher, Elaine M. Faustman, Koenraad Mariën. American Journal of Clinical Nutrition. 2008 (in press).

The survey, conducted by scientists at the Washington State Department of Health and University of Washington, assessed fish consumption in woman in Asian populations, Japanese and Korean, living in Western Washington. The results indicate fish consumption rates higher than the national average. The mean fish consumption rates for the Japanese and Korean populations (73 and 82 grams/day, respectively) fall within the range of mean rates of the surveys assessed by the Human Health Focus Group (shown in Table 3). The 95th percentile of the rates was 188 grams/day for the Japanese population and 230 grams/day for the Korean population. Both of these values also fall within the range of 95th percentiles of surveys assessed by the Human Health Focus Group (shown in Table 3) and thus provide additional support for Pacific Northwest fish consumption values of relevance for Oregon populations.

5.3 OREGON POPULATION-BASED FISH CONSUMPTION RATES

It is important to consider the number of Oregonians who are high consumers of seafood based upon the fish consumption rates shown in Table 3 of this report. In order to do this we have used estimates of the population based upon the 2003 Oregon Population Report of the Population Research Center at Portland State University. In these calculations, we assume that the Oregon population’s dietary patterns are similar to the general U.S. population reported in Table 3. The data for the U.S. general population in Table 3 of this report, which comes from Section 5.2.1.1, Table 4, in USEPA Estimated Per Capita Fish Consumption in the United States August 2002b, is for adult consumers of seafood 18 years of age or older (n=2,634). Here, seafood is defined as finfish and shellfish from fresh, estuarine, and marine environments. The population of Oregon in 2003 was 2,655,700 adults, 18 years and older (see Table 9 of 2003 Oregon Population Report).

In the US EPA 2002 survey used to generate the general population fish consumption rates in Table 1 (located at the end of this document), 28 percent of the population interviewed were consumers (see Section 5.1.1.1 Figure 4 in USEPA Estimated Per Capita Fish Consumption in the United States August 2002b). In the study, participants were asked to recall their seafood consumption on two non-consecutive days and consumers were participants who ate seafood on at least one of the two days. Assuming the Oregon population is similar to the U.S. general population’s diet, we estimate that there are:

2,665,700 X 28% = 746,400 adult Oregonians consuming fish.

If we consider high consumers of fish as being those at the 90th percentile and above (consuming at or above 248 grams of fish per day in Table 3 of this report) this would include:

746,400 X 10% = 74,640 adult Oregonians who are high consumers.

248 grams per day is equivalent to consuming 8.6 oz. of seafood per day, which is a plausible daily intake fish consumption rate for high consumers. This calculation only considers adult consumers and does not consider children who consume fish.

In 2003, the population of Oregonians under the age of 14 years old was 722,885. Applying the same calculation as that used for adults, children with a fish consumption rate of 191 grams of fish per day (USEPA 2002b, Section 5.2.1.1.Table 4)), would result in:

772,885 x 28% x 10%= 21,640 young Oregonians (under 15 years old) who are high consumers.

6. HUMAN HEALTH RISK AND WATER QUALITY CRITERIA

6.1 HUMAN HEALTH RISK

Risk assessment is the determination of the likelihood of adverse human health effects due to exposure to toxic chemicals. This determination is made by combining estimates of exposure through ingestion, inhalation, or skin absorption of a chemical with an estimate of toxic effects of that chemical. Exposure includes measures of duration and frequency of contact as well as body weight. Quantitative and qualitative estimates of exposure and toxicity are combined to estimate risk.

> The lifetime probability of developing cancer for the American male is 1 in 2; for the American female it is 1 in 3 based on data from 2002-2004 (American Cancer Society 2008).

Toxicology provides information on the nature of the adverse effects that can be caused by the pollutant under consideration and the doses that cause the effect. Adverse health effects can range from immunological diseases to birth defects or cancer. The type of health effect caused by exposure to toxic chemicals has historically been divided into two categories based on the biological endpoints observed: 1) cancer and 2) non-cancer effects (e.g. neurological, cardiovascular, reproductive, developmental and immunological effects and blood and metabolic disorders). Toxicity information is usually obtained from animal experiments. Such studies can provide important dose-response information for identifying a reference dose for individual chemicals. The level of effect relates directly to the amount and duration of exposure. Studies of human populations can provide important information about sensitivity and variability of humans and can also provide information about exposure and the absorption, distribution, metabolism and excretion of chemicals in humans.

Non-cancer chemicals affect the function of various organ systems. The measure of effect for these chemicals is the reference dose. The reference dose is defined as an estimate of a daily oral exposure to a chemical by humans, including sensitive subpopulations, which are likely to be without an appreciable risk of causing adverse effects over a lifetime. Exposure below the reference dose is considered to be without statistically or biologically significant adverse effects. Once the reference dose is exceeded an individual is at increased risk of adverse health effects.

For most cancer-causing chemicals there is no toxicity threshold or reference dose. Because carcinogenic chemicals are thought to initiate the cancer process at almost any concentration, a dose-response parameter referred to as the cancer slope factor is used for chemicals that display toxic behavior such that the carcinogenic risk increases linearly as the chemical dose increases. The cancer slope factor is a measure of chemical potency.

Risk estimates for carcinogens are expressed as the incremental probability of developing cancer (e.g., an additional one in one million chance of developing cancer) over a lifetime of exposure to potential carcinogens. Risk estimates for non-cancer causing chemicals are expressed as a hazard index or the ratio of the dose to the individual or population divided by a reference dose.

EPA records the most current scientific judgment on chemical toxicity in the Risk Integrated Information System (IRIS). IRIS is an electronic online data base maintained by EPA that provides chemical-specific risk information on the relationship between chemical exposures and estimated human health effects. The IRIS chemical files contain information on factors that are used in estimating risk or developing water quality such as oral Reference Doses (RfDs) and inhalation Reference Concentrations (RfCs) for chronic noncarcinogenic health effects; oral and inhalation cancer slope factors (CSF) and unit risks for chronic exposures to carcinogens; Drinking Water Health Advisories (HAs); EPA regulatory action summaries; and, supplementary data on acute health hazards and physical/chemical properties. More information on individual pollutants can be found online at: http://www.epa.gov/iriswebp/iris/index.html.

6.2 HUMAN HEALTH WATER QUALITY CRITERIA

A human health water quality criterion is the highest concentration of a pollutant in water that is not expected to pose a significant risk to human health. Human consumption of contaminated aquatic life is of primary concern because the presence of even extremely low ambient concentrations of bioaccumulative pollutants in surface waters can result in chemical residue concentrations in fish tissue that may pose a human health risk.

> EPA's recommended procedures for developing human health criteria are provided in the revised *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (USEPA 2000a).*

ODEQ has numeric human health-based water quality criteria for 130 toxic pollutants. Human health-based water quality criteria regulatory limits are derived for: 1) cancer and 2) non-cancer effects. In the case of carcinogens:

> "the [ambient water quality criterion] represents the water concentration that would be expected to increase an individual's lifetime risk of carcinogenicity from exposure to the particular pollutant by no more than one chance in one

> million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources." (USEPA 2000a)

The acceptable level of cancer risk is usually expressed as an incremental cancer risk or an additional cancer risk.

The mathematical estimation of risk is different for carcinogenic and non-carcinogenic biological endpoints (Equations 1 and 2). When developing water quality criteria, the regulatory agency establishes the acceptable risk level and then determines the concentration in water and fish tissue that will not exceed the acceptable risk levels.

Exposure scenarios for the derivation of human health-based water quality criteria address two types of exposure: 1) combining ingestion of fish and surface water, and 2) ingestion of fish alone. Exposure factors include: bioconcentration, body weight, drinking water ingestion rate, and fish ingestion rates. Other exposure route information (skin absorption, other dietary sources, inhalation, etc) should be considered and incorporated into human exposure evaluations as the RSC values.

EPA generally assigns a mix of central tendency values (e.g., average for the population) and high end values (e.g., 90th or 95th percentiles) for exposure factors such as ingestion rates and body weight. For the purposes of developing water quality criteria EPA uses an average adult body weight of 70 kg. The water quality criteria equations (Equations 1 and 2) for chemical exposure are defined as body weight divided by the drinking water intake rate added to the fish ingestion rate, multiplied by the bioconcentration of the chemical from water into fish tissue.

For carcinogens, the water quality criteria are calculated by dividing the acceptable risk level by the rate of tumor production (cancer slope factor). This estimate of toxicity is then multiplied by the chemical exposure to estimate risk (Equation 1). The regulatory agency or other decision makers prescribe the acceptable risk level. ODEQ established an acceptable cancer risk level of an additional one in one million chance of developing cancer.

> The bioconcentration factor (BCF accounts for the uptake by fish or shellfish of a pollutant from the surrounding water. Units of liters/kg (L/kg)

The following description of the estimation of the water quality criteria for dioxin and DDT illustrates the relationship of toxicity, the fish consumption rate, and the bioconcentration factor with the ambient water quality criterion. Dioxin (cancer slope factor 156,000 per mg/kg-day) is much more potent than DDT (cancer slope factor 0.34 per mg/kg-day). DDT has a higher bioconcentration factor (53,600 L/kg) than dioxin (5,000 L/kg). Using the current ODEQ fish consumption rate of 17.5 grams per day the water quality criterion for dioxin will be 0.00000000513 μg/L; DDT will be 0.000219 μg/L. Even though the uptake of DDT into fish tissue is greater than the uptake of dioxin the high toxicity of dioxin results in a lower ambient water quality criterion.

If the fish consumption rate were increased by ten-fold to 175 grams per day the water quality criterion for dioxin would be 0.000000000513 µg/L; 0.0000219 µg/L for DDT. Thus, if someone eats ten times more fish than the current ODEQ rate of 17.5 grams/day they would exceed the Oregon acceptable cancer risk level of an additional one in one million chance of developing cancer. Their risk of developing cancer from exposure to dioxin or DDT would be one in one hundred thousand.

Equation 1 ***Cancer***

$$\text{AWQC} = \text{Risk/CSF} \bullet \left(\frac{\text{BW}}{\text{DI} + [\text{FCR} \bullet \text{BCF}]} \right)$$

Equation 1 ***Cancer Dioxin***

$$0.00000000513\ \mu\text{g/L} = 156{,}000\text{/mg/kg/day} \bullet \left(\frac{70\text{ kg}}{2\text{ L/day} + [17.5\text{ g/day} \bullet 5{,}000\text{ L/kg}]} \right)$$

Equation 1 ***Cancer DDT***

$$0.000219\ \mu\text{g/L} = 0.34\text{/mg/kg/day} \bullet \left(\frac{70\text{ kg}}{2\text{ L/day} + [17.5\text{ g/day} \bullet 53{,}600\text{ L/kg}]} \right)$$

AWQC = Ambient Water Quality Criteria (µg/L)
BW = Body Weight (kg)
DI = Drinking Water Intake (L/day)
FCR = Fish Consumption Rate (kg/day)
BCF = Bioconcentration Factor of chemical from water to fish tissue (L/kg)
Risk = Acceptable Cancer Risk Level (Oregon = an additional one in one million chance of developing cancer)
CSF = Cancer Slope Factor

For chemicals with a reference dose, the water quality criteria are calculated by multiplying the reference dose times the chemical exposure (Equation 2). The RSC is either subtracted from the reference dose if the concentration of the chemical in other media is known (methylmercury Appendix C) or a percentage of the exposure is attributed to freshwater and estuarine fish and shellfish consumption (20 percent). The effect of toxicity, the fish consumption rate, the bioconcentration factor, and the RSC on the determination of water quality criteria for chemicals with a reference dose is illustrated by the following examples for endrin and pyrene.

The reference dose for the pesticide endrin is 0.0003 mg/kg/day. In addition only a fraction (20 percent) of the exposure to endrin is attributed to freshwater and estuarine fish and shellfish. The primary source of endrin is from its presence in air, water, sediment, soil, fish, and other aquatic organisms (Appendix C). The bioconcentration factor for endrin is 3,970 L/kg. The reference dose for pyrene is 0.03 mg/kg/day. The bioconcentration factor for pyrene is 30 L/kg. With the current ODEQ fish consumption rate of 17.5 grams per day, the water quality criterion for endrin is 0.0605 μg/L; the water quality criterion for pyrene is 4,000 μg/L. Endrin's higher toxicity and bioconcentration factor result in a lower water quality criterion for endrin than pyrene. If the fish consumption rate were increased 10 times to 175 grams per day the water quality criterion for endrin would be 0.00605 μg/L; for pyrene it would be 400 μg/L. The people who eat ten times more fish than the current fish consumption rate would exceed the reference dose by ten.

ODEQ established the level of protection from exposure to chemicals with a reference dose as equal to or less than the reference dose for a specific chemical. The reference dose for endrin is based on adverse effects to the liver; for pyrene its adverse health effects to the kidney. Thus people who eat more than 17.5 grams per day would be at risk to adverse effects to their kidney or liver.

Equation 2 ***Non - Cancer***

$$\text{AWQC} = \text{RFD} \cdot \text{RSC} \cdot \left(\frac{\text{BW}}{\text{DI} + [\text{FCR} \cdot \text{BCF}]} \right)$$

Equation 2 ***Non - Cancer Endrin***

$$0.0605\ \mu\text{g/L} = 0.0003\ \text{mg/kg/day} \cdot 0.2 \cdot \left(\frac{70\ \text{kg}}{2\text{L/day} + [17.5\ \text{g/day} \cdot 3{,}970\ \text{L/kg}]} \right)$$

Equation 2 ***Non - Cancer Pyrene***

$$4000\ \mu\text{g/L} = 0.03\ \text{mg/kg/day} \cdot \left(\frac{70\ \text{kg}}{2\text{L/day} + [17.5\ \text{g/day} \cdot 30\ \text{L/kg}]} \right)$$

AWQC = Ambient Water Quality Criteria (μg/L)
BW = Body Weight (kg)
DI = Drinking Water Intake (L/day)
FCR = Fish Consumption Rate (kg/day)
BCF = Bioconcentration Factor of chemical from water to fish tissue (L/kg)
RFD = Reference Dose (mg/kg/day)
RSC = Relative Source Contribution

6.3 SENSITIVE POPULATIONS AND TOXICITY

The Human Health Focus Group discussed populations that may be more susceptible to environmental toxicants due to special exposure circumstances or sensitivity to the toxicity of certain pollutants. Of importance is early *in utero* and post-natal exposure of infants and children, and the elderly. There are critical periods of fetal development and the effects of prenatal chemical exposures will differ depending on the dose and the timing of the exposure (Needham *et al.* 2008). These populations include fetuses, children, and the elderly. With respect to exposure, children are particularly vulnerable as compared to adults due to their lower body weight, differing metabolism, and behaviors.

The human health-based water quality criteria are calculated using a default adult male body weight of 70 kilograms. For chemical exposure you need to know not only the amount and rate of chemical intake but also body weight. Chemical exposure is expressed relative to body weight and is calculated from the concentration of chemical in fish tissue and the frequency and duration of fish consumption. In the case of adult males (18-74 years of age), mean body weight is 78 kg (172 lbs), with 5th and 95th percentile weights of 59kg (130 lbs) to 103 kg (227 lbs), respectively. Mean adult female body weight for the same age range is 65 kg (143 lbs), with 5th and 95th percentiles of 48 kg (106 lbs) and 93 kg (205 lbs), respectively (USEPA 1997).

The variation of weight between children and adults is significant, considering that newborns typically weigh 4 kg (8 lbs) while adults can reach weights of 113 kg (250 lbs). Thus, risk estimates for children versus adults can vary considerably. In the current water quality criteria guidance EPA recommends using an average adult body weight of 70 kg (154 lbs) as a default body weight value in the water quality criteria calculations. While use of water quality criteria based on the adult default weight provides adequate protection for adults, it may not provide adequate protection for children.

As discussed in USEPA 2000a, the EPA encourages states and authorized tribes to use alternative body weight assumptions for population groups other than the general population and to use local or regional data for its calculations. In the case of children, EPA's water quality guidance (USEPA 2000a) recommends using 30 kg (66 lbs)as a default children's body weight to provide additional protection for children when chemicals of concern indicate that health effects (i.e developmental neurotoxicity, immunotoxicity, etc.) may be of particulate concern for these early ages. As this would potentially be the case for chemicals to be considered under Oregon's water quality standards, we have included Table 4 which lists fish consumption per body weight per children.

In the surveys reviewed for this report, the consumption rate for children was quite variable. In all cases the consumption rate for children was less than that for adults on a gram-per-day basis (Table 1, located at the end of this document). However, when the rates were computed with individual body weight, the children's levels included levels greater than the adults (Table 4). Note that in Tables 4 a, b, c and d, the grams of fish consumed per kg body weight per day for children at ages 6 and under all had 90th or 95th percentile values approximately 2-fold higher than those listed for the adult 90th and 95th percentile values except for the Tulalip and Squaxin Island tribes. Thus, these figures suggest the need to consider greater fish consumption rates than adult rates to ensure full protection of children specific exposure factors.

The term "children" in this document refers to birth through adolescence (16-18 years).

The potential for toxicity and adverse health outcomes varies with life stage and/or health status. Toxicity values should incorporate consideration of developmental life stages that might be particularly vulnerable. The information is then incorporated into a risk assessment. For humans, early life stages (e.g. fetus, infant) may be vulnerable to toxic chemical effects due to immature or developing metabolic and organ systems. Effects that are reversible in adults may not be reversible during the developmental stage. The concern for women of child bearing age is risk to offspring during development. There is also concern for the elderly who may be more susceptible than younger adults because of their reduced capacity for recovery due to illness, age, or ability to eliminate or metabolize chemicals. There are also people whose existing health condition (e.g. immune suppression, asthma) may exacerbate the harmful affects of toxic chemicals.

In many cases, the toxicity of chemicals is derived from laboratory studies of animals. Depending on the pollutant of interest, some of these studies consider sensitive populations, and other studies may not. Many of the toxicity values are in fact based on doses for adults so there is no direct correlation between toxicity and life stage. EPA's Integrated Risk Information System database provides information on how the toxicity of each pollutant was derived.

TABLE 4. FISH CONSUMPTION RATES (PER BODY WEIGHT) FOR CHILDREN					
Table 4a. All fish g/kg-body weight/day (excerpt from Section 4.1.1.2, Table 3 and Table 5 USEPA 2002b)					
Consumers and non consumers					
Age (years)	**N**	**Mean**	**Median**	**90%**	**95%**
3 to 5	4112	0.29		1.10	2.00
6 to 10	1553	0.21		0.78	1.40
11 to 15	975	0.16		0.57	1.10
15 to 44	4644	0.19		0.71	1.10
>44	5333	0.24		0.84	1.30
Table 4b. All fish g/kg- body weight/day (excerpt from Tables T-3 and T-14 Suquamish 2000)					
Children's rate varied from zero consumption of certain shellfish to 100% consumption for salmon					
Age (years)	**N**	**Mean**	**Median**	**90%**	**95%**
0 to 6	31	1.5		3.4	
16 to >55	92	2.7		6.2	
TABLE 4. FISH CONSUMPTION RATES (PER BODY WEIGHT) FOR CHILDREN (CONTINUED)					
Table 4c.All fish g/kg-body weight/ day (excerpt from Table 3 and Table 8, Toy *et al.* 1996)					
Non-consumers for children was 29% for Tulalip Tribes and 25% for Squaxin Island Tribe					
Tulalip Tribes					
Age (years)	**N**	**Mean**	**Median**	**90%**	**95%**

0 to 5	21		0.08	0.74	
18 to >65	73	0.89	0.55		2.88
Squaxin Island Tribe					
Age (years)	**N**	**Mean**	**Median**	**90%**	**95%**
0 to 5	48		0.51	2.06	
18 to >65	117	0.89	0.52		3.01

Table 4d. All fish mg/kg-body weight/day (excerpt from Section 5.2.1.2., Table 3 and Table 5 (USEPA 2002b)

Consumers only					
Age (years)	**N**	**Mean**	**Median**	**90%**	**95%**
3 to 5	779	4.20	3.60	8.00	10.00
6 to 10	250	3.20	2.50	6.50	8.70
11 to 15	164	2.20	1.60	4.40	6.20
15 to 44	1102	1.80	1.40	3.50	4.80
>44	1567	1.70	1.40	3.40	4.30

N=Number of people in survey

NOTE: As with all studies, when measured body weight values are not available for individual study/survey participants, caution must be taken as evaluations of retrospectively added default body weight values can be shown to have potential to both over as well as under estimate relative exposures (Marien *et al.* 2005).

6.4 CHEMICAL INTERACTIONS

Exposure to mixtures of chemicals poses a special circumstance for toxicologists. Individual chemicals may interact in a variety of ways. The impact of multiple chemicals on toxicological response can be additive (e.g., toxicity by the same mode of action), less-than-additive (e.g., zinc inhibits cadmium toxicity by reducing the amount of cadmium absorbed), or greater-than additive (e.g., enhanced carcinogenicity for asbestos and tobacco smoke) (USEPA, 2000b). Chemical interactions may also include antagonistic interactions as well as no influence (USEPA 2000b).

Human health-based water quality criteria are calculated for individual chemicals. The calculated risk of any single chemical does not take into account the interaction of chemical mixtures that may occur when people are exposed to multiple chemicals simultaneously. Thus, human health-based water quality criteria do not take potential exposure to multiple chemicals into account.

The number of complex mixtures that may be found in the environment and concomitantly in fish tissue is difficult to predict. Thus, development of an interactive scheme for all possible chemical combinations is impossible. While the Human Health Focus Group recognizes this limitation, the lack of accounting for chemical interactions is a shortfall in the overall protectiveness of the human health-based water quality criteria. The Human Health Focus Group recommends that there be an accounting for this interaction when criteria are used to establish limits for specific regulatory actions (e.g. Total Maximum Daily Loads, water quality permits, hazardous waste cleanup) where the chemical regime is known.

In addition to concerns with potential exposure regarding the unknown interaction of multiple pollutants in fish tissue that is ingested there are the potential benefits that may occur through the concurrent ingestion of nutrients present in certain fish tissue, such as omega-3-fatty acids (e.g. docosahexaenoic acid and eicosapentaenoic acid) (Oken *et al.* 2005).

7. CONCLUSIONS

The following conclusions are based on the review of the fish consumption surveys discussed in this report as well as the expertise of the Human Health Focus Group.

The Human Health Focus Group was asked to respond to three questions posed by ODEQ, The Confederated Tribes of the Umatilla Reservation and EPA as part of the Fish Consumption Rate Project. The three questions were:

1) Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on when selecting a fish consumption rate to use in setting water quality criteria?
2) How should Pacific salmon be considered in selecting a fish consumption rate and/or setting criteria?
3) To what extent are populations who consume more than the current fish consumption rate of 17.5 g/day at a greater risk for adverse health impacts?

1) Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on when selecting a fish consumption rate to use in setting water quality criteria?

The Human Health Focus Group was able to identify multiple regionally relevant studies of high quality for selecting a fish consumption rate. Indeed, these studies cover not only the Pacific Northwest but the United States and the globe. Each of these studies provides a fresh view of the amount of fish that people consume over their lifetime. The national and international studies, provided as additional references, confirm the view that the level of fish consumption is quite similar across different cultures and countries. The specific types of fish consumed varies across populations.

The Human Health Focus Group reduced its list of nine relevant studies to five that are most useful for recommending fish consumption rate(s) to ODEQ, EPA, and CTUIR. Within these studies there is definitely enough information to provide the State of Oregon with reliable estimates of risk. While these surveys were not specifically done for the people of Oregon, they provide a relevant and reliable range of rates that may be considered by the state.

The Human Health Focus Group also agreed that:

- The current fish consumption rates may be suppressed due to pollution and/or decreased fish abundance
- The current rate of 17.5 grams per day does not reflect Oregon or US population fish consumption rates
- The fish consumption rate should include fish consumers only

- All types of fish should be included in the fish consumption rate regardless of whether they were bought or locally harvested
- An upper-bound fish consumption rate(s) (90 percent or 95 percent, Table 3) should be adopted by ODEQ for Oregon fish consumers

2) How should Pacific salmon be considered in selecting a fish consumption rate and/or setting criteria?

The Human Health Focus Group unanimously agreed Pacific salmon should be included in the fish consumption rate. They generally are the primary choice of fish for most fish consumers in the Pacific Northwest.

The RSC factor is not sufficiently defined to allow accounting for contaminant exposure through consumption of Pacific salmon or marine species. All members of the Human Health Focus Group agreed that data available in the surveys reviewed by the Human Health Focus Group did not distinguish between near shore marine species and deep ocean species. Therefore, the recommended fish consumption rate should include all types of marine species since the open ocean and near shore species typically found in Oregon could not be differentiated in the studies reviewed.

3) To what extent are populations who consume more than the current fish consumption rate of 17.5 grams per day (g/day) at a greater risk for health impacts?

The Human Health Focus Group finds that the current fish consumption rate would leave a proportion of the population of Oregon without protection. People who eat more than 17.5 grams per day are at an increased risk of heart, kidney or liver disease, neurological and developmental effects, cancer, and other health effects. This is a particular concern for vulnerable populations based on age, gender, or health status. The level of concern increases with higher fish consumption rates and for children since the relative consumption per body weight may be greater than these body weight-based values in adults.

In summary, people who eat more than 17.5 g/day of fish and shellfish will exceed the reference dose, or the level which is considered acceptable by EPA and at which there are no expected adverse health effects. The extent and specificity of that risk is dependent upon the toxicity of the individual chemical and cannot be easily quantified without specific pollutant considerations. People consuming more than 17.5 g/day of fish will also exceed the Oregon acceptable cancer risk level of an additional one in one million chance of developing cancer established by the ODEQ.

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
NOTE: THE COLUMN SEAFOOD SOURCE REFERS TO WHETHER FISH WERE HARVESTED LOCALLY OR PURCHASED.
THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile 75th	90th	95th	99th	
Surveys reviewed by the HHFG												
1	Tulalip Tribes[a]	Children (0-5 years old)	Consumer only	All	Anadromous & resident finfish & shellfish	3.6	1.2	4.5	11.2			Toy et al 1996
2	Squaxin Island Tribe[v]	Children (0-5 years old)	Consumer only	All	Anadromous & resident finfish & shellfish	12.5	7.7	18.2	31.3			Toy et al 1996
3	Suquamish Tribe[u]	Children (9 months to 6 years old)	Consumer only	All	Anadromous & resident finfish & shellfish	24	12		57			Toy et al. 1996
4	Columbia River Tribes[p]	Children (0-5 years old)	Consumer only	All	Anadromous & resident fish	19.6		~22	~40	~68	~129	CRITFC 1994
5	Columbia River Tribes - Reevaluation of data[aa]	Children (0-5 years old)	Consumer only	All	Anadromous & resident fish	26.7	16.2		64.8	81	162	CRITFC 1994

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
NOTE: THE COLUMN SEAFOOD SOURCE REFERS TO WHETHER FISH WERE HARVESTED LOCALLY OR PURCHASED.
THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
6	U.S. General Population[q]	Children (3-5 years old)	Consumer + Non-consumer	All	Resident finfish & shellfish from fresh and estuarine environments	2.19		NA	0.05	12.2	52.46	USEPA 2002
7	U.S. General Population[q]	Children (3-5 years old)	Consumer + Non-consumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	7.7		NA	32.56	51	100	USEPA 2002
8	U.S. General Population[r]	Children (3-5 years old)	Consumer only	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	74	64	NA	149	184	363	USEPA 2002
9	U.S. General Population[r]	Children (3-5 years old)	Consumer only	All	Resident finfish & shellfish from fresh and estuarine environments	40	23	NA	95	129	205	USEPA 2002
10	Lake Whatcom (WA) Fisherman[x]	Children	Consumer only	Lake Whatcom (WA)	Resident fish		3.6					WDOH 1997

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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
11	Columbia River Tribes[o]	Women who have breastfed (36% of survey respondents)	Consumer only	All	Anadromous & resident fish	59.1		~58.5	~112	~174	~278	CRITFC 1994
12	U.S. General Population[s]	Women (15-44 years old)	Consumer only	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	108	77	NA	221	315	494	USEPA 2002
13	U.S. General Population[t]	Women (15-44 years old)	Consumer only	All	Resident finfish & shellfish from fresh and estuarine environments	75	36	NA	172	273	502	USEPA 2002
14	Tulalip Tribes[a]	Adults	Consumer only	All	Anadromous & resident finfish & shellfish	72	45	85	186	244	312	Toy et al 1996
15	Tulalip Tribes[a]	Adults	Consumer only	Harvested anywhere	Anadromous & resident finfish & shellfish	63	37	80	159	236	311	Toy et al 1996
16	Tulalip Tribes[a]	Adults	Consumer only	Harvested from Puget Sound	Anadromous & resident finfish & shellfish	54	30	74	139	194	273	Toy et al 1996

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
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THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
17	Tulalip Tribes[a]	Adults	Consumer only	All	Resident finfish & shellfish	36	18	41	116	132	168	Toy et al 1996
18	Tulalip Tribes[a]	Adults	Consumer only	Harvested anywhere	Resident finfish & shellfish	32	14	40	103	116	157	Toy et al 1996
19	Tulalip Tribes[a]	Adults	Consumer only	Harvested from Puget Sound	Resident finfish & shellfish	31	14	39	90	113	157	Toy et al 1996
20	Squaxin Island Tribe[v]	Adult males	Consumer only	All	All Fish and shellfish	73	NA	NA	165	249	NA	Toy et al 1996
2	Squaxin Island Tribe[v]	Adult females	Consumer only	All	All Fish and shellfish	70	NA	NA	220	274	NA	Toy et al 1996
22	Suquamish Island Tribe[b]	Adults (16 or older)	Consumer only	All	Anadromous & resident finfish & shellfish	214	132		489	NA	NA	Suquamish 2000
23	Suquamish Tribe[c]	Adults (16 or older)	Consumer only	Harvested from Puget Sound	Anadromous & resident finfish & shellfish	165	58	221	397	767	NA	Suquamish 2000
24	Suquamish Tribe[c]	Adults (16 or older)	Consumer only	Harvested from Puget Sound	Resident finfish & shellfish	126	49	116	380	674	NA	Suquamish 2000

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
25	Columbia River Tribes[d]	Adults	Consumer only	All	Anadromous & resident fish	63	40	60[e]	113[f]	176[g]	389	CRITFC 1994
26	Columbia River Tribes[m]	Adults	Consumer + Non-consumer	All	Anadromous & resident fish	58.7	~40	~57	~113	170	389	CRITFC 1994
27	Columbia River Tribes[n]	Adults	Consumer only	All	Resident fish	~43		~41	~82	~124	~284	CRITFC 1994
28	Asians & Pacific Islanders[h]	Adults	Consumer only	All	Anadromous & resident finfish & shellfish	117	78	139	236	306	NA	Sechena et al 1999
29	Asians & Pacific Islanders[h]	Adults	Consumer only	Harvested anywhere	Anadromous & resident finfish & shellfish	16	7	16	49	76	NA	Sechena et al 1999
30	Asians & Pacific Islanders[h]	Adults	Consumer only	Harvested from King County	Anadromous & resident finfish & shellfish	14	6	15	26	57	NA	Sechena et al 1999

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
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THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day) Mean	Median	Percentile 75th	90th	95th	99th	Reference
31	Asians & Pacific Islanders[h]	Adults	Consumer only	Harvested anywhere	Resident finfish & shellfish	16	7	18	54	72	NA	Sechena et al 1999
32	Asians & Pacific Islanders[h]	Adults	Consumer only	Harvested from King County	Resident finfish & shellfish	14	7	16	33	57	NA	Sechena et al 1999
33	U.S. General Population[i]	Adults (18 or older)	Consumer + Non-consumer	All	Resident freshwater/estuarine finfish & shellfish[j]	8	0	NA	17	50	143	USEPA 2002
34	U.S. General Population[k]	Adults (18 or older)	Consumer + Non-consumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	20	0	NA	75	111	216	USEPA 2002
35	U.S. General Population[l]	Adults (18 or older)	Consumer only	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	127	99	NA	248	334	519	USEPA 2002
36	U.S. General Population[l]	Adults (18 or older)	Consumer only	All	Resident finfish & shellfish from fresh and estuarine environments	81	47	NA	199	278	505	USEPA 2002

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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
37	Columbia Slough Fisherman[w]	Adults	Consumer only	Columbia Slough	Resident finfish & shellfish from fresh and estuarine environments		24	36				Adolfson Associates 1996
38	Sauvie Island Fisherman[w]	Adults	Consumer only	Sauvie Island	Anadromous & resident finfish & shellfish from fresh and estuarine environments		4	6				Adolfson Associates 1996
39	Lake Whatcom (WA) Fisherman[x]	Adults	Consumer only	Lake Whatcom (WA)	Resident fish	6						WDOH 1997
40	Lake Roosevelt (WA) Fisherman[y]	Adults	Consumer only	Lake Roosevelt (WA)	Resident fish	42					90[z]	WDOH 1997
Angler surveys in the U.S. - useful references - surveys not reviewed by the HHFG												
41	Michigan licensed anglers	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	27		35	73	102		West, 93

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day) Mean	Median	Percentile 75th	90th	95th	99th	Reference
42	Michigan licensed anglers	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	17		20	61	82	489	West, 93
43	S. Carolina	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	48						[ab]jurer et al 1999
44	Michigan	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	27						Chan et al 1999 Having et al 1992 reported in Chan et al 1999
45	Great Lakes	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	21						Chan et al 199 Health Canada 1995 reported in Chan et al 1999
46	Santa Monica Bay (CA) Seafood consumers	anglers who ate fish from Santa Monica Bay	consumer only	harvested locally	All self caught species	50	21		107			SCCWRP and MBC (1994)
Native American - useful references												
47	Lakes Huron, Michigan, Superior	Adults	subsistence-recall	harvested locally	fresh water fish	62						[ac]Dellinger 2004

Table 1. Comparison of Fish Consumption Rates
Note: The column Seafood Source refers to whether fish were harvested locally or purchased.
The column Seafood Species refers to all types of fish from a variety of habitats.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile				
								75th	90th	95th	99th	
48	Lake superior	Adults	subsistence-recall	harvested locally	fresh water fish	60						[ad]Dellinger 2004
49	Inland Lakes	Adults	subsistence-recall	harvested locally	fresh water fish	46						[ad]Dellinger 2004
50	Menominee	Adults	subsistence-recall	harvested locally	fresh water fish	34						[ad]Dellinger 2004
51	Other Res	Adults	subsistence-recall	harvested locally	fresh water fish	87						[ad]Dellinger 2004
52	All tribes	Adults	subsistence-recall	harvested locally	fresh water fish	60						[ad]Dellinger 2004
53	Lakes Huron, Michigan, Superior	Adults	subsistence-actual	harvested locally	fresh water fish	4						[ad]Dellinger 2004
54	Lake superior	Adults	subsistence-actual	harvested locally	fresh water fish	11						[ad]Dellinger 2004
55	Inland Lakes	Adults	subsistence-actual	harvested locally	fresh water fish	8						[ad]Dellinger 2004
56	Menominee	Adults	subsistence-actual	harvested locally	fresh water fish	34						[ad]Dellinger 2004

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
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THE COLUMN SEAFOOD SPECIES REFERS TO ALL TYPES OF FISH FROM A VARIETY OF HABITATS.

line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day) Mean	Median	Percentile 75th	90th	95th	99th	Reference
57	Other Res	Adults	subsistence-actual	harvested locally	fresh water fish	8						[ad]Dellinger 2004
58	All tribes	Adults	subsistence-actual	harvested locally	fresh water fish	8						[ad]Dellinger 2004
59	Mohawk, Montreal	Adults	consumers	harvested locally	fresh water fish	33						[ae]Chan et al, 1999
60	Mohawk, Montreal	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	23						[ae]Chan et al, 1999
61	Akwasasne	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	25						Chan et al 1999 Forti et al 1995 reported in Chan et al 1999
62	Wisconsin Chippewa	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	26						Chan et al Peterson et al 1994 reported in Chan et al 1999
63	Ojibwa	Adults	Consumer + Non-consumer	harvested locally	fresh water fish	23						Burger et al 1999; Dellinger et al 1997 reported in Burger et al 1999

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day) Mean	Median	Percentile 75th	90th	95th	99th	Reference
64	Canadian First Nation	All ages	consumers	harvested locally	salmon only	28						[am]Mos et al, 2004
65	Canadian First Nation	All ages	consumers	harvested locally	salmon only	48						[af]Mos et al, 2004
66	Canadian First Nation	All ages	consumers	harvested locally	all marine species including salmon	44						[af]Mos et al, 2004
World												
67	Japan	Adults	Consumer + Non-consumer	All	fresh water and marine fish & shellfish	96						[ag]Nakagawa et al, 1997 (1976 data from Kitamura et al 1976)
68	Japan	Adults	Consumer + Non-consumer	All	fresh water and marine fish & shellfish	163						[ag]Nakagawa et al, 1997
69	Hong Kong	Adults	Consumer + Non-consumer	All	fresh water and marine fish & shellfish	52						[ah]Dickman and Leung, 1998

TABLE 1. COMPARISON OF FISH CONSUMPTION RATES
NOTE: THE COLUMN SEAFOOD SOURCE REFERS TO WHETHER FISH WERE HARVESTED LOCALLY OR PURCHASED.
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line #	Group	Subgroup = gender or age	Fish Consumer only / fish Consumer + Non Consumer	Seafood Source	Seafood Species included in consumption rate evaluation	Statistic (grams/day)						Reference
						Mean	Median	Percentile 75th	90th	95th	99th	
70	Hong Kong	Adults	Consumer + Non-consumer	All	fresh water and marine fish & shellfish	164						[ah]Dickman and Leung, 1998 extracted from Euromonitor 1997

Footnotes:
[a] Values computed from Toy et al. 1996 study data (Kissinger 2003).
[b] Values g/kg/day for "all seafood" taken from Table T-3 of the Suquamish Survey (Suquamish 2000) and converted to g/day by multiplying by the average body weight for men and women of 79 kg
[c] Values computed by ShiQuan Liao and Nayak Polissar of the Mountain Whisper Light Statistical Consulting company for the Suquamish Tribe (Liao and Polissar 2007)
[d] Values compiled from Table 10 "Number of Grams per Day Consumed by Adult Fish Consumers" of the Columbia River Intertribal Fish Commission Study (CRITFC 1994)
[a] A value of 60 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 75th percentile (48.6 g/day, 65.1%) and (64.8 g/day, 79.1%)
[f] A value of 113 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 90th percentile (97.2 g/day, 88.5%) and (130 g/day, 91.6%)
[g] A value of 176 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 95th percentile (170 g/day, 94.4%) and (194 g/day, 97%)
[h] Values computed from 1999 EPA Asian Pacific Islander seafood consumption survey data (Kissinger 2005). Kissinger (2005) converted mixed cooked and raw wet weight consumption rate information from the 1999 publication into a wet weight consumption rate.
[i] Values taken from EPA 2002 Section 5.1.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "freshwater/estuarine" section of the table are used.
[j] Pacific salmon were assigned to consumption of marine species rather than estuarine species (SEE Section 2.1.1 of EPA 2002 for an explanation).
[k] Values taken from EPA 2002 Section 5.1.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "all fish" section of the table are used.
[l] Values taken from EPA 2002 Section 5.2.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "all fish" section of the table are used.
[m] Values compiled from Table 7 "Number of Grams per Day of Fish Consumed by Adult Respondents (Fish consumers and non-fish consumers) combined - Throughout the year" of the Columbia River Intertribal Fish Commission Study (CRITFC 1994)
[n] Values compiled from Tables 10, 18 and 19 from CRITFC 1994. The average consumption rate for Pacific Northwest Salmon was estimated to be 20 grams/day. That was subtracted from the average for all fish for consumers only to result in 43 grams/day as the average fish consumption for adult consumers only for resident fish. The ratio of .73% (all fish/resident) was then applied to the other percentiles. All values are estimates.
[o] The mean values were taken from Table 16 and all other percentiles were estimated from Table 15 in CRITFC 1994. All calculated values are estimates.
[p] The mean values were taken from Table 24 and all other percentiles were estimated from Table 24 in CRITFC 1994. All calculated values are estimates.

[q] All values taken from EPA 2002 Section 5.1.1.1, Table 5
[r] All values taken from EPA 2002 Section 5.2.1.1, Table 5
[s] All values taken from EPA 2002 Section 5.2.1.1, Table 3
[t] All values taken from EPA 2002 Section 5.2.1.1, Table 1
[u] All values calculated using 16.8 as the average body weight of children and applying that body weight to values in Table T-14 in Suquamish 2000
[v] All values were calculated using an average child BW of 15.2 kg (from Table A1) and the consumption rates Toy et al., 1996, Table A9
[v] All values were calculated using an average adult female BW of 76 kg and adult male body weight of 86 kg (from Table A1) and the consumption rates Toy et al., 1996, Table A4
[w] All values taken from Adolphson 1996, Table 4, page 20. Values were converted to grams/day from kg/person/year.
[x] All values taken from Dave McBride's summary of the Lake Whatcom 2001 study. Adult average consumption of 225 g/meal was used along with a median children rate of 131 g/meal. 10 meals were assumed per year
[y] All values taken from Dave McBride's summary of the Lake Roosevelt 1997 study.
[z] All values taken from Dave McBride's summary of the Lake Roosevelt 1997 study. 90g/day was labeled as "high end consumers" and placed in the 99th percentile column for that reason.
[aa] All values taken from Rhodes 2006, Table 32.
[ab] Burger et al 1999; interview of Savannah R fisherman; n=258; mean serving size 376 g; mean fish/month 1.46 kg; mean fish per year 17.6 kg; mean age 43; 48 g/day
[ac] Chan et al 1999 questionnaire of consumption over the past 12 months; n= 42, average age 39 years; 474 to 766 grams per meal
[ad] Dellinger, 2004 questionnaire fish consumption for 12 months; estimated grams per meal = 280 grams, GLIFWC 2003 summarized in Dellinger 2003 147 tribal members from 1999 to 2002

Lake Huron Michigan, Superior male & female adults (n=271 age 40)
Lake Superior male & female adults (n= 346; 41 years)
Inland Lakes male & female adults (n=63; age=40)
Menominee male & female adults (n=66; age=39)
Other Res male & female adults (n=76; age=43)
All tribes male & female adults (n=822; age=41)

[ae] Moss et al 2004, interview of 4 Sencoten villages during summer of 2001; n=76 ages 13-75; individuals selected at random; focused on marine species; estimate monthly or yearly number of meals;
estimate grams per day (1 portion = 180 grams); 36 meals of salmon per year= 10.3 kg per person per year; 86 meals of all marine food per person per year;
Note adults over 40 years consume more fish than youth or young adults (13-40 years)
44 g/day 86 meals x 186 grams/meal divided by 365
28 g/day 10.3 kg x 100 g/kg divided by 365
48 g/day 17.5 kg x 100 g/kg divided by 365

[af] Nagakawa et al 1997 study of mercury in fish; fish rates are mean consumption of eatable fish per capita per day. Methodology for consumption survey was not reported.
1976 data are extracted from Kitamura, s. Kondo, m. Takizawa, t. Fuji, m. Mercury Kodansha Japan 267-273 1976

[ag] Dickman and Leung 1998; study of mercury and PCBs in fish tissue; Hong Kong Asians consume fish 3 to 4 times per week; Hong Kong average person 4 or more times per week average 60 kg per year; Finland and Europe fish consumption is lower; assuming 1/2 of what is imported is consumed = 18.9 kg fresh fish per person or 52 grams per day.
164 g/day 60 kg/year extracted from Consumer Asia Euromonitor plc 60-61 Britton St. London ECIM 5NA 1997
52 g/day 234500 tonnes of fish imported 1/2 consumed = 117245 tonnes by 6.2 million people 18.9 kg fresh fish per person or 52 grams per day

[ah] Values computed using a weighted average of body weight for males and females from Table A1, which was calculated as 82kg. Body weight was multiplied by "total fish" values in Table A2 to obtain final values listed.

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10. GLOSSARY OF ACRONYMS AND UNITS OF MEASURE

10.1 ACRONYMS

AWQC	Ambient Water Quality Criteria.
BCF	Bioconcentration factor (generally expressed in liters per kilogram)
BW	Body weight (generally expressed in kilograms)
CRITFC	Columbia River Inter-Tribal Fish Commission, including the Warm Springs, Yakama, Umatilla, and Nez Perce Tribes
CROET	Center for Research on Occupational and Environmental Toxicology (CROET), Oregon Health & Science University
CSFII	Continuing Survey of Food Intakes by Individuals. A survey conducted by the United States Department of Agriculture (USDA) 1994-1996 and 1998
CTUIR	Confederated Tribes of the Umatilla Indian Reservation, including the Cayuse, Umatilla and Walla Walla Tribes
CWA	Clean Water Act.
DABT	Diplomat of the American Board of Toxicology
DEQ	Oregon Department of Environmental Quality
DHS	Oregon Department of Human Services
DI	Drinking water intake (generally expressed in liters per day)
EPA	United States Environmental Protection Agency
EQC	Environmental Quality Commission
FCR Project	Oregon Fish and Shellfish Consumption Rate Project
FCR	Fish Consumption Rate
HHFG	Human Health Focus Group
HQ	Hazard Quotient

NMFS	National Marine Fisheries Service
NPDES	National Pollutant Discharge Elimination System program
OAR	Oregon Administrative Rules
OEHHA	Office of Environmental Health Hazard Assessment; a division of the California Environmental Protection Agency
PAC	Policy Advisory Committee
PCB	Polychlorinated biphenyl
RfD	Reference dose
RSC	Relative Source Contribution
TAC	Technical Advisory Committee
TMDL	Total Maximum Daily Load
URL	Uniform Resource Locator, the global address of documents and other resources on the World Wide Web
USDA	United States Department of Agriculture
WQC	Water quality criteria.
WQS	Water quality standards
WSDOH	Washington State Department of Health.

10.2 UNITS OF MEASURE

g/day	grams per day
g/kg/day	grams per kilogram per day
kg	kilogram
kg/day	kilogram per day
L/day	liter per day
L/kg	liter per kilogram
µg/L	micrograms per liter
mg/kg	milligrams per kilogram
mg/kg/day	milligrams per kilogram per day

APPENDIX A: FISH SPECIES IDENTIFIED AS CONSUMED IN SELECT SURVEYS

APPENDIX A – 1. SPECIES GROUPS LISTED IN A FISH CONSUMPTION SURVEY OF THE UMATILLA, NEZ PERCE, YAKAMA, AND WARM SPRINGS TRIBES OF THE COLUMBIA RIVER BASIN (CRITFC, 1994)

Anadromous	Resident
Salmon	Trout
Steelhead	Whitefish
Lamprey	Sturgeon
Smelt	Walleye
Shad	Squawfish
	Sucker

APPENDIX A – 2. SPECIES GROUPS LISTED IN A FISH CONSUMPTION SURVEY OF THE TULALIP AND SQUAXIN ISLAND TRIBES OF THE PUGET SOUND REGION (TOY ET AL. 1996)

Group A	Group B	Group C	Group D	Group E	Group F
Anadromous	**Pelagic**	**Bottom**	**Shellfish**	**Other**	**Other 2**
Chinook salmon	Cod	Halibut	Clams (Manila/Littleneck)	Canned Tuna	Trout
Pink salmon	Pollock	Sole/Flounder	Horse clam		
Sockeye salmon	Sablefish	Sturgeon	Butter clam		
Coho salmon	Rockfish	Skate	Cockles		
Chum salmon	Greenling	Eel	Mussels		
unidentified salmon	Herring	Grunters	Oysters		
Steelhead	Spiny		Shrimp		
Smelt	Dogfish		Dungeness Crab		
	Perch		Red Rock Crab		
	Mackeral		Moon Snail		
	Shark		Scallops		
			Squid		
			Sea Urchin		
			Sea Cucumber		
			Sea Urchin		
			Geoduck		
			Limpets		
			Lobster		
			Bullhead		
			Manta Ray		
			Razor clam		
			Chitons		
			Octopus		
			Abalone		
			Chitons		
			Barnacles		
			Crayfish		

Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region (Suquamish, 2000)

APPENDIX A-3. SPECIES GROUPS LISTED IN FISH CONSUMPTION SURVEY OF THE SUQUAMISH TRIBES OF THE PORT MADISON INDIAN RESERVATION, PUGET SOUND REGION (SUQUAMISH, 2000)

Group A	Group B	Group C	Group D	Group E	Group F	Group G
King salmon	Smelt	Cod	Halibut	Manila/Littleneck clams	Cabezon	Abalone
Sockeye salmon	Herring	Perch	Sole/Flounder	Horse clams	Blue Back (sockeye)	Lobster
Coho salmon		Pollock	Rockfish	Butter clams	Trout/cutthroat	Octopus
Chum salmon		Sturgeon		Geoduck	Tuna (fresh/canned)	Limpets
Pink salmon		Sable fish		Cockles	Groupers	Miscellaneous
unidentified salmon		Spiny dogfish		Oysters	Sardine	
Steelhead		Greenling		Mussels	Grunter	
Salmon (gatherings)		Bull Cod		Moon snails	Mackerel	
				Shrimp	Shark	
				Dungeness crab		
				Red rock crab		
				Scallops		
				Squid		
				Sea urchin		
				Sea cucumber		
				Oysters (gatherings)		
				Clams (gatherings)		
				Crab (gatherings)		
				Clams (razor, unspecified)		
				Crab (king/snow)		

APPENDIX A-4 SPECIES GROUPS IN ASIAN AND PACIFIC ISLANDER SEAFOOD CONSUMPTION STUDY (SECHENA ET AL. 1999).

Anadromous Fish	%	Pelagic Fish	%	Freshwater Fish	%	Bottom Fish	%	Shellfish	%	Seaweed /Kelp	%
Salmon	93	tuna	86	catfish	58	halibut	65	shrimp	98	seaweed	57
Trout	61	cod	66	tilapia	45	sole/flounder	42	crab	96	kelp	29
Smelt	45	mackerel	62	perch	39	sturgeon	13	squid	82		
Salmon eggs	27	snapper	50	bass	28	suckers	4	oysters	71		
		rockfish	34	carp	22			manila/ littleneck clams	72		
		herring	21	crappie	17			lobster	65		
		dogfish	7					mussel	62		
		snowfish	6					scallops	57		
								butter clams	39		
								geoduck	34		
								cockles	21		
								abalone	15		
								razor clams	16		
								sea cucumber	51		
								sea urchin	14		
								horse clams	13		
								macoma clams	9		
								moonsnail	4		

APPENDIX B: RELATIVE SOURCE CONTRIBUTION FACTOR FOR METHYLMERCURY

Excerpt from EPA Criterion document for Methylmercury Table 5-14, Average Mercury Concentrations in Marine Fish and Shellfish Species (EPA 2001).

Species	Concentration [a] (µg Hg/g Wet Wt.)	Species	Concentration [a] (µg Hg/g Wet Wt.)
Finfish			
Anchovy	0.047	Pompano*	0.104
Barracuda, Pacific	0.177	Porgy*	0.522[b]
Cod*	0.121	Ray	0.176
Croaker, Atlantic	0.125	***Salmon****	***0.035***
Eel, American	0.213	Sardines*	0.1
Flounder*,[e]	0.092	Sea Bass*	0.135
Haddock*	0.089	Shark*	1.327
Hake	0.145	Skate	0.176
Halibut*	0.25	Smelt, Rainbow*	0.1
Herring	0.013	Snapper*	0.25
Kingfish	0.10	Sturgeon	0.235
Mackerel*	0.081	Swordfish*	0.95[c]
Mullet	0.009	Tuna*	0.206
Ocean Perch*	0.116	Whiting (silver hake)*	0.041
Pollock*	0.15	Whitefish*	0.054[d]
Shellfish			
Abalone	0.016	Oysters	0.023
Clam*	0.023	Scallop*	0.042
Crab*	0.117	Shrimp	0.047
Lobster*	0.232	Other shellfish*	0.012b
Molluscan Cephalopods			
Octopus*	0.029	Squid*	0.026

Source: U.S. EPA (1997c).
*Denotes species used in calculation of methylmercury intake from marine fish for one or more populations of concern, based on existence of data for consumption in the CSFII (U.S. EPA, 2000b).
[a] Mercury concentrations are from NMFS (1978) as reported in U.S. EPA (1997d) unless otherwise noted, measured as ug of total mercury per gram wet weight of fish tissue.
[b] Mercury concentration data are from Stern et al. (1996) as cited in U.S. EPA (1997c).
[c] Mercury concentration data are from U.S. FDA Compliance Testing as cited in U.S. EPA (1997c).
[d] Mercury concentration data are from U.S. FDA (1978) as cited in U.S. EPA (1997c).
[e] Mercury data for flounder were used as an estimate of mercury concentration in marine flatfish in marine intake calculations.

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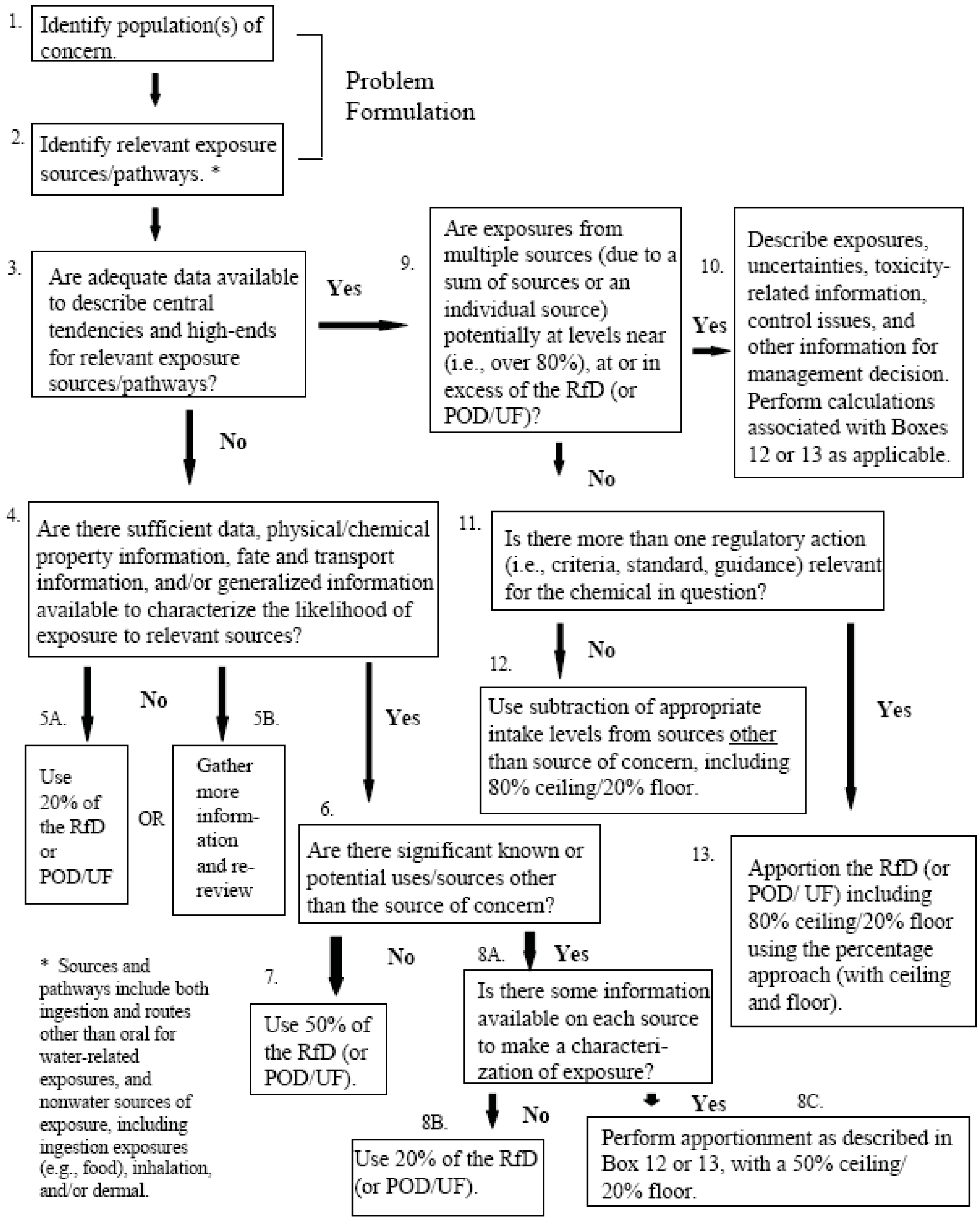
APPENDIX C: BASIS FOR RELATIVE SOURCE CONTRIBUTION VARIABLES

Compound	EPA's Recommended RSC[1, 2]	Sources of Exposure	Citation
Antimony	40%	Drinking Water Contribution= 40% Diet Contribution=50%, Inhalation Contribution=10%	Drinking Water: National Primary Drinking Water Regulations (7/17/1992) 57 FR 31784
Methylmercury	2.7 x 10^{-5} mg/kg BW/day (subtracted from RfD)	Accounts for marine fish consumption	EPA Methylmercury Criterion Document (1/2001) EPA 823-R-01-001
Thallium	20%		
Cyanide	20%	Available data on dietary exposure are inadequate, so apply the default value of 20% RSC.	Drinking Water: National Primary Drinking Water Regulations (7/17/1992) 57 FR 31784
Chlorobenzene	20%		
1,1 Dichloroethylene	20%	Detected in several sources (i.e. air, and wells contaminated with other solvents).	EPA Health Advisory for 1,1-Dichloroethylene of Office of Drinking Water (3/31/1987)
Ethylbenzene	20%	Primary source of exposure is from the air, although contaminants in drinking water can be quite high for wells near leaking gasoline storage tanks and drinking waters taken from surface waters.	Technical Fact Sheet on Ethylbenzene for the National Primary Drinking Water Regulations. http://www.epa.gov/safewater/dwh/t-voc/ethylben.html
Toluene	20%	Based on available data, the major source of toluene exposure is from air; occurs in low levels in drinking water, food and air. Where actual exposure data are not available, 20% RSC is assumed.	EPA Health Advisory for Toluene of Office of Drinking Water (3/31/1987)
1,2 Transdichloroethylene	20%		
1,2 Dichlorobenzene	20%	Detected in multiple sources (i.e. ground water, surface water, air), however there are insufficient data to determine where the major route of environmental exposure.	EPA Health Advisory for Ortho-, Meta-, and Para-Dichlorobenzenes of Office of Drinking Water (3/31/1987)

Compound	EPA's Recommended RSC[1, 2]	Sources of Exposure	Citation
1,4 Dichlorobenzene	20%	Detected in multiple sources (i.e. ground water, surface water, air), however there are insufficient data to determine where the major route of environmental exposure.	EPA Health Advisory for Ortho-, Meta-, and Para-Dichlorobenzenes of Office of Drinking Water (3/31/1987)
Heachlorocyclo-pentadiene	20%		
1,2,4 Trichlorobenzene	20%		
Gamma BHC	20%		
Endrin	20%	Human exposure appears to most come from food or an occupational source. Monitoring data demonstrates it continues to be a contaminant from air, water, sediment, soil, fish, and other aquatic organisms.	Technical Fact Sheet on Endrin for the National Primary Drinking Water Regulations. http://www.epa.gov/safewater/dwh/t-soc/endrin.html

[1] EPA, 2002. National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix. EPA-822-R-02-012.
[2] EPA, 2003. National Recommended Water Quality Criteria for the protection of Human Health. 68 FR 75507-75515.

APPENDIX D: EPA's DECISION TREE FOR DEVELOPING A RELATIVE SOURCE CONTRIBUTION [2]



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[2] EPA, 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. EPA 822-B-00-0004. P. 4-8.

The Mountain-Whisper-Light Statistics

1827 23rd Ave. East, Seattle, WA 98112-2913

Date: 10/31/13

To: Cheryl Niemi, Becca Conklin

From: Nayak Polissar, Dan Hippe

Re: Fish consumption rates for a hypothetical combination of Puget Sound tribes.

Here is our report on consumption rates for a hypothetical population of pooled Native American Tribes, pooling fish consumption rates from the Squaxin Island Tribe, Squamish Tribe and Tulalip Tribes.

Background and Objectives

We were asked by the Washington Department of Ecology (Ecology) to provide estimates of fish consumption rates for a hypothetical population. The composition of that population would consist of an equal proportions of members drawn from three Native American Tribes residing in the Puget Sound region: the Squaxin Island Tribe, the Squamish Tribe and the Tulalip Tribes[1]. The fish consumption rates for these three Tribes were to be drawn from publicly available sources. Our objective was to provide estimates of the mean consumption rate and selected percentiles of the consumption rate distribution for the combined population. Further, the rates were to derived under three scenarios: 1) including all fish and shellfish consumption; 2) the same, but excluding anadromous fish consumption; 3) the same as #1 but including only part (58.8%) of anadromous fish consumption (see *Methods*.)

Summary of findings

A selection of the derived rates for the combined population are presented in Table A and additional rates are provided later. The scenario of reduced anadromous consumption (scenario 2) decreases the mean consumption rate about 15% compared to the rate for all seafood without reduction (scenario 1.) Complete elimination of anadromous consumption (scenario 3) reduces the mean rate by 37% compared to scenario 1. A rough estimate of the margin of error of these rates is also presented later and indicates moderate uncertainty.

[1] Throughout this document, all consumption rates refer to adults and all rates are for consumers.

The percentiles of consumption rates for the hypothetical combined population can differ substantially from the percentiles for the three individual tribes. For example, the 90^{th} percentile value for all seafood consumption, 302.9 g/day from Table A, indicates that 90% of the hypothetical combined population consumes at a rate of 302.9 g/day or less and 10% of the combined population consumes at a higher rate. For the underlying tribal populations, 22% of the Suquamish Tribe consumes at a higher rate than 302.9 g/day along with 3.2%% of the Tulalip Tribes and 1.5% of the Squaxin Island Tribe. Similarly, for the three consumption scenarios and for the higher percentiles, a larger percentage of the Suquamish Tribe and smaller percentages of the Tulalip and Squaxin Island Tribes consume more than the given rate than in the combined population.

Table A. Fish consumption rates (grams/day) for a combined population: mean and selected percentiles for three scenarios.

Statistic	All seafood (g/day)	All, incl. part of anadromous (g/day)	All except anadromous (g/day)
Mean	127.2	108.0	80.4
50^{th} percentile (median)	60.9	49.0	32.2
90^{th} percentile	*302.9	*265.7	*208.5
95^{th} percentile	*466.5	*407.6	**

*Estimation involved extrapolation beyond published rates for at least one of the three tribes.
**Percentile not provided because extrapolation beyond the 99^{th} percentile for at least one tribe would be needed.

Methods

A percentile of a population's consumption rates is a value calculated to include the stated percentage of the population consuming at or below the consumption rate. For example, if 302.9 g/day is the 90^{th} percentile rate, then 90% of the population consumes at or below that rate per day. A collection of percentiles of consumption for a population is usually referred to as a distribution.

The mean (average) and selected percentiles of seafood consumption rates were extracted from published reports for three tribes (Squamish Tribe: Suquamish 2000 and Liao 2002; Tulalip and Squaxin Island Tribes: Polissar 2006). Intermediate percentiles that were not available were estimated using interpolation between pairs of percentiles. Extrapolation of rates to percentiles beyond the 95^{th} percentile (the largest available percentile from previous reports) up to the 99^{th} percentile were calculated for each Tribe[2]. These estimated seafood consumption distributions were combined using formal statistical methods, giving each Tribe equal

[2] Interpolation and extrapolation of percentiles were based on the lognormal distribution. See the technical appendix.

weight, i.e., 1/3 weight for each Tribe, summing to 1.0. For example, if 100 g/day corresponded to the 40^{th}, 50^{th} and 60^{th} percentiles of the three Tribes, respectively, then 100 g/day would correspond to the 50^{th} percentile of the combined distribution (i.e., [40+50+60]/3). This operation corresponds to pooling three tribes into a hypothetical population which has equal numbers of members from each tribe.

Three scenarios of fish consumption were considered, The scenarios differ only in the amount of anadromous fish consumption that is included, as follows: 1) include all seafood; 2) all seafood except reduced anadromous consumption; 3) all seafood except no anadromous consumption. The source reports provided estimates for all-seafood consumption rates (used directly for scenario 1) and for anadromous species consumption rates. The previous reports were used to statistically estimate an overall proportion of anadromous seafood consumed per tribe, which was removed from the all-seafood consumption estimates to generate scenario 3. An adjustment to the proportion of anadromous seafood to be removed was made to generate scenario 2—partial removal of anadromous consumption from all-seafood consumption rates. The Washington Department of Ecology provided the adjustment factors that were the basis for partial removal of anadromous consumption from all-seafood consumption. The adjustment retained 58.8% of each tribe's anadromous fish consumption prior to pooling consumption to yield rates for the hypothetical combined of tribes. The value of 58.8% retained has been based on the following assumptions and values supplied by Ecology[3].

1. Anadromous consumption is composed of 50% Chinook and 50% Coho consumption.

2. Among the consumed Chinook species, 70% are migratory and 30% are non-migratory (resident in Puget Sound.)

3. Among the non-migratory Puget Sound Chinook (the 30% component) 100% of contaminants are from Washington. Retain 100% of this component in the adjusted consumption rate.

4. Among the Puget Sound migratory Chinook (the 70% component) 78% of contaminants are from Washington. Retain 78% of this component in the adjusted consumption rate.

5. Among the Puget Sound migratory Coho salmon 33% of the contaminants are from Washington. Retain 33% of this component in the adjusted consumption rate.

These values lead to the following calculation of the proportion of anadromous consumption to be retained in the adjusted rate. Percentages have been converted to proportions.

Proportion retained = 0.5*0.3*1.0 + 0.5*0.7*0.78 + 0.5*0.33 = 0.588.

[3] Email message from Ecology, 10/14/13.

Approximate uncertainty bounds were computed for selected rates (see technical appendix.) They indicate "margin of error" for the selected percentile rates. These bounds should be viewed as a rough guide and should only be used qualitatively, e.g., narrow or wide[4].

RESULTS AND DISCUSSION.

Key summaries of the combined consumption rates under the three scenarios are shown in tabular form in Table 1 and graphically in Figures 1.S1, 1.S2 and 1.S3. For example, under scenario 1 (all seafood consumption), the 50th percentile (also known as the median) was estimated as 60.9 g/day. The interpretation is that 50% of individuals in the hypothetical combined population consume seafood at this daily rate or less and that 50% consume at a higher rate. The 90th percentile for scenario 1 was estimated as 302.9 g/day, so 90% of individuals would consume at or below this rate and 10% would consume at a higher rate. The margin of error, or uncertainty bounds on the rate of 302.9 g/day is 237.3 g/day up to 386.6 g/day, as shown in Table 1. Thus, it is plausible that the true 90th percentile consumption rate for this combined population is between 237 and 387 g/day, a moderately wide interval of uncertainty. The uncertainty bounds for selected percentiles of each scenario are shown in Figures 1.S1-1.S4. For example, the 90th percentile rate of 302.9 g/day for scenario 1 (all seafood) is shown as a vertical bar in figure 1.S1, and the "whiskers" extending above and below the bar indicate the uncertainty interval, extending down to 237 g/day and up to 387 g/day.

The 95th percentile of each individual tribe was available in published reports, but in some cases higher percentiles were needed for at least one of the tribes in order to compute the combined population's 95th percentile rate. When needed, these higher percentiles (beyond the 95th percentile) were calculated by extrapolation[5]. However, we do not present any combined population rates that would require extrapolation to a 99th percentile rate or higher from one of the individual tribes.

All rates which involved extrapolation are noted in the tables and figures with asterisks (*). More caution is needed in using these rates. Tables 4.S1-4.S3 show which percentiles were needed from each Tribe, with values >95% bolded. For example, from Table 1.S1, to compute the scenario 1 (all seafood) 90th percentile of 302.9 g/day, the 78th Suquamish percentile, 96.8th Tulalip percentile and 95.5th Squaxin percentile were needed. The latter two percentile rates were calculated by extrapolation.

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[4] The bounds are calculated in the methodologic spirit of 95% confidence intervals, but they are quite approximate and should not be taken as formal 95% confidence intervals. See the technical appendix.

[5] The extrapolation was carried out assuming that each Tribe's consumption followed a log-normal distribution (which appeared reasonable between the 5th and 95th percentiles for each Tribe—see Technical Appendix.) Without additional data the quality of these extrapolations is unknown.

The consumption rates of the combined population are different than those of the three individual tribes. The preceding paragraph shows that diverse percentiles from the individual tribes were needed to calculate a given percentile of consumption rates for the combined population. In the example given in the preceding paragraph 10% of the combined population would have consumption rates higher than the 90th percentile consumption rate of 302.9 g/day. That is simply the definition of a 90th percentile—10% of the consumers lie beyond the 90th percentile. In constructing that combined percentile rate the individual tribes had quite diverse percentages of their members consuming more than 302.9 g/day. The value of 302.9 g/day was the 78th percentile consumption rate of the Suquamish Tribe, which means that the tribe had 22% of adult members consuming more than 302.9 g/day. Stated differently, the tribe had more than twice as many people consuming above the noted rate compared to what would be expected from the combined population. On the other hand, the Tulalip and Squaxin Island Tribes had, respectively, less than half or about half as many of their members consuming above the noted rate compared to the combined tribe. This shows that the combined population is its own population that its percentiles of consumption may differ quite substantially from the percentiles of the individual tribes.

Figures 2 and 3 are provided as technical illustrations of the consumption rate distributions. Figure 2 illustrates how estimated consumption distributions were combined. The dotted blue (Tulalip) and green (Squaxin Island) curves start at the 95th percentile (see y-axis) and show the extrapolation for the corresponding Tribes. These curves end at the extrapolated 99th percentile. Note that the black curve corresponding to the combined distribution, which is in between the other three curves, starts to become dotted at the same point on the x-axis as the blue curve (Tulalip), because that is when the extrapolation for the Tulalip was needed. The black curve ends at the same point on the x-axis as the blue curve ends.

Figure 3 illustrates combined consumption distributions under the three scenarios. Note, in particular, where scenario 2 falls between scenario 1 and 3. The scenario 1 curve (red) is the same as the black curve in Figure 2.

Tables

- Table 1: Selected percentiles and uncertainty estimates of fish consumption rates for the hypothetical combined population
- Table 2: Percentiles from 10% to 95%
- Table 3: Mean consumption rates
- Table 4.S1: Scenario 1 percentiles for individual tribes used to calculate percentiles for the combined population
- Table 4.S2: Scenario 2 percentiles for individual tribes used to calculate percentiles for the combined population
- Table 4.S3: Scenario 3 percentiles for individual tribes

Figures

- Figure 1.S1: Selected percentiles and uncertainty estimates for the combined consumption distributions under scenario 1
- Figure 1.S2: Selected percentiles and uncertainty estimates for the combined consumption distributions under scenario 2
- Figure 1.S3: Selected percentiles and uncertainty estimates for the combined consumption distributions under scenario 3
- Figure 2: Individual and combined consumption distributions for scenario 1
- Figure 3: Combined consumption distributions under the three scenarios

Table 1. Selected consumption rate estimates with uncertainty estimates for the combined population, adult consumers, under three scenarios: 1) all seafood; 2) all seafood including reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption.

	Combined Estimates, g/day								
	Scenario 1			Scenario 2			Scenario 3		
Statistic	**Estimate**	**LB**	**UB**	**Estimate**	**LB**	**UB**	**Estimate**	**LB**	**UB**
Mean	127.2	100.4	161.3	108.0	84.7	137.6	80.4	62.0	104.3
p10	9.8	7.2	12.4	7.7	5.6	9.7	**	-	-
p25	26.0	21.1	32.1	20.7	16.8	25.6	12.3	9.9	15.3
p50 (median)	60.9	50.8	72.9	49.0	40.8	58.9	32.2	26.6	39.0
p75	145.8	120.0	177.2	124.0	101.6	151.4	85.2	68.9	105.3
p80	179.4	145.8	220.6	151.5	122.5	187.3	*109.8	88.0	137.0
p85	216.8	174.3	269.6	*180.5	144.8	225.1	*135.6	107.4	171.1
p90	*302.9	237.3	386.6	*265.7	207.3	340.7	*208.5	163.3	266.4
p95	*466.5	354.2	614.6	*407.6	311.9	532.7	**	-	-

LB=lower approximate uncertainty bound; UB=upper approximate uncertainty bound; pXX is the XXth percentile;
*Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption;
**Percentile not provided because extrapolation beyond the 99th percentile or below the 1st percentile would be needed.

Table 2. Consumption rate estimates for the combined population, adult consumers, under three scenarios: 1) all seafood; 2) all seafood including reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption.

	Combined Estimate, g/day		
	Scenario 1	**Scenario 2**	**Scenario 3**
Mean	127.2	108.0	80.4
p10	9.8	7.7	**
p15	15.1	11.8	6.7
p20	20.8	16.5	9.3
p25	26.0	20.7	12.3
p30	31.9	25.4	15.4
p35	38.7	30.9	18.7
p40	45.2	36.9	22.6
p45	52.0	42.4	27.3
p50 (median)	60.9	49.0	32.2
p55	70.9	57.7	37.7
p60	79.1	67.5	45.1
p65	96.5	77.6	54.8
p70	120.9	99.1	64.4
p75	145.8	124.0	85.2
p80	179.4	151.5	*109.8
p85	216.8	*180.5	*135.6
p90	*302.9	*265.7	*208.5
p95	*466.5	*407.6	**

pXX is the XXth percentile;

*Percentiles were extrapolated beyond the 95th percentile for some individual Tribes using a log-normal assumption;

**Percentile not provided because extrapolation beyond the 99th percentile or below the 1st percentile would be needed.

Table 3. Mean consumption for individual Tribes and combined under three scenarios: 1) all seafood; 2) all seafood including reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption.

	Mean, g/day		
	Scenario 1	**Scenario 2**	**Scenario 3**
Suquamish	213.9	193.7	165.0
Tulalip	84.1	69.1	47.7
Squaxin	83.7	61.0	28.6
Combined	127.2	108.0	80.4

Table 4.S1. Select percentiles from the combined consumption distribution from scenario 1 (all seafood) and the corresponding percentiles used from each individual Tribe.

		Percentile evaluated from individual Tribe, %		
Statistic	**Combined, g/day**	**Suquamish**	**Tulalip**	**Squaxin**
p10	9.8	2	15	13
p25	26.0	9	33	33
p50 (Median)	60.9	28	61	61
p75	145.8	55	85	84
p80	179.4	63	89	88
p85	216.8	69	95.0	91
p90	*302.9	78	**96.8**	**95.5**
p95	*466.5	89	**98.2**	**97.7**

pXX is the XXth percentile; extrapolated percentiles (i.e. > 95th percentile) are bolded;

*Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

Table 4.S2. Select percentiles from the combined consumption distribution from <u>scenario 2</u> (all seafood minus adjusted anadromous consumption) and the corresponding percentiles used from each individual Tribe.

		Percentile evaluated from individual Tribe, %		
Statistic	**Combined, g/day**	**Suquamish**	**Tulalip**	**Squaxin**
p10	7.7	2	14	14
p25	20.7	7	32	36
p50 (Median)	49.0	26	60	64
p75	124.0	52	86	87
p80	151.5	61	89	90
p85	*180.5	67	**95.1**	93
p90	*265.7	76	**97.0**	**96.6**
p95	*407.6	88	**98.4**	**98.3**

pXX is the XX^th^ percentile; extrapolated percentiles (i.e. > 95^th^ percentile) are bolded;

*Percentiles were extrapolated beyond the 95^th^ percentile for at least one individual tribe using a log-normal assumption.

Table 4.S3. Select percentiles from the combined consumption distribution from <u>scenario 3</u> (all seafood minus all anadromous consumption) and the corresponding percentiles used from each individual Tribe.

		Percentile evaluated from individual Tribe, %		
Statistic	**Combined, g/day**	**Suquamish**	**Tulalip**	**Squaxin**
p10	**	-	-	-
p25	12.3	4	28	43
p50 (Median)	32.2	17	58	75
p75	85.2	46	86	93
p80	*109.8	54	90	**95.9**
p85	*135.6	62	**95.6**	**97.0**
p90	*208.5	74	**97.5**	**98.5**
p95	**	87	**98.8**	**99.4**

pXX is the XX^th^ percentile; extrapolated percentiles (i.e. > 95^th^ percentile) are bolded;

*Percentiles were extrapolated beyond the 95^th^ percentile for at least one individual tribe using a log-normal assumption.

**Percentile not provided because extrapolation beyond the 99^th^ percentile or below the 1^st^ percentile would be needed.

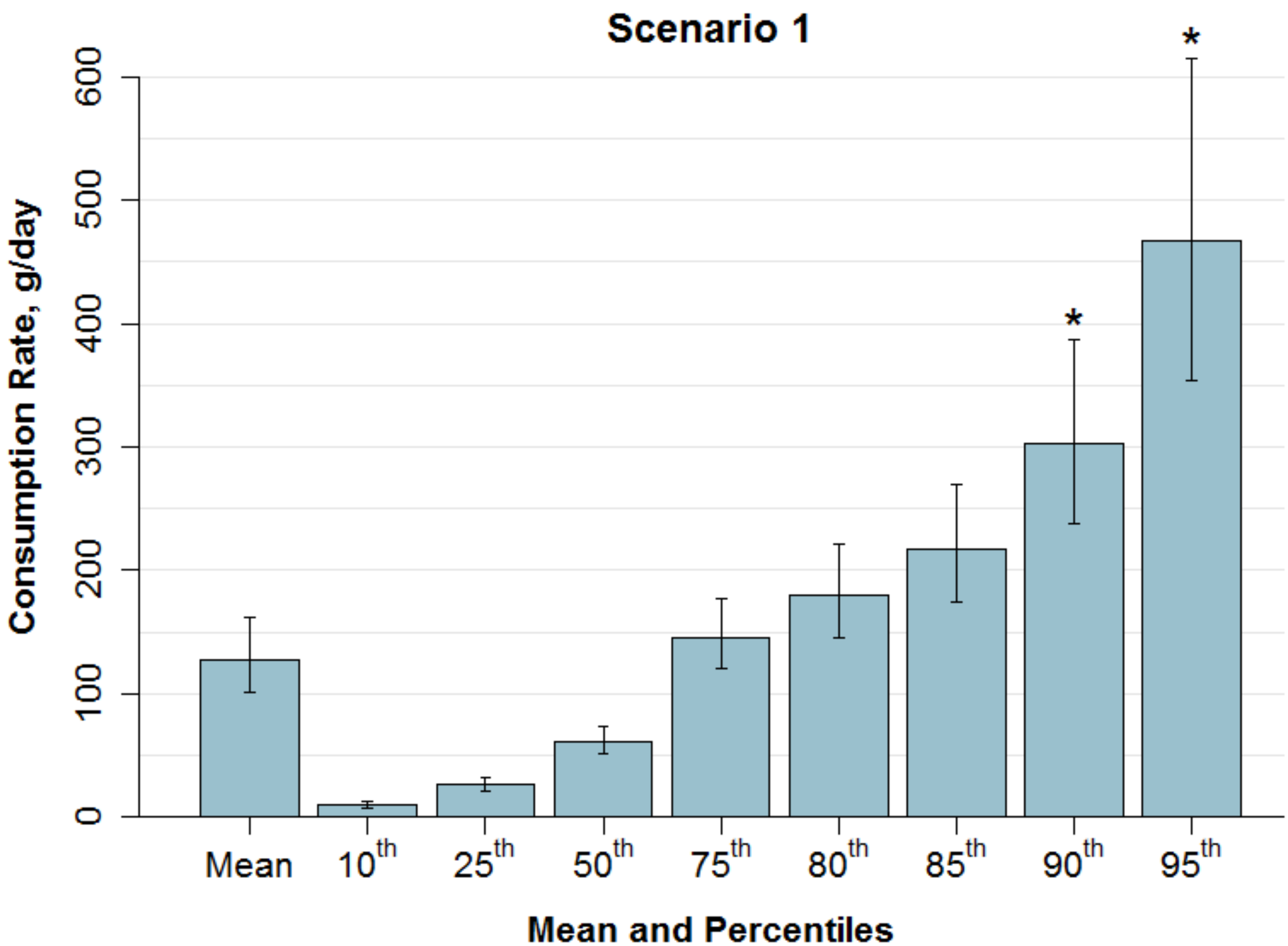

Figure 1.S1. Mean and percentiles of the combined consumption distribution in scenario 1 (all seafood). The error bars indicate approximate uncertainty bounds. *Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

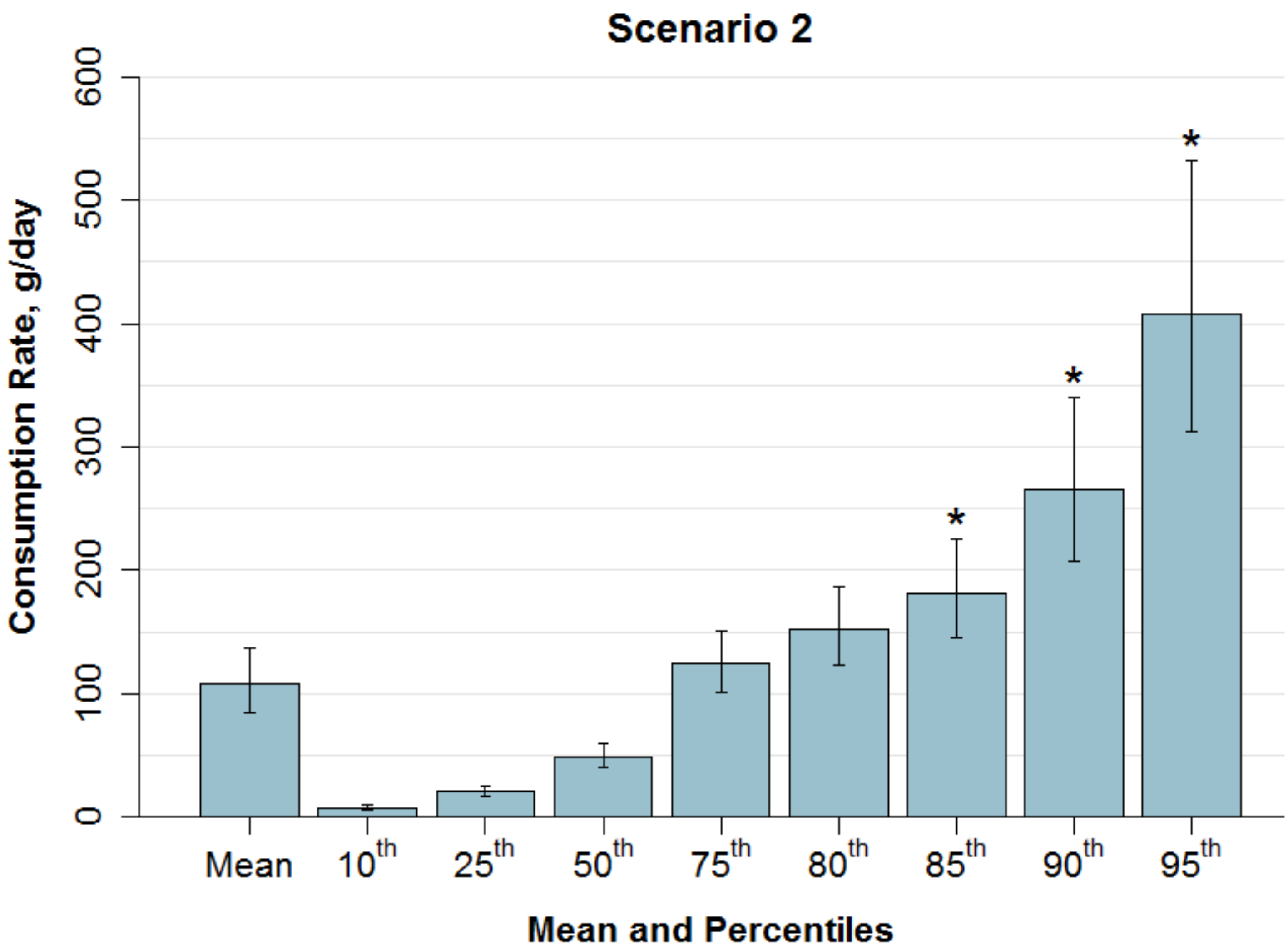

Figure 1.S2. Mean and percentiles of the combined consumption distribution in scenario 2 (all seafood minus adjusted anadromous consumption). The error bars indicate approximate uncertainty bounds. *Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

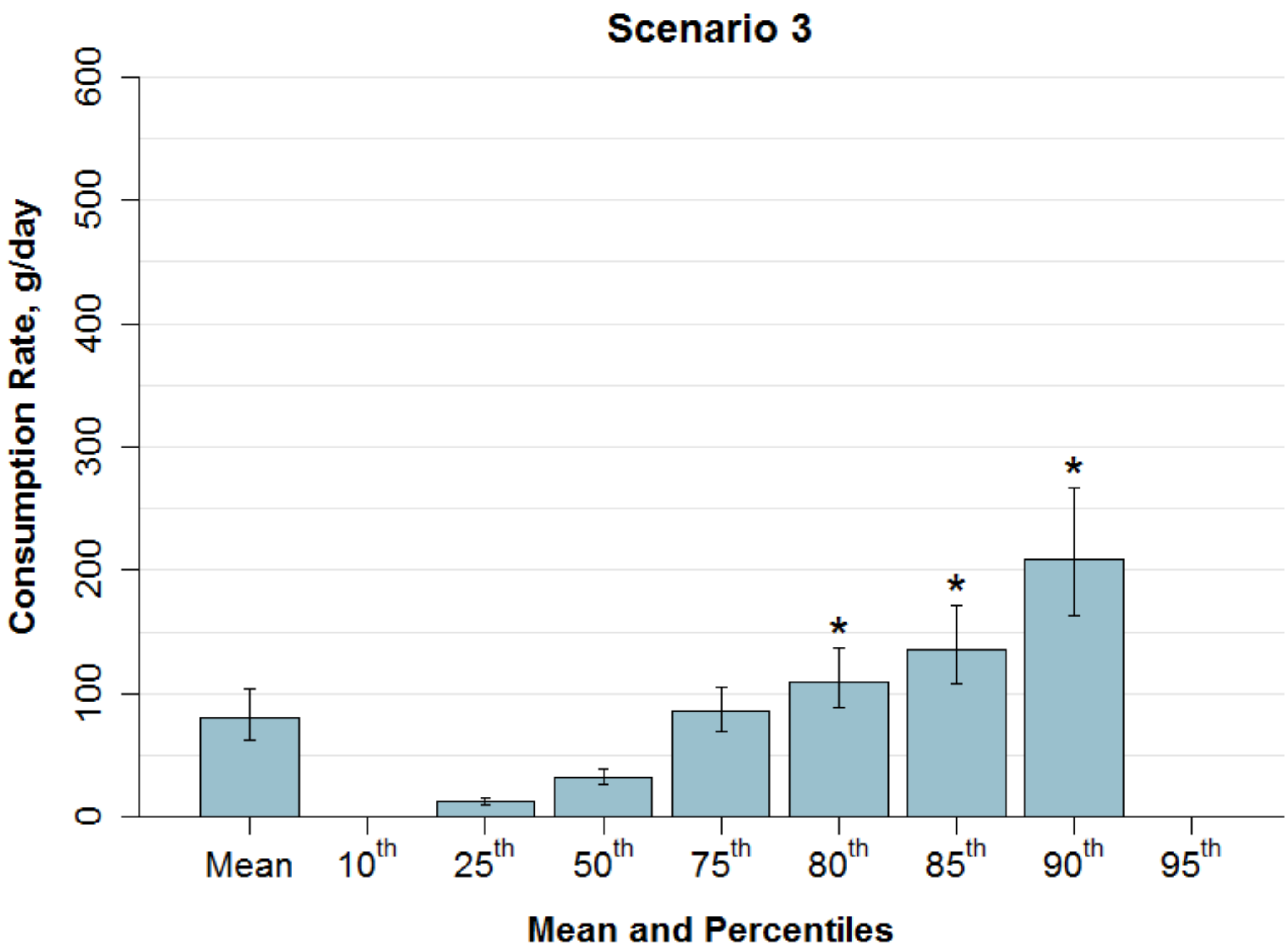

Figure 1.S3. Mean and percentiles of the combined consumption distribution in scenario 2 (all seafood minus all anadromous consumption). The error bars indicate approximate uncertainty bounds. Missing bars correspond to percentiles not provided because extrapolation beyond the 99th percentile or below the 1st percentile would be needed. *Percentiles were extrapolated beyond the 95th percentile for at least one individual tribe using a log-normal assumption.

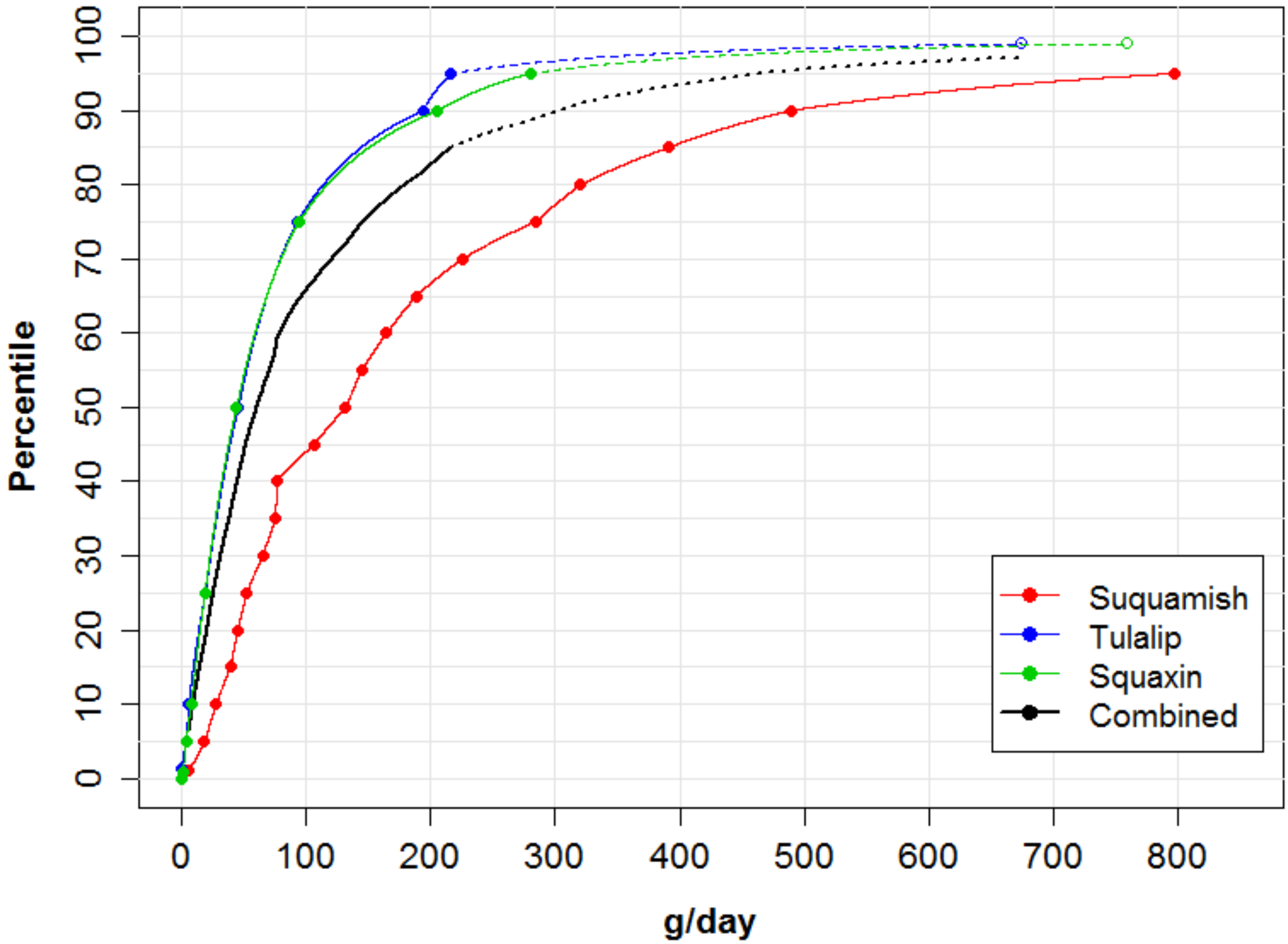

Figure 2. Each Tribe's estimated cumulative consumption distribution and the combined population consumption distribution giving each tribe equal weight (scenario 1). Closed points correspond to original estimates and the open points correspond to extrapolated 99th percentiles. Dotted and dashed lines indicate where extrapolation beyond the 95th percentile for at least one Tribe was needed (see Tables 4.S1-4.S3). Note that fewer intermediate percentiles were available from the Squaxin and Tulalip Tribes. Intermediate percentiles were based on log-normal interpolation.

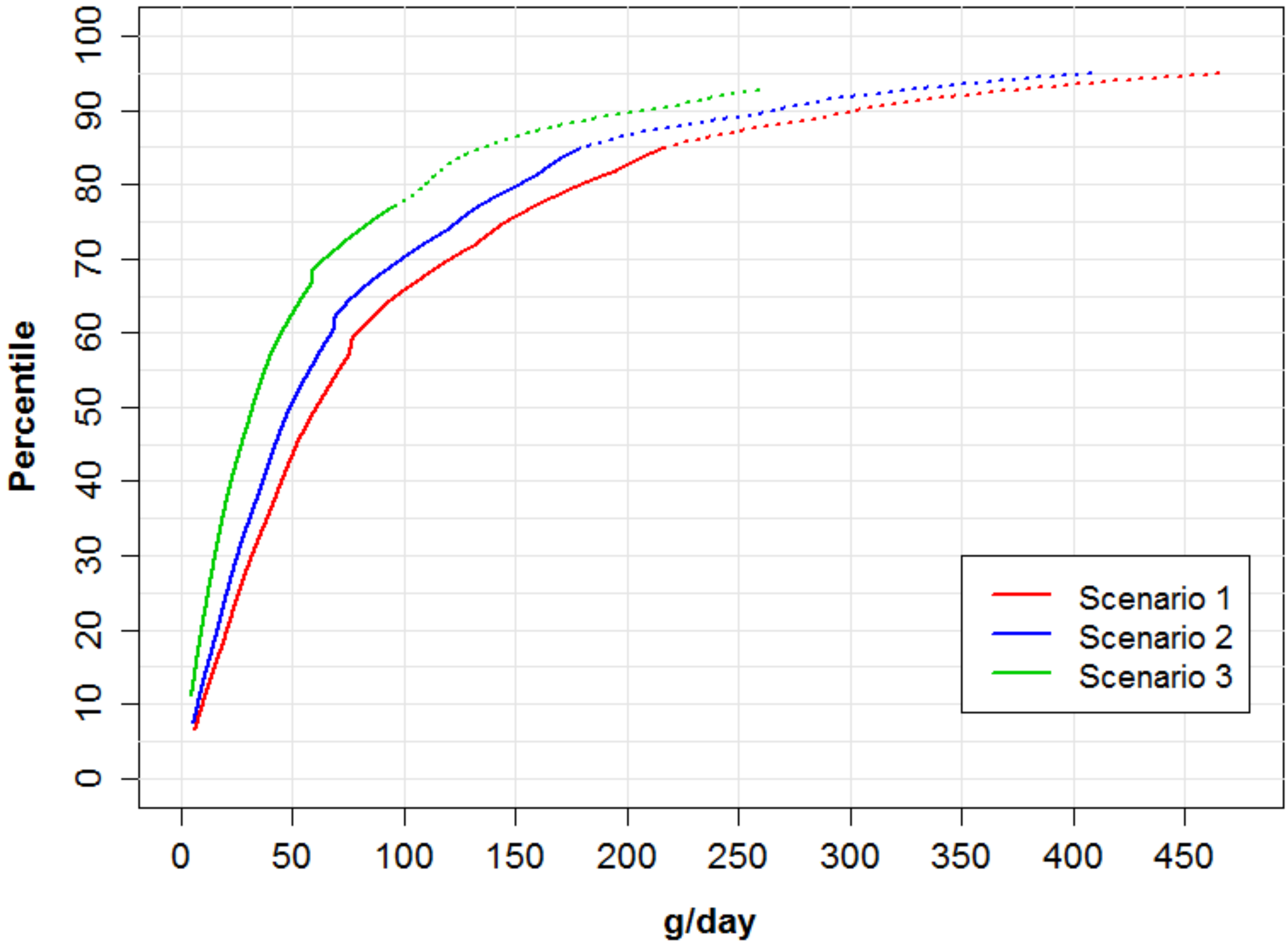

Figure 3. Combined population distributions for the three scenarios: 1) all seafood; 2) all seafood with reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption. The dotted lines indicate where extrapolation beyond the 95th percentile for at least one Tribe was needed (see Tables 4.S1-S3).

References

Liao S. 2002. Excel spreadsheets of percentiles of consumer-only rates (g/kg-day) for the Suquamish Tribe—various species groups.

Polissar, Nayak L.; Stanford, Derek; Liao, Shiquan; Neradilek, Blazej; Mittelstaedt, Gillian D.; Toy, Kelly A. A fish Consumption Survey Of The Tulalip and Squaxin Island Tribes of the Puget Sound Region—Consumption Rates For Fish Consumers Only. Report by The Mountain-Whisper-Light Statistics[6], 2006. *This was designated as an EPA contractor report. A final report which is an extension of this work is expected to be released by EPA.*

The Suquamish Tribe. 2000. "Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation." Puget Sound Region. August 2000. Report writing group: Duncan M, Polissar NL, Liao S, LaFlamme D.

[6] Know then as 'The Mountain-Whisper-Light Statistical Consulting.'

Date: 10/31/13

This technical appendix, prepared by Nayak Polissar and Dan Hippe, is intended to accompany our memo of 10/31/13, "Fish consumption rates for a hypothetical combination of Puget Sound tribes."

Technical Appendix: Methodology

Mathematically, the cumulative distribution function (CDF) of consumption rates from each tribe can be combined into a pooled CDF by a simple weighted sum, where the weights are between 0 and 1 and sum to 1. The cumulative percent in the combined population corresponding to a given consumption rate is calculated as the weighted sum of cumulative percentages for the three tribes. The inverse of this combined function would return percentiles of pooled consumption as a function of the desired percentage, e.g. the input of 75% would return as output the level of consumption that meets or exceeds the consumption of 75% of (weighted) consumers. The following procedure was performed:

1. Mean, available percentiles and the minimum consumption rates were tabulated from published reports—Suquamish 2000, Liao 2002 and Polissar 2006—and the original g/kg/day estimates were converted to g/day by multiplying by the mean body weight specific to each tribe's survey sample
    a. Tables A1 and A2 show the original data used
    b. All rates correspond to adult consumers only

2. The minimum consumption rate reported for each tribe was used as the 100 x 1/(N+1) percentile, where N is the sample size of the reported survey. This was typically around 1% for each tribe. No extrapolation was performed below this percentile.

3. The maximum consumption rate was not previously reported for the Tulalip and Squaxin Island tribes. As an alternative approach to estimating percentiles beyond the 95^{th}, the 99^{th} percentile was extrapolated for each of the three tribes using a log-normal assumption (described below.)

4. Estimated CDFs were formed as piecewise continuous interpolations of the available estimates and the extrapolated 99^{th} percentile (termed the base percentiles), where the original estimates were always retained
    a. Percentiles were interpolated between adjacent base percentiles using a log-normal assumption.
    b. This procedure amounts to linearly interpolating between points after 1) log transforming the consumption rate percentile and 2) transforming the percentile number (between 0 and 1) using the inverse of standard normal CDF $\Phi(\cdot)$
    c. Figure 2 illustrates the interpolation

5. The combined CDF was formed as a weighted sum of each tribe's CDF, where each tribe was given equal weight, i.e. (1/3, 1/3, 1/3)
   a. Example: if the input was 100 g/day, and this corresponded to the 40th, 50th and 60th percentiles of the three tribes, respectively, then it would correspond to the 50th percentile of the combined CDF (i.e., [40+50+60]/3).

6. The desired parameters were computed as follows
   a. Mean consumption: weighted sum of each tribe's mean consumption using the same weights as for the combined CDF
   b. Percentiles: combined CDF inverted numerically

Table A1. Summary of reports of adult consumer consumption rates from all sources (including from and outside Puget Sound.)

Tribe	Consumption group	N	Mean body weight, kg	Mean consumption in g/kg/day	Source Report
Suquamish	All seafood	92	79	2.707	Suquamish 2000 (Table C1); Liao 2002
Suquamish	Anadromous	92	79	0.618	Suquamish 2000 (Table C1); Liao 2002
Tulalip	All seafood	73	82	1.026	Polissar 2006 (Table A1.T)
Tulalip	Anadromous	72	82	0.451	Polissar 2006 (Table A1.T)
Squaxin	All seafood	117	82	1.021	Polissar 2006 (Table A1.S)
Squaxin	Anadromous	117	82	0.672	Polissar 2006 (Table A1.S)

Table A2. Source percentiles for all seafood consumption. Blank cells indicate that the percentile was not previously reported.

	Consumption rate percentiles in g/kg/day		
	Suquamish	**Tulalip**	**Squaxin**
Min	0.080	0.006	0.017
p5	0.236	0.049	0.05
p10	0.354	0.074	0.097
p15	0.498		
p20	0.574		
p25	0.665	0.238	0.233
p30	0.826		
p35	0.960		
p40	0.969		
p45	1.352		
p50	1.672	0.560	0.543
p55	1.831		
p60	2.087		
p65	2.385		
p70	2.851		
p75	3.598	1.134	1.151
p80	4.058		
p85	4.942		
p90	6.190	2.363	2.51
p95	10.087	2.641	3.417

pXX is the XXth percentile;

Scenarios

Three scenarios were considered: 1) all seafood (no adjustment); 2) all seafood including reduced anadromous consumption; 3) all seafood, excluding all anadromous consumption. The source reports provided estimates for all seafood consumption rates (used directly for scenario 1) and for total anadromous rates (used to derived scenario 2 and 3 rates.)

The Washington Department of Ecology provided an adjustment factor (AF) where only a portion of the anadromous fish consumption was retained in the rates. The adjustment factor was derived as follows:

1. It was assumed that all anadromous fish consumed were coho or Chinook salmon

2. Coho were assumed to constitute 50% of the anadromous fish consumed, of which 33% of contaminants were from Puget Sound and should be retained
3. Chinook were assumed to constitute the other 50% of anadromous fish consumed
    a. 70% of Chinook were migratory with 78% of contaminants from Puget Sound and so retained
    b. 30% of Chinook were resident with all contaminants from Puget Sound, so all would be retained
4. Thus 0.5*0.33 + 0.5*(0.7*0.78 + 0.3*1.0)=0.588 of anadromous fish should be retained in the rates
5. The AF=1-0.588 represents the proportion of anadromous fish that should be excluded from the rates

It was assumed that anadromous fish represented a fixed proportion (which differs per tribe) of the total seafood consumption. This proportion (pAna) was estimated as the proportion of anadromous biomass consumed out of the total biomass consumed. Biomass consumed was computed as the number of consumers (in the survey sample) times the mean consumption rate.

The mean and percentiles of non-anadromous consumption (scenario 3) were then estimated as (1-pAna) times the corresponding total seafood consumption statistics. The adjusted anadromous consumption statistics (scenario 2) were estimated analogously but with the factor (1-pAna*AF.) Table A3 shows the calculations.

Table A3. Illustration of scaling factors applied to generate the consumption scenarios. See text for more details.

	Suquamish	Tulalip	Squaxin
Anadromous biomass consumed, g/day	4492	2663	6447
All seafood biomass consumed, g/day	19674	6142	9795
pAna	0.2283	0.4335	0.6582
1-pAna	0.7717	0.5665	0.3418
1-pAna*AF	0.9059	0.8214	0.7288

Log-Normal Assumption

Some calculations assumed that the consumption rates from each tribe were log-normally distributed or that the distribution resembled a particular log-normal over a particular range. The QQ-plots shown in Figures A1 - A3 show that the observed data do resemble a log-normal distribution over the range of percentiles available.

Extrapolation to 99th Percentile

The highest percentile available for all tribes was the 95th, but due to differences between tribes, individual percentiles greater than the 95th were needed for some percentiles of the combined CDF. The 99th percentile was extrapolated for each tribe by first estimating log-normal parameters (mean and SD of consumption on the log-scale) using a least-squares regression of the log of the observed percentiles (all available between the 5th and 95th) onto the standard normal percentiles. Then those estimates were plugged into the theoretical CDF, from which the 99th percentile was derived.

Approximate Uncertainty Bounds

The parametric bootstrap was used to compute approximate uncertainty bounds based on an underlying log-normal assumption. As this model may not be fully correct and not all sources of variability could be simulated, these bounds should be interpreted as a rough guide to the level of precision available rather than as formal 95% confidence intervals.

For each tribe, the log-normal parameters (mean and SD of consumption on the log-scale) were estimated using a least-squares regression of the log of the consumption percentiles (all available between the 5th and 95th) onto the standard normal percentiles. This is the same method as used for the extrapolation approach described above. A total of 999 replicate data sets of tribal consumption rates were generated by randomly drawing from the corresponding log-normal distributions using the same sample sizes as in the original surveys. For each replicate, the same sequence of computations was applied as was used to compute the results from the original data. These computations include estimating the mean and percentiles as found in the previous reports (e.g. minimum, 5%, 10%, 25%, etc.), interpolating between those percentiles, extrapolating to the 99th percentile, combining the three tribes and calculating the summary statistics of the combined distribution (mean and percentiles.)

Because each replicate came from a different random sample, the values of the final statistics computed varied. The collection of these values formed estimates of the bootstrap distribution for each statistic (mean and percentiles.) The log transform was applied to these statistics to reduce right skewness, except for the 10th percentile which was not skewed on the original scale. The standard error (SE) was estimated as the standard deviation of the transformed estimates generated from each replicate. Uncertainty bounds were then computed on the log-scale as log(original estimate) $\pm$ 1.96 x SE. The antilog was applied to produce bounds on the original scale. For the 10th percentile, the calculation was (original estimate) $\pm$ 1.96 x SE without any transformations, as none were needed in this case.

Any bias between the original estimates and the replicates was ignored as this could be due to the lognormal model being incorrect. Thus, these uncertainty bounds primarily capture variability. For some replicates particular percentiles were not available in some scenarios (most often the 10th or 95th.) These replicates were ignored for the calculations of the uncertainty bounds for the missing percentiles.

The ratio between mean seafood consumption and mean anadromous finfish consumption was kept constant per tribe as the dependence between the total consumption and anadromous consumption could not be simulated. The anadromous adjustment factor provided by Washington Department of Ecology was also kept constant. Thus these two sources of variable were not accounted for in the uncertainty bounds. The uncertainty bounds may also tend to under-estimate uncertainty, because in the simulation the log-normal assumption used throughout the calculations was assumed to be true, while this assumption may not be true for the originally observed data.

Figures

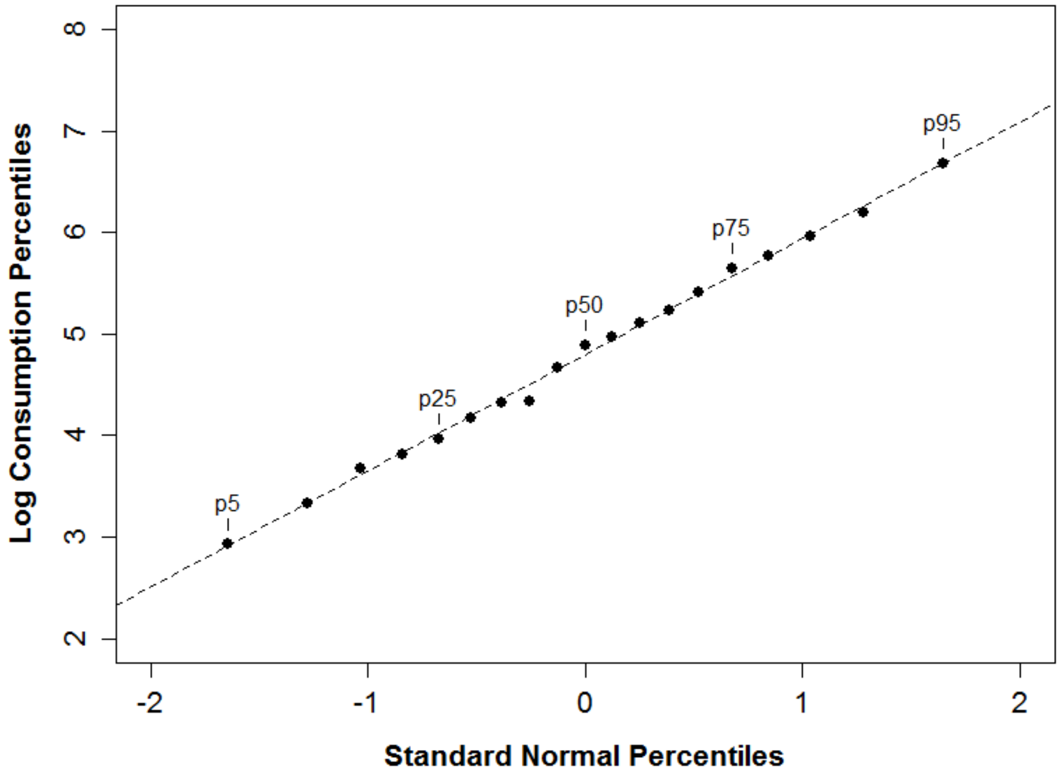

Figure A1. QQ-plot of log consumption for the Suquamish Tribe. The dashed line shows the least squares regression. The closer the points fit a straight line the better the fit to a log-normal distribution.

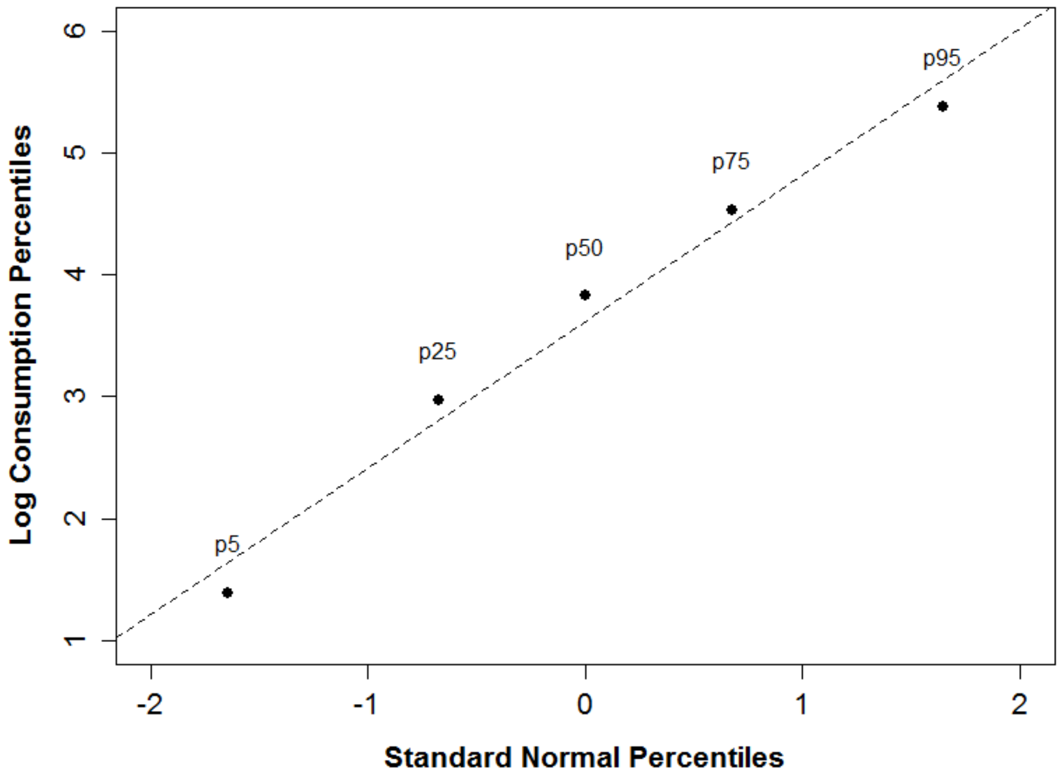

Figure A2. QQ-plot of log consumption for the Tulalip Tribes. The dashed line shows the least squares regression. The closer the points fit a straight line the better the fit to a log-normal distribution.

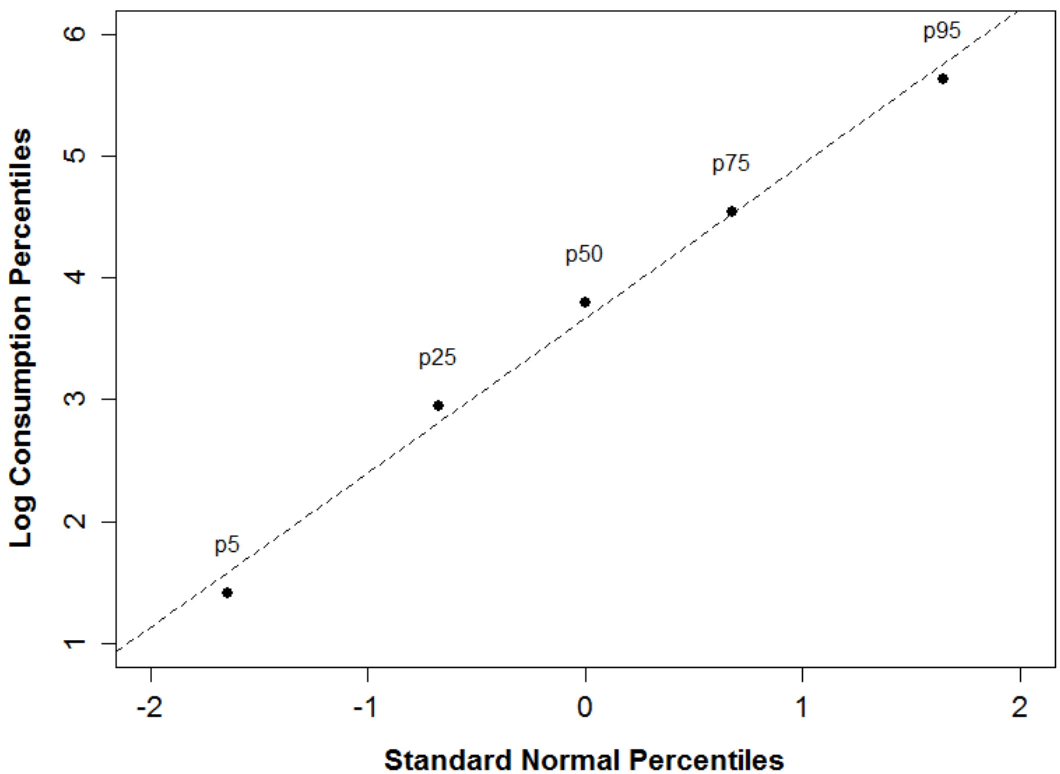

Figure A3. QQ-plot of log consumption for the Squaxin Island Tribe. The dashed line shows the least squares regression. The closer the points fit a straight line the better the fit to a log-normal distribution.

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Derivation of Alternative Human Health Risk-Based Ambient Water Quality Criteria Using Probabilistic Methods for the State of Washington

February 4, 2014

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Attachments

A Development of a Fish Consumption Rate Distribution for Residents of the State of Washington

Acronyms and Abbreviations

aAWQC	alternative ambient water quality criteria
AT_c	averaging time for carcinogenic effects
AT_{nc}	averaging time for noncarcinogenic effects
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	ambient water quality criteria
BCF_{lipid}	lipid-based bioconcentration factor
BCF_{tissue}	tissue-based bioconcentration factor
BW	body weight
C_w	concentration in water
CL	cooking loss
CLF	catch location factor
CSF	cancer slope factor
CSFII	Continuing Survey of Food Intakes by Individuals
DI	drinking water intake
ED	exposure duration
ELCR	excess lifetime cancer risk
FCR	fish consumption rate
FDEP	Florida Department of Environmental Protection
HEAST	Health Effects Assessment Summary Tables
HQ	hazard quotient
IRIS	Integrated Risk Information System
LHF	life history factor
NHANES	National Health and Nutrition Examination Survey

NWPPA	Northwest Pulp & Paper Association
PAWQCC	Probabilistic Ambient Water Quality Criteria Calculator
PCB	polychlorinated biphenyl
PPRTV	Provisional Peer Reviewed Toxicity Values
RBA_w	relative bioavailability, water
RBA_f	relative bioavailability, fish
RfD	reference dose
RSC	relative source contribution
TSD	Technical Support Document
USEPA	United States Environmental Protection Agency
WDOE	Washington Department of Ecology

1. Introduction

On behalf of the Northwest Pulp & Paper Association (NWPPA), ARCADIS used probabilistic risk assessment methods to derive alternative ambient water quality criteria (also referred to as aAWQC in the report) for 114 chemicals listed in the United States Environmental Protection Agency's (USEPA's) 2013 Human Health Criteria Table (USEPA 2013a). The input assumptions used to derive the alternative AWQC were developed to be representative of residents of the State of Washington and, thus, the alternative AWQC represent criteria that are protective of Washington residents.

When using the traditional deterministic approach to deriving AWQC, point estimates are selected to represent exposure parameters such as body weight, drinking water intake, and fish consumption rate. Typically, high-end or maximum values are chosen to represent most of these parameters, which, when combined, lead to unlikely exposure scenarios and overestimates of potential risk. The phenomenon of a combination of high-end assumptions leading to an overestimate of risk is known as "compounded conservatism."

In contrast to the deterministic approach, the probabilistic approach accounts for variability within populations by allowing one or more of the exposure parameters to be defined as distributions of potential values (i.e., probability density functions). The result is a distribution of potential risk representing a range of possible exposures. The probabilistic approach therefore provides explicit estimates of potential risk for different segments of the population, including both the general population (e.g., arithmetic mean or 50th percentile) and individuals with high-end exposures (e.g., the 90th, 95th or 99th percentiles). In this report, for example, fish consumption rates representative of both the general and tribal populations of Washington State are accounted for, with total fish consumption rates as high as 291 grams per day (g/day) at the 99th percentile of the tribal population included in the development of the fish consumption rate distribution. As long as one or more of the exposure parameters used to estimate risk are defined as distributions of values, the outcome will be a distribution of estimated risks. To derive AWQC using the information developed by the probabilistic approach, regulators must make risk management decisions to determine what level of protection will be afforded to a given segment of the population, recognizing that different segments of the population by definition will always have varying levels of potential risk.

The concept of probabilistic assessment is not a new one; USEPA has issued formal guidance for conducting probabilistic risk assessments (USEPA 2001). However, most agencies, including USEPA, have continued to use the traditional deterministic approach to deriving AWQC, despite criticism that the deterministic approach is overly conservative and can lead to unrealistic estimates of risk. Recently, the benefits of using the probabilistic approach to derive AWQC have been recognized. For example, the Florida Department of Environmental Protection (FDEP) is currently revising its state criteria using probabilistic methods that allow the State to demonstrate all segments of the population, including high end consumers, are protected, albeit at varying acceptable risk levels. While USEPA has not yet formally accepted FDEP's revised criteria, they have reviewed the derivation methods and have indicated a probabilistic approach is acceptable.

2. Methods

The general AWQC derivation process uses equations that account for the key exposure pathways (i.e., consumption of water and fish). Deterministic AWQC are derived using equations that include both exposure and toxicity parameters combined with a risk management threshold (i.e., an acceptable risk level). Probabilistic AWQC are derived by using these same equations, combined with distributions for one or more parameters representing the inherent variability in a population's physical characteristics and behaviors, to generate a distribution of risk. The AWQC derived using probabilistic methods is the water concentration that has associated with it a distribution of potential risk that meets (i.e., does not exceed) the risk management threshold(s) selected by the regulatory agency. In some cases, a regulatory agency may select a single risk management threshold. For example, a regulatory agency might require that the Hazard Quotient (HQ) for the 90th percentile of the population be equal to or less than 1.0. Alternatively, a regulatory agency may select multiple risk management thresholds that need to be met by an AWQC. For example, that the 50th percentile of the population (the median) must have an excess lifetime cancer risk (ELCR) equal to or less than $1x10^{-5}$ and that the 99th percentile of the population must have an ELCR equal to or less than $1x10^{-4}$. Both of these risk management thresholds must be met by the AWQC and are used in this report to derive alternate AWQC.

2.1 Risk Characterization

Risks were estimated using the fundamental equations employed by USEPA to derive AWQC (USEPA 2000). The USEPA equation for chemicals with noncarcinogenic endpoints is:

$$HQ = \frac{C_W \ x \ [DI + (FCR \ x \ BCF_{tissue})]}{BW \ x \ RSC \ x \ RfD} \qquad \textbf{(Equation 1)}$$

The USEPA equation for chemicals with noncarcinogenic endpoints is:

$$ELCR = \frac{C_W \ x \ [DI + (FCR \ x \ BCF_{tissue})] \ x \ CSF}{BW} \qquad \textbf{(Equation 2)}$$

Where:

HQ = hazard quotient (unitless);
ELCR = excess lifetime cancer risk (unitless);
C_w = concentration in water (mg/L);
DI = drinking water intake (L/day);

FCR = fish consumption rate (kg/day);
BCF_{tissue} = tissue-based bioconcentration factor (L/kg tissue);
BW = body weight (kg);
RSC = relative source contribution (unitless);
RfD = reference dose (mg/kg-day); and
CSF = cancer slope factor $(mg/kg\text{-}day)^{-1}$.

In addition to the parameters explicitly listed in the USEPA equations, additional implicit parameters (e.g., cooking loss, relative bioavailability, life history factor) also affect the characterization of risk and can be included in the risk characterization equations. The expanded equation for chemicals with noncarcinogenic health endpoints is:

$$HQ = \frac{C_W\ x\left[(RBA_W\ x\ DI)+\left(RBA_f\ x\ FCR\ x\ CLF\ x\ LHF\ x\ BCF_{lipid}\ x\ lipid\ x\ (1-CL)\right)\right]x\ ED}{BW\ x\ AT_{nc}\ x\ RSC\ x\ RfD} \quad \textbf{(Equation 3)}$$

The expanded equation for chemicals with carcinogenic health endpoints is:

$$ELCR = \frac{C_W\ x\left[(RBA_W\ x\ DI)+\left(RBA_f\ x\ FCR\ x\ CLF\ x\ LHF\ x\ BCF_{tissue}\ x\ lipid\ x\ (1-CL)\right)\right]x\ ED\ x\ CSF}{BW\ x\ AT_c} \quad \textbf{(Equation 4)}$$

Where the additional implicit parameters include:

RBA_w = relative bioavailability, water (unitless);
RBA_f = relative bioavailability, fish (unitless);
CLF = catch location factor (unitless);
LHF = life history factor (unitless);
BCF_{lipid} = bioconcentration factor (L/kg lipid)
Lipid = proportion of lipid in fish tissue (kg lipid/kg tissue);
CL = cooking loss (unitless);
ED = exposure duration (years);
AT_{nc} = averaging time for noncarcinogenic effects (years); and
AT_c = averaging time for carcinogenic effects (years).

2.2 Probabilistic Approach

The equations presented in Section 2.1 are referred to as “forward” risk equations; that is, the equations estimate risk from a chemical concentration, exposure dose, and toxicity. When deriving AWQC using a deterministic approach, USEPA rearranges the equations such that they predict an allowable water concentration (i.e., the AWQC) based on an allowable risk and the same exposure and toxicity factors used by the forward equation to estimate risk. These rearranged equations are sometimes referred to as "backward" equations and are typically used for deterministic calculation of risk-based acceptable media concentrations (e.g., AWQC or preliminary remediation goals at waste sites).

Deriving AWQC using probabilistic methods requires forward equations. The reasons for using the forward equations for probabilistic assessments are mathematically complex and are described in greater detail elsewhere (e.g., Burmaster et al. 1995, Ferson 1996). In essence, the forward equation will yield a distribution of risks dependent on several inputs that are also distributions. If the equation is "flipped" to solve for one of the inputs, the resulting distribution and the original input distribution may have similar means, but the spread of the distributions will be different. Because it is the tails of a distribution that are typically of interest when setting acceptable risk or acceptable media concentrations, this disparity has marked effects on the outcome of the calculation. Therefore, USEPA recommends using forward equations when conducting probabilistic assessments to avoid the mathematical limitations associated with backcalculation (USEPA 2001).

For probabilistic derivation of AWQC, the process of estimating risk by selecting from the input point estimates or distributions is repeated until the number of desired iterations (e.g., 100,000 iterations in the case of the alternative AWQC presented herein) is complete. One complete set of iterations is called a simulation. As long as one or more of the input parameters are distributions, the final output of a simulation will be a distribution of risks associated with a particular concentration of a chemical in water. If the estimate of risk at a specific percentile meets the risk management requirements selected by the regulatory agency, the chemical concentration that was used to generate the output is the AWQC.

Typically, multiple simulations are required to derive probabilistic AWQC. Two methods can be used to develop the AWQC.

- **Trial and Error** – Select a water concentration, run a simulation, and compare the resulting risk distribution to risk management thresholds. If one or more thresholds is not met, repeat the process inserting alternative chemical concentrations until a concentration is identified that results in a risk distribution that meets risk management thresholds. That concentration is the AWQC.
- **Systematic Linear Derivation** – Run simulations at three or more alternative chemical concentrations. Plot the estimated risk at the percentile of the risk distribution corresponding to the risk management threshold versus the chemical concentration used for each simulation. Generate a least-squares linear regression line based on the plot of paired ELCRs and concentrations. Use that equation to solve for the chemical concentration that corresponds to the allowable risk level for the percentile of the population specified by the risk management threshold. That concentration is the AWQC. This process is recommended by USEPA (2001) as a "shortcut" for the trial-and-error method when using probabilistic methods to calculate risk-based acceptable media concentrations.

The systematic linear derivation method was used to derive the alternative AWQC presented in this report. Simulations using 100,000 iterations each were run using the Probabilistic Ambient Water Quality Criteria Calculator (PAWQCC) developed by ARCADIS. PAWQCC is an Excel-based calculator tool that employs @Risk software (Palisade Corporation 2013) to develop probabilistically based estimates of risk. The calculator, along with the inputs used to derive the AWQC presented in this report, will be provided under separate cover.

2.3 Risk Management Thresholds

For chemicals with noncarcinogenic health endpoints, the alternative AWQC are based on a target HQ of 1.0 at the 90th percentile of the risk distribution. For chemicals with carcinogenic health endpoints, the alternative AWQC are based on a target ELCR of one in one hundred thousand (1×10^{-5}) at the 50th percentile (i.e., median) of the risk distribution and one in ten thousand (1×10^{-4}) at the 99th percentile of the risk distribution. This is consistent with USEPA methodology, which states “EPA believes that both 10^{-6} and 10^{-5} may be acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level” (USEPA 2000).

2.4 Input Assumptions

To derive alternative AWQC using a probabilistic approach, distributions were selected to represent a number of the input parameters. Washington-specific data were used to incorporate information about fish consumption rate and the life history factor into the fish consumption rate distribution. The other distributions were based on data representing the general United States population.

2.4.1 Toxicity

The toxicity values used to derive AWQC were obtained from the USEPA National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix (USEPA 2002a). To determine whether the toxicity values listed in USEPA (2002a) still reflect the current understanding of each chemical’s health effects, the following sources were consulted, in accordance with the recommended hierarchy presented in USEPA guidance (2003), in order of priority:

- USEPA's Integrated Risk Information System (IRIS) (USEPA 2014a);
- USEPA’s Provisional Peer Reviewed Toxicity Values (PPRTVs) (USEPA 2014b);
- Additional USEPA and non-USEPA sources of toxicity information, including but not limited to the California Environmental Protection Agency toxicity values, the Agency for Toxic Substances and Disease Registry (ATSDR) minimum risk levels, and toxicity values published in the USEPA Health Effects Assessment Summary Tables (HEAST) (USEPA 1997).

In cases where the toxicity values listed in USEPA (2002a) have been superseded by newer data (e.g., a toxicity value had been withdrawn or updated in IRIS), the current toxicity values were used, in accordance with the hierarchy listed above.

In some cases, USEPA (2002a) was not able to identify toxicity values for a given chemical. In these cases, USEPA (2002a) chose surrogate toxicity values from a chemical that is considered structurally and toxicologically similar to the chemical that did not have toxicity values from the above sources (e.g., the toxicity value for endosulfan was selected to represent both alpha- and beta-endosulfan, for which toxicity values are not available). The same chemical surrogates used by USEPA (2002a) were used in this report. A summary of toxicity values used to derive alternative AWQC is presented in **Table 1**.

The derivation of probabilistic alternative AWQC presented in this report treats all toxicity values as point estimates.

2.4.2 Relative Source Contribution

Relative source contribution (RSC) refers to the portion of an individual's daily exposure to a chemical that is allocated to exposure from the regulated surface water (i.e., the consumption of water and fish). The RSC accounts for the possibility that individuals can be exposed to a chemical through sources other than surface water (e.g., food or air). The RSC applies only to AWQC with noncarcinogenc health endpoints.

USEPA (2000) describes a decision process to select an RSC. That process leads to RSCs of no greater than 0.8 and as low as 0.2. However, for the majority of chemicals, national AWQC are based on an RSC of 1.0, though USEPA has indicated that in the future, the decision process described in USEPA (2000) for selecting an RSC will need to be followed when revising AWQC. In response to comments from USEPA regarding Florida's proposed AWQC, Florida is currently deriving RSCs for several chemicals.

Because RSCs can have a substantial effect on AWQC (a five-fold difference between AWQC based on an RSC of 1.0 versus an RSC of 0.2), alternative AWQC protective of noncarcinogenic endpoints were derived in two ways.

- First, AWQC were derived assuming an RSC of 1.0 for all chemicals (i.e., all of a person's exposure to a chemical is assumed to come from the regulated surface water). This approach is consistent with most of the existing national AWQC derived by USEPA.
- Second, USEPA has derived RSCs of less than 1.0 for 19 of the 114 chemicals addressed in this report (USEPA 2013b). Alternative AWQC were also derived for these 19 chemicals using the RSCs recommended by USEPA (**Table 2**).

The derivation of probabilistic alternative AWQC presented in this report treats all RSCs as point estimates.

2.4.3 Bioconcentration and Percent Lipid

Bioconcentration refers to the process by which a chemical present in ambient water accumulates in fish tissue. The lipid-based bioconcentration factor (BCF) used in Equations 1 and 2, expressed in units of liters per kilogram lipid, is defined as the ratio of the concentration of the chemical in fish lipid to its concentration in the surrounding water. The lipid-based BCF is multiplied by the proportion of lipid in fish tissue to ultimately express bioconcentration on a fish tissue basis (i.e., units of liters per kilogram tissue). USEPA (2002a) provides default BCFs expressed on a fish tissue basis and normalized to a default lipid content of 3%. The default USEPA BCFs and 3% lipid were used to derive the alternative AWQC presented in this report. Where a default BCF was unavailable, AWQC were derived based on the consumption of water only. A summary of bioconcentration factors used to derive AWQC for the State of Washington is presented in **Table 3**.

The derivation of probabilistic alternative AWQC presented in this report treats all BCFs and lipid content as point estimates.

2.4.4 Cooking Loss

Cooking loss refers to the proportion of the chemical present in fish tissue that is lost as part of the cooking process. The AWQC presented in this report conservatively assume no cooking loss and that all of the chemical in raw fish remains in cooked fish. This assumption is consistent with the approach USEPA has used to derive national AWQC. For lipophilic chemicals (e.g., polychlorinated biphenyls [PCBs]) this is likely to lead to conservative AWQC because concentrations of such chemicals tend to be reduced by cooking. The amount of loss depends upon cooking method and the frequency at which various methods are used. Sufficient data are available for some chemicals (e.g., PCBs) to develop an input distribution for cooking loss. Thus, cooking loss could be incorporated in AWQC in the future.

2.4.5 Exposure Duration

As a matter of default and to be consistent with USEPA's approach to derivation of AWQC, exposure duration was assumed to occur over an entire lifetime (equal to 70 years). This conservative approach assumes that every member of the population lives in the same place and is exposed to the same chemical concentration in water and/or fish tissue each day over the duration of their 70-year lifetime. In reality, this is unlikely to be the case; the mean residential occupancy period according to USEPA is 12 years, and the 95th percentile is only 33 years (USEPA 2011). Even if an individual lives in the same state their entire life, it is highly unlikely that they will live only near (and thus be exposed only to) contaminated waters over the course of their lifetime.

2.4.6 Body Weight

The 2011 Exposure Factors Handbook (USEPA 2011) provides age-specific distributions of body weight computed by Portier et al. (2007) using National Health and Nutrition Examination Survey (NHANES) II, III, and IV data. USEPA recommends using the Portier et al. (2007) data when body weight distributions are required, because the data are based on a large sample size and are representative of the general United States population. The body weight distribution derived from the NHANES IV survey for ages 18-65, males and females combined, was used to develop the alternative AWQC presented in this report (USEPA 2011; Table 8-25). Body weight was truncated at a lower limit of 44 kilograms (97 pounds), corresponding to the 1st percentile of the distribution. This approach is consistent with the approach used by the State of Florida to derive AWQC (FDEP 2013). Summary statistics for the body weight distribution are provided in **Table 4**.

2.4.7 Drinking Water Intake

In 2010, USEPA analyzed the 2003-2006 NHANES survey data to assess water ingestion rates across the general United States population. The results of the USEPA analysis are presented in the 2011 Exposure Factors Handbook (USEPA 2011). The consumer-only direct and indirect water intake distribution for ages 21 and above was used to derive the alternative AWQC presented in this report (USEPA 2011; Table 3-36). Using @Risk, a distribution was fit to the data using the range of reported percentiles as fit parameters. The resulting distribution was truncated at a lower limit of 0 liters per day. Summary statistics for the drinking water intake distribution are provided in **Table 4**.

2.4.8 Catch Location Factor

Catch location factor refers to the proportion of fish consumed that are caught in state or local waters. The alternative AWQC presented in this report assume that all fish consumed are caught locally (i.e., catch location factor [CLF] equals 1.0). This approach leads to conservative AWQC because it assumes that no one consumes either fresh or pre-packaged fish products that may have been produced in other states or outside of the United States.

2.4.9 Life History Factor

In this report, life history factor (LHF) refers to the portion of the fish life cycle that is spent in state or local waters. For true freshwater fish, the LHF will be 1. For anadromous species that spend the majority of their life cycle in marine waters, including many species and populations of salmon, the LHF will be some value less than 1. If it is assumed that bioaccumulation of chemicals by aquatic organisms is a linear function of time, a life history factor reflecting time spent in waters of the state is equivalent to the fraction of the chemical body burden in adult salmon acquired in waters of the state. Thus, life history factors based on residence time were developed for five species of Pacific Northwest salmon to account for the fraction of salmon chemical body burden acquired in state or local waters (**Appendix A in Attachment A**). An alternative and perhaps more accurate approach would consider when and where chemical body burden is accumulated as a function of relative growth. Deriving life history factors based on residence time is a simplifying assumption and one that is likely to overstate the importance of bioaccumulation during early life stages, when salmon are not accruing a significant portion of their body mass. In other words, the residence time-based life history factors derived for salmon are believed to serve as a conservative approximation. Ultimately, a composite life history factor for all Pacific Northwest salmon species was derived using weighting factors reflecting the species-specific consumption patterns of the Suquamish Tribe. The final composite life history factor (i.e., 0.318) was then incorporated directly into the derivation of a Washington State fish consumption rate, as summarized below in Section 2.4.10 and detailed in **Appendix A in Attachment A**.

2.4.10 Fish Consumption Rate

The Washington Department of Ecology (WDOE) released two Technical Support Documents (TSDs) reviewing fish consumption rates for both the general and tribal populations of Washington State (WDOE 2011, 2013). Using the data presented in these WDOE TSDs, a composite fish consumption rate distribution was developed to represent both general population and tribal consumption of freshwater species, estuarine species, and salmon (**Attachment A**).

The general population distribution provided in the WDOE TSD (2013) for consumption of all fish species has a mean of 19 g/day, ranging up to 91 g/day at the 99th percentile. Several steps were taken to refine the fish consumption rate distribution to make sure it is representative of Washington residents. First, the general population distribution was adjusted to reflect only freshwater and estuarine species (i.e., off-shore marine species were removed from the distribution) using data from USEPA's Continuing Survey of Food Intakes by Individuals (CSFII) survey (USEPA 2002b). Next, the distribution was adjusted upward to add back the portion of overall fish consumption that is salmon (because USEPA's CSFII survey classifies salmon as a marine species and marine species were excluded in the first step of the fish consumption rate [FCR] distribution derivation process). This salmon component was multiplied by the composite salmon life history factor before being added to the final distribution; thus, only the consumption of salmon associated with waters of the State based on salmon life history was included in the distribution.

The tribal population distribution provided in the WDOE TSD (2011; Appendix C) for consumption of all fish species has a mean of 71 g/day, ranging up to 291 g/day at the 99th percentile. It was assumed that the only marine species consumed by the tribal population is salmon. Therefore, the only adjustment made to the tribal fish consumption rate distribution was to incorporate the salmon life history factor. It was assumed that 46% of tribal fish consumption is comprised of salmon, based on data provided in the WDOE TSD. The salmon life history factor was applied to this portion of the overall tribal fish consumption rate.

Once the general and tribal fish consumption rate distributions were adjusted to reflect only freshwater species, estuarine species, and salmon associated with waters of the State, the two distributions were combined to reflect the entire population of Washington State. A single, composite fish consumption rate distribution was derived using weighting factors based on relative population size. Using data provided in the WDOE TSD, weighting factors of 98% and 2% were used for the general and tribal portions of the population, respectively. Using @Risk, a distribution was fit to the data using the range of percentiles as fit parameters. The resulting distribution was truncated at a lower limit of 0 g/day. An upper truncation limit for the fish consumption rate distribution was not defined, meaning that the fitted distribution can theoretically extend to any positive value. The actual maximum values achieved by the distribution ranged from 135 to 250 g/day, with a mean of 150 g/day, after 500 simulations of 100,000 iterations each. Summary statistics for the fish consumption rate distribution are provided in **Table 4**, and a detailed description of the complete derivation process is provided in **Attachment A**.

3. Results and Discussion

ARCADIS developed alternative AWQC (abbreviated aAWQC in the supporting tables) for 114 chemicals using a probabilistic approach. Alternative AWQC were developed for the consumption of water and organisms as well as for the consumption of organisms only (**Table 5**). All alternative AWQC were developed using an RSC of 1.0. Alternate AWQC were also derived for the 19 chemicals having USEPA-recommended RSCs lower than 1.0, (**Table 6**).

All alternative AWQC were compared to the corresponding national AWQC listed in USEPA's 2013 Human Health Criteria Table (USEPA 2013a) (**Table 7**). Differences between existing national AWQC and the probabilistically derived alternative AWQC arise due to the fundamental differences in derivation approach; the current national criteria were derived using deterministic methods assuming single point estimates for all inputs, while the alternative criteria were derived using a probabilistic approach that incorporates distributions for several of the inputs that determine exposure. Differences also arise due to changes in the understanding of the health effects associated with select chemicals (i.e., changes in the USEPA toxicity factors).

The alternative AWQC presented in this report were derived using probabilistic methods to be protective of Washington residents. The exposure assumptions used to derive these alternate criteria were developed to represent the full range of potential exposures as they are understood today, including both the general population as well as highly exposed individuals, such as tribal members who consume large amounts of fish (i.e., greater than 200 g/day).

National data were used to develop distributions for drinking water intake and body weight. Both national and Washington-specific data were used to develop a distribution of fish consumption rates representative of the entire population of Washington State. The national data were used to represent general fish consumption rates and tribal rate data published by Washington State Department of Ecology (WDOE 2011, 2013) were used to represent tribal consumption rates.

Even with the inclusion of probabilistic methods to better represent the range of fish consumption expected among residents of Washington State as well as distributions for body weight and drinking water consumption, the alternative AWQC retain several conservative elements and are more protective than implied by the risk management thresholds employed in this report. For example, point estimates equal to the maximum value were used for several implicit parameters (e.g., cooking loss, catch location factor, relative bioavailability) leading to an overestimate of potential risk and alternative AWQC that are more stringent than necessary to meet the specified level of protection. Additionally, point estimates were used for toxicity factors and those too are upper bounds (in the case of cancer slope factors) or are derived using several uncertainty factors (in the case of reference doses) as well as other conservative assumptions designed to overstate the potential toxicity of a chemical to protect public health.

Combined the assumptions and approach used in this report lead to alternative AWQC that are protective of public health but are based on a more complete representation of the range of risks associated with consumption of fish and drinking water than is possible with a deterministic approach, leading to improved risk management decision-making.

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Tables

Table 1. Toxicity Values

CAS Number	Chemical	Noncarcinogenic Effects Reference Dose (RfD)		Carcinogenic Effects Cancer Slope Factor (CSF)	
		mg/kg-day	source	$(mg/kg\text{-}day)^{-1}$	source
71-55-6	1,1,1-Trichloroethane	2.0E+00	IRIS	NA	
79-34-5	1,1,2,2-Tetrachloroethane	2.0E-02	IRIS	2.0E-01	IRIS
79-00-5	1,1,2-Trichloroethane	4.0E-03	IRIS	5.7E-02	IRIS
75-35-4	1,1-Dichloroethene	5.0E-02	IRIS	NA	
95-94-3	1,2,4,5-Tetrachlorobenzene	3.0E-04	IRIS	NA	
120-82-1	1,2,4-Trichlorobenzene	1.0E-02	IRIS	2.9E-02	PPRTV
95-50-1	1,2-Dichlorobenzene	9.0E-02	IRIS	NA	
107-06-2	1,2-Dichloroethane	NA		9.1E-02	IRIS
78-87-5	1,2-Dichloropropane	9.0E-02	ATSDR	3.6E-02	CalEPA
122-66-7	1,2-Diphenylhydrazine	NA		8.0E-01	IRIS
541-73-1	1,3-Dichlorobenzene	9.0E-02	IRIS [1]	NA	
542-75-6	1,3-Dichloropropene	3.0E-02	IRIS	1.0E-01	IRIS
106-46-7	1,4-Dichlorobenzene	7.0E-02	ATSDR	5.4E-03	CalEPA
1746-01-6	2,3,7,8-TCDD	7.0E-10	IRIS	1.3E+05	CalEPA
95-95-4	2,4,5-Trichlorophenol	1.0E-01	IRIS	NA	
88-06-2	2,4,6-Trichlorophenol	1.0E-03	PPRTV	1.1E-02	IRIS
120-83-2	2,4-Dichlorophenol	3.0E-03	IRIS	NA	
105-67-9	2,4-Dimethylphenol	2.0E-02	IRIS	NA	
51-28-5	2,4-Dinitrophenol	2.0E-03	IRIS	NA	
121-14-2	2,4-Dinitrotoluene	2.0E-03	IRIS	3.1E-01	CalEPA
91-58-7	2-Chloronaphthalene	8.0E-02	IRIS	NA	
95-57-8	2-Chlorophenol	5.0E-03	IRIS	NA	
534-52-1	2-Methyl-4,6-Dinitrophenol	8.0E-05	PPRTV	NA	
91-94-1	3,3-Dichlorobenzidine	NA		4.5E-01	IRIS
72-54-8	4,4-DDD	NA		2.4E-01	IRIS
72-55-9	4,4-DDE	NA		3.4E-01	IRIS
50-29-3	4,4-DDT	5.0E-04	IRIS	3.4E-01	IRIS
83-32-9	Acenaphthene	6.0E-02	IRIS	NA	
107-02-8	Acrolein	5.0E-04	IRIS	NA	
107-13-1	Acrylonitrile	4.0E-02	ATSDR	5.4E-01	IRIS
309-00-2	Aldrin	3.0E-05	IRIS	1.7E+01	IRIS
319-84-6	alpha-BHC	8.0E-03	ATSDR	6.3E+00	IRIS
959-98-8	alpha-Endosulfan	6.0E-03	IRIS [2]	NA	
120-12-7	Anthracene	3.0E-01	IRIS	NA	
7440-36-0	Antimony	4.0E-04	IRIS	NA	
7440-38-2	Arsenic (Inorganic)	3.0E-04	IRIS	1.5E+00	IRIS
7440-39-3	Barium	2.0E-01	IRIS	NA	
56-55-3	Benz[a]anthracene	NA		7.3E-01	ECAO
71-43-2	Benzene	4.0E-03	IRIS	1.5E-02	IRIS [3]
92-87-5	Benzidine	3.0E-03	IRIS	2.3E+02	IRIS
50-32-8	Benzo[a]pyrene	NA		7.3E+00	IRIS
205-99-2	Benzo[b]fluoranthene	NA		7.3E-01	ECAO
207-08-9	Benzo[k]fluoranthene	NA		7.3E-02	ECAO
7440-41-7	Beryllium	2.0E-03	IRIS	NA	
319-85-7	beta-BHC	NA		1.8E+00	IRIS
33213-65-9	beta-Endosulfan	6.0E-03	IRIS [2]	NA	
111-44-4	Bis(2-Chloroethyl)ether	NA		1.1E+00	IRIS
108-60-1	Bis(2-Chloroisopropyl)ether	4.0E-02	IRIS	7.0E-02	HEAST
117-81-7	Bis(2-Ethylhexyl) Phthalate	2.0E-02	IRIS	1.4E-02	IRIS
542-88-1	Bis(Chloromethyl)ether	NA		2.2E+02	IRIS
75-25-2	Bromoform	2.0E-02	IRIS	7.9E-03	IRIS
85-68-7	Butylbenzyl phthalate	2.0E-01	IRIS	1.9E-03	PPRTV
7440-43-9	Cadmium	5.0E-04	IRIS [4]	NA	
56-23-5	Carbon Tetrachloride	4.0E-03	IRIS	7.0E-02	IRIS
12789-03-6	Chlordane	5.0E-04	IRIS	3.5E-01	IRIS
108-90-7	Chlorobenzene	2.0E-02	IRIS	NA	
124-48-1	Chlorodibromomethane	2.0E-02	IRIS	8.4E-02	IRIS

Table 1. Toxicity Values

CAS Number	Chemical	Noncarcinogenic Effects Reference Dose (RfD)		Carcinogenic Effects Cancer Slope Factor (CSF)	
		mg/kg-day	source	$(mg/kg\text{-}day)^{-1}$	source
67-66-3	Chloroform	1.0E-02	IRIS	3.1E-02	CalEPA
94-75-7	Chlorophenoxy Herbicide (2,4-D)	1.0E-02	IRIS	NA	
16065-83-1	Chromium III	1.5E+00	IRIS	NA	
18540-29-9	Chromium VI	3.0E-03	IRIS	5.0E-01	NJDEP
218-01-9	Chrysene	NA		7.3E-03	ECAO
7440-50-8	Copper	4.0E-02	HEAST	NA	
57-12-5	Cyanide	6.0E-04	IRIS	NA	
53-70-3	Dibenz[a,h]anthracene	NA		7.3E+00	ECAO
75-27-4	Dichlorobromomethane	2.0E-02	IRIS	6.2E-02	IRIS
75-09-2	Dichloromethane	6.0E-03	IRIS	2.0E-03	IRIS
60-57-1	Dieldrin	5.0E-05	IRIS	1.6E+01	IRIS
84-66-2	Diethyl phthalate	8.0E-01	IRIS	NA	
131-11-3	Dimethyl Phthalate	1.0E+01	[5]	NA	
25550-58-7	Dinitrophenols	2.0E-03	IRIS [6]	NA	
84-74-2	Di-n-Butyl phthalate	1.0E-01	IRIS	NA	
1031-07-8	Endosulfan Sulfate	6.0E-03	IRIS [2]	NA	
72-20-8	Endrin	3.0E-04	IRIS	NA	
7421-93-4	Endrin Aldehyde	3.0E-04	IRIS [7]	NA	
100-41-4	Ethylbenzene	1.0E-01	IRIS	1.1E-02	CalEPA
206-44-0	Fluoranthene	4.0E-02	IRIS	NA	
86-73-7	Fluorene	4.0E-02	IRIS	NA	
76-44-8	Heptachlor	5.0E-04	IRIS	4.5E+00	IRIS
1024-57-3	Heptachlor Epoxide	1.3E-05	IRIS	9.1E+00	IRIS
118-74-1	Hexachlorobenzene	8.0E-04	IRIS	1.6E+00	IRIS
87-68-3	Hexachlorobutadiene	1.0E-03	PPRTV	7.8E-02	IRIS
608-73-1	Hexachlorocyclohexane (Technical)	NA		1.8E+00	IRIS
77-47-4	Hexachlorocyclopentadiene	6.0E-03	IRIS	NA	
67-72-1	Hexachloroethane	7.0E-04	IRIS	4.0E-02	IRIS
193-39-5	Indeno[1,2,3-cd]pyrene	NA		7.3E-01	ECAO
78-59-1	Isophorone	2.0E-01	IRIS	9.5E-04	IRIS
58-89-9	Lindane (gamma-BHC)	3.0E-04	IRIS	1.1E+00	CalEPA
7439-96-5	Manganese	1.4E-01	IRIS	NA	
72-43-5	Methoxychlor	5.0E-02	IRIS	NA	
74-83-9	Methyl bromide	1.4E-03	IRIS	NA	
7440-02-0	Nickel	2.0E-02	IRIS	NA	
14797-55-8	Nitrates	1.6E+00	IRIS	NA	
98-95-3	Nitrobenzene	2.0E-03	IRIS	NA	
—	Nitrosamines	NA		1.5E+02	IRIS [8]
924-16-3	N-Nitrosodibutylamine	NA		5.4E+00	IRIS
55-18-5	N-Nitrosodiethylamine	NA		1.5E+02	IRIS
62-75-9	N-Nitrosodimethylamine	8.0E-06	PPRTV	5.1E+01	IRIS
621-64-7	N-Nitrosodi-n-propylamine	NA		7.0E+00	IRIS
86-30-6	N-Nitrosodiphenylamine	NA		4.9E-03	IRIS
930-55-2	N-Nitrosopyrrolidine	NA		2.1E+00	IRIS
1336-36-3	PCBs	NA		2.0E+00	IRIS
608-93-5	Pentachlorobenzene	8.0E-04	IRIS	NA	
87-86-5	Pentachlorophenol	5.0E-03	IRIS	4.0E-01	IRIS
108-95-2	Phenol	3.0E-01	IRIS	NA	
129-00-0	Pyrene	3.0E-02	IRIS	NA	
7782-49-2	Selenium	5.0E-03	IRIS	NA	
127-18-4	Tetrachloroethene	6.0E-03	IRIS	2.1E-03	IRIS
7440-28-0	Thallium	6.8E-05	IRIS [9]	NA	
108-88-3	Toluene	8.0E-02	IRIS	NA	
8001-35-2	Toxaphene	NA		1.1E+00	IRIS
156-60-5	trans-1,2-Dichloroethylene	2.0E-02	IRIS	NA	
79-01-6	Trichloroethene	5.0E-04	IRIS	4.6E-02	IRIS

Table 1. Toxicity Values

CAS Number	Chemical	Noncarcinogenic Effects Reference Dose (RfD)		Carcinogenic Effects Cancer Slope Factor (CSF)	
		mg/kg-day	source	$(mg/kg\text{-}day)^{-1}$	source
75-01-4	Vinyl Chloride	3.0E-03	IRIS	1.4E+00	IRIS [10]
7440-66-6	Zinc	3.0E-01	IRIS	NA	

Sources:

IRIS = USEPA Integrated Risk Information System
PPRTV = Provisional Peer-Reviewed Toxicity Values
HEAST = Health Effects Assessment Summary Tables
CalEPA = California Environmental Protection Agency
ECAO = Environmental Criteria and Assessment Office
NJDEP = New Jersey Department of Environmental Protection
ATSDR = Agency for Toxic Substances and Disease Registry

USEPA. 2002a. National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix. EPA-822-R-02-012. Washington, DC: United States Environmental Protection Agency Office of Water Office of Science and Technology.

USEPA. 2013a. National Recommended Water Quality Criteria: Human Health Criteria Table. Accessible via: http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm. Last updated: August 22.

Notes:

CAS = Chemical Abstracts Service
mg/kg-day = milligrams per kilogram per day
NA = not available
USEPA = United States Environmental Protection Agency

[1] 1,2-Dichlorobenzene was used as a surrogate, consistent with the USEPA (2002a) approach.
[2] Endosulfan was used as a surrogate, consistent with the USEPA (2002a) approach.
[3] The CSF for benzene ranges from 1.5×10^{-2} to 5.5×10^{-2} per mg/kg-day. The lower value was used (1.5×10^{-2}), consistent with the USEPA (2013a) approach.
[4] Reference dose for cadmium in water.
[5] An average daily intake (ADI) of 10 mg/kg-day was used by USEPA (2002a) to derive the national criterion for dimethyl phthalate.
[6] 2,4-Dinitrophenol was used as a surrogate, consistent with the USEPA (2002a) approach.
[7] Endrin was used as a surrogate, consistent with the USEPA (2002a) approach.
[8] N-Nitrosodiethylamine was used as a surrogate, consistent with the USEPA (2002a) approach.
[9] In 2009, USEPA withdrew the oral RfD for thallium noting the available toxicity database contains studies that are generally of poor quality.
[10] The CSF for vinyl chloride assumes continuous lifetime exposure from birth.

Table 2. USEPA-Recommended Relative Source Contribution Factors (RSCs)

Chemical	USEPA-Recommended RSC
1,1-Dichloroethene	0.2
1,2,4-Trichlorobenzene	0.2
1,2-Dichlorobenzene	0.2
1,4-Dichlorobenzene	0.2
Antimony	0.4
Cadmium	0.25 [1]
Chlorobenzene	0.2
Chromium III	0.2
Chromium VI	0.2
Copper	0.2
Cyanide	0.2
Endrin	0.2
Ethylbenzene	0.2
Hexachlorocyclopentadiene	0.2
Lindane (gamma-BHC)	0.2 – 0.8
Methoxychlor	0.2
Thallium	0.2
Toluene	0.2
trans-1,2-Dichloroethylene	0.2

Source:

USEPA. 2013b. Technical Support Document for Action on the Revised Surface Water Quality Standards of the Spokane Tribe of Indians Submitted April 2010. U.S. Environmental Protection Agency, Region 10, Seattle, Washington. December.

Notes:

RSC = relative source contribution

USEPA = United Stated Environmental Protection Agency

[1] Based on the RSC used to develop the cadmium drinking water Maximum Contaminant Level Goal (MCLG).

Table 3. Default USEPA Bioconcentration Factors

CAS Number	Chemical	Tissue-Based Bioconcentration Factor (BCF_{tissue}) L/kg tissue
71-55-6	1,1,1-Trichloroethane	5.6
79-34-5	1,1,2,2-Tetrachloroethane	5
79-00-5	1,1,2-Trichloroethane	4.5
75-35-4	1,1-Dichloroethene	5.6
95-94-3	1,2,4,5-Tetrachlorobenzene	1125
120-82-1	1,2,4-Trichlorobenzene	114
95-50-1	1,2-Dichlorobenzene	55.6
107-06-2	1,2-Dichloroethane	1.2
78-87-5	1,2-Dichloropropane	4.1
122-66-7	1,2-Diphenylhydrazine	24.9
541-73-1	1,3-Dichlorobenzene	55.6
542-75-6	1,3-Dichloropropene	1.9
106-46-7	1,4-Dichlorobenzene	55.6
1746-01-6	2,3,7,8-TCDD	5000
95-95-4	2,4,5-Trichlorophenol	110
88-06-2	2,4,6-Trichlorophenol	150
120-83-2	2,4-Dichlorophenol	40.7
105-67-9	2,4-Dimethylphenol	93.8
51-28-5	2,4-Dinitrophenol	1.5
121-14-2	2,4-Dinitrotoluene	3.8
91-58-7	2-Chloronaphthalene	202
95-57-8	2-Chlorophenol	134
534-52-1	2-Methyl-4,6-Dinitrophenol	5.5
91-94-1	3,3-Dichlorobenzidine	312
72-54-8	4,4-DDD	53600
72-55-9	4,4-DDE	53600
50-29-3	4,4-DDT	53600
83-32-9	Acenaphthene	242
107-02-8	Acrolein	215
107-13-1	Acrylonitrile	30
309-00-2	Aldrin	4670
319-84-6	alpha-BHC	130
959-98-8	alpha-Endosulfan	270
120-12-7	Anthracene	30
7440-36-0	Antimony	1
7440-38-2	Arsenic (Inorganic)	44
7440-39-3	Barium	NA [1]
56-55-3	Benz[a]anthracene	30
71-43-2	Benzene	5.2
92-87-5	Benzidine	87.5
50-32-8	Benzo[a]pyrene	30
205-99-2	Benzo[b]fluoranthene	30
207-08-9	Benzo[k]fluoranthene	30
7440-41-7	Beryllium	19
319-85-7	beta-BHC	130
33213-65-9	beta-Endosulfan	270
111-44-4	Bis(2-Chloroethyl)ether	6.9
108-60-1	Bis(2-Chloroisopropyl)ether	2.47
117-81-7	Bis(2-Ethylhexyl) Phthalate	130
542-88-1	Bis(Chloromethyl)ether	63
75-25-2	Bromoform	3.75
85-68-7	Butylbenzyl phthalate	414
7440-43-9	Cadmium	NA [2]
56-23-5	Carbon Tetrachloride	18.75

Table 3. Default USEPA Bioconcentration Factors

CAS Number	Chemical	Tissue-Based Bioconcentration Factor (BCF_{tissue}) L/kg tissue
12789-03-6	Chlordane	14100
108-90-7	Chlorobenzene	10.3
124-48-1	Chlorodibromomethane	3.75
67-66-3	Chloroform	3.75
94-75-7	Chlorophenoxy Herbicide (2,4-D)	NA [1]
16065-83-1	Chromium III	16
18540-29-9	Chromium VI	16
218-01-9	Chrysene	30
7440-50-8	Copper	36
57-12-5	Cyanide	1
53-70-3	Dibenz[a,h]anthracene	30
75-27-4	Dichlorobromomethane	3.75
75-09-2	Dichloromethane	0.9
60-57-1	Dieldrin	4670
84-66-2	Diethyl phthalate	73
131-11-3	Dimethyl Phthalate	36
84-74-2	Di-n-Butyl phthalate	89
25550-58-7	Dinitrophenols	1.51
1031-07-8	Endosulfan Sulfate	270
72-20-8	Endrin	3970
7421-93-4	Endrin Aldehyde	3970
100-41-4	Ethylbenzene	37.5
206-44-0	Fluoranthene	1150
86-73-7	Fluorene	30
76-44-8	Heptachlor	11200
1024-57-3	Heptachlor Epoxide	11200
118-74-1	Hexachlorobenzene	8690
87-68-3	Hexachlorobutadiene	2.78
608-73-1	Hexachlorocyclohexane (Technical)	130
77-47-4	Hexachlorocyclopentadiene	4.34
67-72-1	Hexachloroethane	86.9
193-39-5	Indeno[1,2,3-cd]pyrene	30
78-59-1	Isophorone	4.38
58-89-9	Lindane (gamma-BHC)	130
7439-96-5	Manganese	NA [1]
72-43-5	Methoxychlor	NA [1]
74-83-9	Methyl bromide	3.75
7440-02-0	Nickel	47
14797-55-8	Nitrates	NA [1]
98-95-3	Nitrobenzene	2.89
—	Nitrosamines	0.2
924-16-3	N-Nitrosodibutylamine	3.38
55-18-5	N-Nitrosodiethylamine	0.2
62-75-9	N-Nitrosodimethylamine	0.026
621-64-7	N-Nitrosodi-n-propylamine	1.13
86-30-6	N-Nitrosodiphenylamine	136
930-55-2	N-Nitrosopyrrolidine	0.055
1336-36-3	PCBs	31200
608-93-5	Pentachlorobenzene	2125
87-86-5	Pentachlorophenol	11
108-95-2	Phenol	1.4
129-00-0	Pyrene	30
7782-49-2	Selenium	4.8
127-18-4	Tetrachloroethene	30.6

Table 3. Default USEPA Bioconcentration Factors

CAS Number	Chemical	Tissue-Based Bioconcentration Factor (BCF_{tissue}) L/kg tissue
7440-28-0	Thallium	116
108-88-3	Toluene	10.7
8001-35-2	Toxaphene	13100
156-60-5	trans-1,2-Dichloroethylene	1.58
79-01-6	Trichloroethene	10.6
75-01-4	Vinyl Chloride	1.17
7440-66-6	Zinc	47

Source:

USEPA. 2002a. National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix. EPA-822-R-02-012. Washington, DC: United States Environmental Protection Agency Office of Water Office of Science and Technology.

Notes:

CAS = Chemical Abstracts Service

L/kg tissue = liters per kilogram tissue

NA = not available

USEPA = United States Environmental Protection Agency

[1] The national criterion for this chemical was originally published in the 1976 USEPA Red Book, which did not utilize the fish ingestion BCF approach. No default USEPA BCF is provided.

[2] The national criterion for cadmium is based on the Maximum Contaminant Level (MCL) issued by USEPA. No default USEPA BCF is provided.

Table 4. Input Distribution Summary Statistics

Input Parameter	Drinking Water Intake	Body Weight	Fish Consumption Rate
Units	liters per day (L/day)	kilograms (g)	grams per day (g/day)
Distribution Type	Pearson Type V	Lognormal	Inverse Gaussian
Minimum	0	44	0
Maximum	∞	∞	∞
Mean	1.72	80.5	8.59
Mode	1.20	72.5	2.29
Median	1.53	77.7	5.79
Std Dev	1.07	20.3	8.86
1%	0.110	46.6	0.385
5%	0.358	52.4	1.02
10%	0.552	56.8	1.56
15%	0.703	60.1	2.03
20%	0.835	63.1	2.49
25%	0.957	65.7	2.96
30%	1.07	68.2	3.44
35%	1.19	70.6	3.96
40%	1.30	72.9	4.51
45%	1.41	75.3	5.12
50%	1.53	77.7	5.79
55%	1.66	80.2	6.54
60%	1.79	82.9	7.39
65%	1.93	85.7	8.39
70%	2.09	88.7	9.56
75%	2.27	92.2	11.0
80%	2.48	96.2	12.8
85%	2.75	101	15.3
90%	3.12	108	19.0
95%	3.73	118	25.7
99%	5.15	140	43.3

Table 5. Alternate AWQC for the State of Washington (Assuming Relative Source Contribution = 1.0)

Chemical		Water + Organism				Organism Only			
		aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]
1,1,1-Trichloroethane		4.61E+04	1.0	NA	NA	1.42E+06	1.0	NA	NA
1,1,2,2-Tetrachloroethane		2.50E+00	0.0054	1.0E-05	3.8E-05	1.35E+02	0.0085	1.0E-05	8.2E-05
1,1,2-Trichloroethane		8.78E+00	0.095	1.0E-05	3.8E-05	5.29E+02	0.15	1.0E-05	8.1E-05
1,1-Dichloroethene		1.16E+03	1.0	NA	NA	3.54E+04	1.0	NA	NA
1,2,4,5-Tetrachlorobenzene		9.71E-01	1.0	NA	NA	1.06E+00	1.0	NA	NA
1,2,4-Trichlorobenzene		1.11E+01	0.070	1.0E-05	3.5E-05	4.09E+01	0.12	1.0E-05	8.2E-05
1,2-Dichlorobenzene		1.74E+03	1.0	NA	NA	6.39E+03	1.0	NA	NA
1,2-Dichloroethane		5.62E+00	NA	1.0E-05	3.8E-05	1.24E+03	NA	1.0E-05	8.2E-05
1,2-Dichloropropane		1.40E+01	0.0067	1.0E-05	3.8E-05	9.17E+02	0.011	1.0E-05	8.2E-05
1,2-Diphenylhydrazine		5.63E-01	NA	1.0E-05	3.6E-05	6.80E+00	NA	1.0E-05	8.1E-05
1,3-Dichlorobenzene		1.74E+03	1.0	NA	NA	6.39E+03	1.0	NA	NA
1,3-Dichloropropene		5.11E+00	0.0073	1.0E-05	3.9E-05	7.11E+02	0.011	1.0E-05	8.1E-05
1,4-Dichlorobenzene		7.29E+01	0.054	1.0E-05	3.4E-05	4.50E+02	0.090	1.0E-05	8.1E-05
2,3,7,8-TCDD		1.96E-07	0.36	1.0E-05	7.8E-05	2.09E-07	0.38	1.0E-05	8.2E-05
2,4,5-Trichlorophenol		1.61E+03	1.0	NA	NA	3.59E+03	1.0	NA	NA
2,4,6-Trichlorophenol		1.41E+01	1.0	5.3E-06	2.0E-05	2.64E+01	1.0	3.2E-06	2.6E-05
2,4-Dichlorophenol		6.13E+01	1.0	NA	NA	2.92E+02	1.0	NA	NA
2,4-Dimethylphenol		3.39E+02	1.0	NA	NA	8.45E+02	1.0	NA	NA
2,4-Dinitrophenol		4.67E+01	1.0	NA	NA	5.26E+03	0.99	NA	NA
2,4-Dinitrotoluene		1.63E+00	0.035	1.0E-05	3.8E-05	1.15E+02	0.055	1.0E-05	8.2E-05
2-Chloronaphthalene		9.71E+02	1.0	NA	NA	1.57E+03	1.0	NA	NA
2-Chlorophenol		7.40E+01	1.0	NA	NA	1.47E+02	1.0	NA	NA
2-Methyl-4,6-Dinitrophenol		1.85E+00	1.0	NA	NA	5.78E+01	1.0	NA	NA
3,3-Dichlorobenzidine		4.73E-01	NA	1.0E-05	4.6E-05	9.61E-01	NA	1.0E-05	8.2E-05
4,4-DDD		1.04E-02	NA	9.9E-06	8.1E-05	1.05E-02	NA	1.0E-05	8.2E-05
4,4-DDE		7.39E-03	NA	1.0E-05	8.1E-05	7.43E-03	NA	1.0E-05	8.2E-05
4,4-DDT		7.38E-03	0.2	1.0E-05	8.2E-05	7.44E-03	0.20	1.0E-05	8.2E-05
Acenaphthene		6.56E+02	1.0	NA	NA	9.84E+02	1.0	NA	NA
Acrolein		5.89E+00	1.0	NA	NA	9.21E+00	1.0	NA	NA
Acrylonitrile		8.13E-01	0.00096	1.0E-05	3.5E-05	8.36E+00	0.0016	1.0E-05	8.2E-05
Aldrin		1.59E-03	0.064	1.0E-05	7.7E-05	1.70E-03	0.067	1.0E-05	8.2E-05
alpha-BHC		4.90E-02	0.00041	1.0E-05	3.6E-05	1.65E-01	0.00068	1.0E-05	8.2E-05
alpha-Endosulfan		6.10E+01	1.0	NA	NA	8.79E+01	1.0	NA	NA
Anthracene		6.37E+03	1.0	NA	NA	3.97E+04	1.0	NA	NA
Antimony		9.35E+00	1.0	NA	NA	1.58E+03	0.99	NA	NA
Arsenic (Inorganic)	[3]	NA	NA	NA	NA	NA	NA	NA	NA
Barium	[4]	4.70E+03	1.0	NA	NA	NA	NA	NA	NA
Benz[a]anthracene		6.02E-01	NA	1.0E-05	3.5E-05	6.18E+00	NA	1.0E-05	8.1E-05
Benzene		3.34E+01	0.36	1.0E-05	3.8E-05	1.73E+03	0.57	1.0E-05	8.1E-05
Benzidine		1.52E-03	0.000029	1.0E-05	3.5E-05	6.72E-03	0.000049	1.0E-05	8.2E-05
Benzo[a]pyrene		6.02E-02	NA	1.0E-05	3.5E-05	6.17E-01	NA	1.0E-05	8.2E-05
Benzo[b]fluoranthene		6.02E-01	NA	1.0E-05	3.5E-05	6.19E+00	NA	1.0E-05	8.2E-05
Benzo[k]fluoranthene		6.01E+00	NA	1.0E-05	3.5E-05	6.17E+01	NA	1.0E-05	8.1E-05

Table 5. Alternate AWQC for the State of Washington (Assuming Relative Source Contribution = 1.0)

Chemical		Water + Organism				Organism Only			
		aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]
Beryllium		4.42E+01	1.0	NA	NA	4.16E+02	1.0	NA	NA
beta-BHC		1.72E-01	NA	1.0E-05	3.6E-05	5.80E-01	NA	1.0E-05	8.2E-05
beta-Endosulfan		6.13E+01	1.0	NA	NA	8.78E+01	0.99	NA	NA
Bis(2-Chloroethyl)ether		4.50E-01	NA	1.0E-05	3.8E-05	1.78E+01	NA	1.0E-05	8.1E-05
Bis(2-Chloroisopropyl)ether		7.24E+00	0.0078	1.0E-05	3.8E-05	7.82E+02	0.012	1.0E-05	8.1E-05
Bis(2-Ethylhexyl) Phthalate		2.21E+01	0.074	1.0E-05	3.6E-05	7.44E+01	0.12	1.0E-05	8.2E-05
Bis(Chloromethyl)ether		1.74E-03	NA	1.0E-05	3.4E-05	9.74E-03	NA	1.0E-05	8.2E-05
Bromoform		6.38E+01	0.14	1.0E-05	3.8E-05	4.55E+03	0.22	1.0E-05	8.1E-05
Butylbenzyl phthalate		9.62E+01	0.064	1.0E-05	5.1E-05	1.72E+02	0.090	1.0E-05	8.1E-05
Cadmium	[4]	1.17E+01	1.0	NA	NA	NA	NA	NA	NA
Carbon Tetrachloride		6.63E+00	0.075	1.0E-05	3.6E-05	1.03E+02	0.12	1.0E-05	8.1E-05
Chlordane		2.68E-02	0.19	1.0E-05	8.0E-05	2.75E-02	0.20	1.0E-05	8.0E-05
Chlorobenzene		4.55E+02	1.0	NA	NA	7.70E+03	1.0	NA	NA
Chlorodibromomethane		5.99E+00	0.013	1.0E-05	3.8E-05	4.30E+02	0.020	1.0E-05	8.2E-05
Chloroform		1.62E+01	0.070	1.0E-05	3.8E-05	1.16E+03	0.11	1.0E-05	8.1E-05
Chlorophenoxy Herbicide (2,4-D)	[4]	2.34E+02	1.0	NA	NA	NA	NA	NA	NA
Chromium III		3.34E+04	1.0	NA	NA	3.72E+05	1.0	NA	NA
Chromium VI		9.41E-01	0.014	1.0E-05	3.6E-05	1.69E+01	0.023	1.0E-05	8.1E-05
Chrysene		6.02E+01	NA	1.0E-05	3.5E-05	6.16E+02	NA	1.0E-05	8.1E-05
Copper		8.34E+02	1.0	NA	NA	4.40E+03	1.0	NA	NA
Cyanide		1.40E+01	1.0	NA	NA	2.37E+03	0.99	NA	NA
Dibenz[a,h]anthracene		6.01E-02	NA	1.0E-05	3.5E-05	6.19E-01	NA	1.0E-05	8.1E-05
Dichlorobromomethane		8.13E+00	0.018	1.0E-05	3.8E-05	5.81E+02	0.028	1.0E-05	8.1E-05
Dichloromethane		1.40E+02	1.0	5.5E-06	2.1E-05	2.65E+04	1.0	3.5E-06	2.8E-05
Dieldrin		1.70E-03	0.041	1.0E-05	7.7E-05	1.81E-03	0.043	1.0E-05	8.1E-05
Diethyl phthalate		1.46E+04	1.0	NA	NA	4.32E+04	0.99	NA	NA
Dimethyl Phthalate		2.08E+05	1.0	NA	NA	1.10E+06	1.0	NA	NA
Di-n-Butyl phthalate		1.73E+03	1.0	NA	NA	4.45E+03	1.0	NA	NA
Dinitrophenols		4.68E+01	1.0	NA	NA	5.25E+03	1.0	NA	NA
Endosulfan Sulfate		6.13E+01	1.0	NA	NA	8.79E+01	1.0	NA	NA
Endrin		2.92E-01	1.0	NA	NA	2.99E-01	1.0	NA	NA
Endrin Aldehyde		2.93E-01	1.0	NA	NA	3.00E-01	1.0	NA	NA
Ethylbenzene		3.86E+01	0.019	1.0E-05	3.5E-05	3.27E+02	0.031	9.9E-06	8.1E-05
Fluoranthene		1.26E+02	1.0	NA	NA	1.38E+02	1.0	NA	NA
Fluorene		8.50E+02	1.0	NA	NA	5.29E+03	1.0	NA	NA
Heptachlor		2.62E-03	0.015	1.0E-05	8.1E-05	2.69E-03	0.015	1.0E-05	8.2E-05
Heptachlor Epoxide		1.29E-03	0.28	1.0E-05	8.0E-05	1.33E-03	0.29	1.0E-05	8.1E-05
Hexachlorobenzene		9.36E-03	0.026	9.9E-06	7.9E-05	9.73E-03	0.027	1.0E-05	8.2E-05
Hexachlorobutadiene		6.49E+00	0.28	1.0E-05	3.8E-05	6.23E+02	0.44	1.0E-05	8.1E-05
Hexachlorocyclohexane (Technical)		1.72E-01	NA	1.0E-05	3.6E-05	5.79E-01	NA	1.0E-05	8.1E-05
Hexachlorocyclopentadiene		1.39E+02	1.0	NA	NA	5.46E+03	1.0	NA	NA
Hexachloroethane		8.79E+00	0.73	1.0E-05	3.4E-05	3.20E+01	1.0	8.2E-06	6.8E-05
Indeno[1,2,3-cd]pyrene		6.03E-01	NA	1.0E-05	3.5E-05	6.18E+00	NA	1.0E-05	8.2E-05

Table 5. Alternate AWQC for the State of Washington (Assuming Relative Source Contribution = 1.0)

Chemical		Water + Organism				Organism Only			
		aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]	aAWQC (ug/L)	HQ at 90th Percentile [1]	ELCR at 50th Percentile [2]	ELCR at 99th Percentile [2]
Isophorone		5.29E+02	0.11	1.0E-05	3.8E-05	3.24E+04	0.18	1.0E-05	8.1E-05
Lindane (gamma-BHC)		2.80E-01	0.062	1.0E-05	3.6E-05	9.46E-01	0.10	1.0E-05	8.1E-05
Manganese	[4]	3.29E+03	1.0	NA	NA	NA	NA	NA	NA
Methoxychlor	[4]	1.17E+03	1.0	NA	NA	NA	NA	NA	NA
Methyl bromide		3.25E+01	1.0	NA	NA	1.47E+03	1.0	NA	NA
Nickel		3.99E+02	1.0	NA	NA	1.69E+03	1.0	NA	NA
Nitrates	[4]	3.74E+04	1.0	NA	NA	NA	NA	NA	NA
Nitrobenzene		4.66E+01	1.0	NA	NA	2.74E+03	1.0	NA	NA
Nitrosamines		3.45E-03	NA	1.0E-05	3.9E-05	4.52E+00	NA	1.0E-05	8.2E-05
N-Nitrosodibutylamine		9.36E-02	NA	1.0E-05	3.9E-05	7.41E+00	NA	1.0E-05	8.1E-05
N-Nitrosodiethylamine		3.42E-03	NA	1.0E-05	3.9E-05	4.51E+00	NA	1.0E-05	8.1E-05
N-Nitrosodimethylamine		1.01E-02	0.054	1.0E-05	3.9E-05	1.02E+02	0.084	1.0E-05	8.1E-05
N-Nitrosodi-n-propylamine		7.31E-02	NA	1.0E-05	3.9E-05	1.71E+01	NA	1.0E-05	8.2E-05
N-Nitrosodiphenylamine		6.21E+01	NA	1.0E-05	3.7E-05	2.03E+02	NA	1.0E-05	8.1E-05
N-Nitrosopyrrolidine		2.45E-01	NA	1.0E-05	3.9E-05	1.17E+03	NA	1.0E-05	8.2E-05
PCBs		2.15E-03	NA	1.0E-05	8.0E-05	2.17E-03	NA	1.0E-05	8.2E-05
Pentachlorobenzene		1.42E+00	1.0	NA	NA	1.49E+00	1.0	NA	NA
Pentachlorophenol		1.21E+00	0.011	1.0E-05	3.7E-05	3.07E+01	0.017	1.0E-05	8.2E-05
Phenol		7.01E+03	1.0	NA	NA	8.48E+05	1.0	NA	NA
Pyrene		6.38E+02	1.0	NA	NA	3.96E+03	1.0	NA	NA
Selenium		1.15E+02	1.0	NA	NA	4.11E+03	1.0	NA	NA
Tetrachloroethene		1.27E+02	1.0	6.1E-06	2.1E-05	7.76E+02	1.0	3.7E-06	3.0E-05
Thallium		1.07E+00	1.0	NA	NA	2.32E+00	1.0	NA	NA
Toluene		1.82E+03	1.0	NA	NA	2.97E+04	1.0	NA	NA
Toxaphene		9.14E-03	NA	1.0E-05	8.1E-05	9.37E-03	NA	1.0E-05	8.1E-05
trans-1,2-Dichloroethylene		4.66E+02	1.0	NA	NA	5.04E+04	1.0	NA	NA
Trichloroethene		1.06E+01	0.93	1.0E-05	3.7E-05	1.87E+02	1.0	6.7E-06	5.5E-05
Vinyl Chloride		3.66E-01	0.0052	1.0E-05	3.8E-05	8.24E+01	0.0081	1.0E-05	8.1E-05
Zinc		5.98E+03	1.0	NA	NA	2.52E+04	1.0	NA	NA

Notes:

aAWQC = alternate ambient water quality criterion
ELCR = excess lifetime cancer risk
HQ = hazard quotient
NA = not available/not applicable
ug/L = micrograms per liter

[1] Hazard quotient calculated only for chemicals for which a reference dose (RfD) is available.
[2] Excess lifetime cancer risk calculated only for chemcials for which a cancer slope factor (CSF) is available.
[3] Arsenic criteria is blank because in public forums the Washington Department of Ecology has stated they may consider an alternative approach for arsenic criteria.
[4] No bioconcentration factor (BCF) available; criteria are based on drinking water exposure only.

Table 6. Alternate AWQC Derived Using USEPA-Recommended Relative Source Contribution Factors

Chemical		USEPA RSC	Water + Organism aAWQC (ug/L)		Organism Only aAWQC (ug/L)	
			RSC = 1	USEPA RSC	RSC = 1	USEPA RSC
1,1-Dichloroethene		0.2	1.16E+03	2.31E+02	3.54E+04	7.07E+03
1,2,4-Trichlorobenzene	[1]	0.2	1.11E+01	1.11E+01	4.09E+01	4.09E+01
1,2-Dichlorobenzene		0.2	1.74E+03	3.49E+02	6.39E+03	1.28E+03
1,4-Dichlorobenzene	[1]	0.2	7.29E+01	7.29E+01	4.50E+02	4.50E+02
Antimony		0.4	9.35E+00	3.74E+00	1.58E+03	6.34E+02
Cadmium	[2]	0.25	1.17E+01	2.93E+00	NA	NA
Chlorobenzene		0.2	4.55E+02	9.10E+01	7.70E+03	1.54E+03
Chromium III		0.2	3.34E+04	6.69E+03	3.72E+05	7.43E+04
Chromium VI	[1]	0.2	9.41E-01	9.41E-01	1.69E+01	1.69E+01
Copper		0.2	8.34E+02	1.67E+02	4.40E+03	8.79E+02
Cyanide		0.2	1.40E+01	2.80E+00	2.37E+03	4.74E+02
Endrin		0.2	2.92E-01	5.84E-02	2.99E-01	5.97E-02
Ethylbenzene	[1]	0.2	3.86E+01	3.86E+01	3.27E+02	3.27E+02
Hexachlorocyclopentadiene		0.2	1.39E+02	2.78E+01	5.46E+03	1.09E+03
Lindane (gamma-BHC)	[1,3]	0.5	2.80E-01	2.80E-01	9.46E-01	9.46E-01
Methoxychlor	[2]	0.2	1.17E+03	2.34E+02	NA	NA
Thallium		0.2	1.07E+00	2.14E-01	2.32E+00	4.63E-01
Toluene		0.2	1.82E+03	3.63E+02	2.97E+04	5.94E+03
trans-1,2-Dichloroethylene		0.2	4.66E+02	9.32E+01	5.04E+04	1.01E+04

Notes:

aAWQC = alternate ambient water quality criterion
NA = not available/not applicable
RSC = relative source contribution
ug/L = micrograms per liter
USEPA = United States Environmental Protection Agency

[1] AWQC is based on carcinogenic health endpoint; RSC adjustment does not affect the AWQC because the AWQC is driven by the carcinogenic endpoint.
[2] No bioconcentration factor (BCF) available; criteria are based on drinking water exposure only.
[3] Average of USEPA-recommended range of RSCs.

Table 7. Comparison of Alternate AWQC to National AWQC

Chemical		Water + Organism		Organism Only	
		aAWQC (ug/L)	National AWQC (ug/L)	aAWQC (ug/L)	National AWQC (ug/L)
1,1,1-Trichloroethane	[1]	4.61E+04	NA	1.42E+06	NA
1,1,2,2-Tetrachloroethane		2.50E+00	1.70E-01	1.35E+02	4.00E+00
1,1,2-Trichloroethane		8.78E+00	5.90E-01	5.29E+02	1.60E+01
1,1-Dichloroethene		1.16E+03	3.30E+02	3.54E+04	7.10E+03
1,2,4,5-Tetrachlorobenzene		9.71E-01	9.70E-01	1.06E+00	1.10E+00
1,2,4-Trichlorobenzene		1.11E+01	3.50E+01	4.09E+01	7.00E+01
1,2-Dichlorobenzene		1.74E+03	4.20E+02	6.39E+03	1.30E+03
1,2-Dichloroethane		5.62E+00	3.80E-01	1.24E+03	3.70E+01
1,2-Dichloropropane		1.40E+01	5.00E-01	9.17E+02	1.50E+01
1,2-Diphenylhydrazine		5.63E-01	3.60E-02	6.80E+00	2.00E-01
1,3-Dichlorobenzene		1.74E+03	3.20E+02	6.39E+03	9.60E+02
1,3-Dichloropropene		5.11E+00	3.40E-01	7.11E+02	2.10E+01
1,4-Dichlorobenzene		7.29E+01	6.30E+01	4.50E+02	1.90E+02
2,3,7,8-TCDD		1.96E-07	5.00E-09	2.09E-07	5.10E-09
2,4,5-Trichlorophenol		1.61E+03	1.80E+03	3.59E+03	3.60E+03
2,4,6-Trichlorophenol		1.41E+01	1.40E+00	2.64E+01	2.40E+00
2,4-Dichlorophenol		6.13E+01	7.70E+01	2.92E+02	2.90E+02
2,4-Dimethylphenol		3.39E+02	3.80E+02	8.45E+02	8.50E+02
2,4-Dinitrophenol		4.67E+01	6.90E+01	5.26E+03	5.30E+03
2,4-Dinitrotoluene		1.63E+00	1.10E-01	1.15E+02	3.40E+00
2-Chloronaphthalene		9.71E+02	1.00E+03	1.57E+03	1.60E+03
2-Chlorophenol		7.40E+01	8.10E+01	1.47E+02	1.50E+02
2-Methyl-4,6-Dinitrophenol		1.85E+00	1.30E+01	5.78E+01	2.80E+02
3,3-Dichlorobenzidine		4.73E-01	2.10E-02	9.61E-01	2.80E-02
4,4-DDD		1.04E-02	3.10E-04	1.05E-02	3.10E-04
4,4-DDE		7.39E-03	2.20E-04	7.43E-03	2.20E-04
4,4-DDT		7.38E-03	2.20E-04	7.44E-03	2.20E-04
Acenaphthene		6.56E+02	6.70E+02	9.84E+02	9.90E+02
Acrolein		5.89E+00	6.00E+00	9.21E+00	9.00E+00
Acrylonitrile		8.13E-01	5.10E-02	8.36E+00	2.50E-01
Aldrin		1.59E-03	4.90E-05	1.70E-03	5.00E-05
alpha-BHC		4.90E-02	2.60E-03	1.65E-01	4.90E-03
alpha-Endosulfan		6.10E+01	6.20E+01	8.79E+01	8.90E+01
Anthracene		6.37E+03	8.30E+03	3.97E+04	4.00E+04
Antimony		9.35E+00	5.60E+00	1.58E+03	6.40E+02
Arsenic (Inorganic)	[2]	NA	NA	NA	NA
Barium	[3]	4.70E+03	1.00E+03	NA	NA
Benz[a]anthracene		6.02E-01	3.80E-03	6.18E+00	1.80E-02
Benzene		3.34E+01	2.20E+00	1.73E+03	5.10E+01
Benzidine		1.52E-03	8.60E-05	6.72E-03	2.00E-04
Benzo[a]pyrene		6.02E-02	3.80E-03	6.17E-01	1.80E-02
Benzo[b]fluoranthene		6.02E-01	3.80E-03	6.19E+00	1.80E-02
Benzo[k]fluoranthene		6.01E+00	3.80E-03	6.17E+01	1.80E-02
Beryllium	[1]	4.42E+01	NA	4.16E+02	NA
beta-BHC		1.72E-01	9.10E-03	5.80E-01	1.70E-02
beta-Endosulfan		6.13E+01	6.20E+01	8.78E+01	8.90E+01
Bis(2-Chloroethyl)ether		4.50E-01	3.00E-02	1.78E+01	5.30E-01
Bis(2-Chloroisopropyl)ether		7.24E+00	1.40E+03	7.82E+02	6.50E+04
Bis(2-Ethylhexyl) Phthalate		2.21E+01	1.20E+00	7.44E+01	2.20E+00
Bis(Chloromethyl)ether		1.74E-03	1.00E-04	9.74E-03	2.90E-04
Bromoform		6.38E+01	4.30E+00	4.55E+03	1.40E+02
Butylbenzyl phthalate		9.62E+01	1.50E+03	1.72E+02	1.90E+03
Cadmium	[1,3]	1.17E+01	NA	NA	NA
Carbon Tetrachloride		6.63E+00	2.30E-01	1.03E+02	1.60E+00

Table 7. Comparison of Alternate AWQC to National AWQC

Chemical		Water + Organism		Organism Only	
		aAWQC (ug/L)	National AWQC (ug/L)	aAWQC (ug/L)	National AWQC (ug/L)
Chlordane		2.68E-02	8.00E-04	2.75E-02	8.10E-04
Chlorobenzene		4.55E+02	1.30E+02	7.70E+03	1.60E+03
Chlorodibromomethane		5.99E+00	4.00E-01	4.30E+02	1.30E+01
Chloroform		1.62E+01	5.70E+00	1.16E+03	4.70E+02
Chlorophenoxy Herbicide (2,4-D)	[3]	2.34E+02	1.00E+02	NA	NA
Chromium III	[1]	3.34E+04	NA	3.72E+05	NA
Chromium VI	[1]	9.41E-01	NA	1.69E+01	NA
Chrysene		6.02E+01	3.80E-03	6.16E+02	1.80E-02
Copper		8.34E+02	1.30E+03	4.40E+03	1.30E+03
Cyanide		1.40E+01	1.40E+02	2.37E+03	1.40E+02
Dibenz[a,h]anthracene		6.01E-02	3.80E-03	6.19E-01	1.80E-02
Dichlorobromomethane		8.13E+00	5.50E-01	5.81E+02	1.70E+01
Dichloromethane		1.40E+02	4.60E+00	2.65E+04	5.90E+02
Dieldrin		1.70E-03	5.20E-05	1.81E-03	5.40E-05
Diethyl phthalate		1.46E+04	1.70E+04	4.32E+04	4.40E+04
Dimethyl Phthalate		2.08E+05	2.70E+05	1.10E+06	1.10E+06
Di-n-Butyl phthalate		1.73E+03	2.00E+03	4.45E+03	4.50E+03
Dinitrophenols		4.68E+01	6.90E+01	5.25E+03	5.30E+03
Endosulfan Sulfate		6.13E+01	6.20E+01	8.79E+01	8.90E+01
Endrin		2.92E-01	5.90E-02	2.99E-01	6.00E-02
Endrin Aldehyde		2.93E-01	2.90E-01	3.00E-01	3.00E-01
Ethylbenzene		3.86E+01	5.30E+02	3.27E+02	2.10E+03
Fluoranthene		1.26E+02	1.30E+02	1.38E+02	1.40E+02
Fluorene		8.50E+02	1.10E+03	5.29E+03	5.30E+03
Heptachlor		2.62E-03	7.90E-05	2.69E-03	7.90E-05
Heptachlor Epoxide		1.29E-03	3.90E-05	1.33E-03	3.90E-05
Hexachlorobenzene		9.36E-03	2.80E-04	9.73E-03	2.90E-04
Hexachlorobutadiene		6.49E+00	4.40E-01	6.23E+02	1.80E+01
Hexachlorocyclohexane (Technical)		1.72E-01	1.23E-02	5.79E-01	4.14E-02
Hexachlorocyclopentadiene		1.39E+02	4.00E+01	5.46E+03	1.10E+03
Hexachloroethane		8.79E+00	1.40E+00	3.20E+01	3.30E+00
Indeno[1,2,3-cd]pyrene		6.03E-01	3.80E-03	6.18E+00	1.80E-02
Isophorone		5.29E+02	3.50E+01	3.24E+04	9.60E+02
Lindane (gamma-BHC)		2.80E-01	9.80E-01	9.46E-01	1.80E+00
Manganese	[3]	3.29E+03	5.00E+01	NA	NA
Methoxychlor	[3]	1.17E+03	1.00E+02	NA	NA
Methyl bromide		3.25E+01	4.70E+01	1.47E+03	1.50E+03
Nickel		3.99E+02	6.10E+02	1.69E+03	4.60E+03
Nitrates	[3]	3.74E+04	1.00E+04	NA	NA
Nitrobenzene		4.66E+01	1.70E+01	2.74E+03	6.90E+02
Nitrosamines		3.45E-03	8.00E-04	4.52E+00	1.24E+00
N-Nitrosodibutylamine		9.36E-02	6.30E-03	7.41E+00	2.20E-01
N-Nitrosodiethylamine		3.42E-03	8.00E-04	4.51E+00	1.24E+00
N-Nitrosodimethylamine		1.01E-02	6.90E-04	1.02E+02	3.00E+00
N-Nitrosodi-n-propylamine		7.31E-02	5.00E-03	1.71E+01	5.10E-01
N-Nitrosodiphenylamine		6.21E+01	3.30E+00	2.03E+02	6.00E+00
N-Nitrosopyrrolidine		2.45E-01	1.60E-02	1.17E+03	3.40E+01
PCBs		2.15E-03	6.40E-05	2.17E-03	6.40E-05
Pentachlorobenzene		1.42E+00	1.40E+00	1.49E+00	1.50E+00
Pentachlorophenol		1.21E+00	2.70E-01	3.07E+01	3.00E+00
Phenol		7.01E+03	1.00E+04	8.48E+05	8.60E+05
Pyrene		6.38E+02	8.30E+02	3.96E+03	4.00E+03
Selenium		1.15E+02	1.70E+02	4.11E+03	4.20E+03
Tetrachloroethene		1.27E+02	6.90E-01	7.76E+02	3.30E+00

Table 7. Comparison of Alternate AWQC to National AWQC

Chemical	Water + Organism		Organism Only	
	aAWQC (ug/L)	National AWQC (ug/L)	aAWQC (ug/L)	National AWQC (ug/L)
Thallium	1.07E+00	2.40E-01	2.32E+00	4.70E-01
Toluene	1.82E+03	1.30E+03	2.97E+04	1.50E+04
Toxaphene	9.14E-03	2.80E-04	9.37E-03	2.80E-04
trans-1,2-Dichloroethylene	4.66E+02	1.40E+02	5.04E+04	1.00E+04
Trichloroethene	1.06E+01	2.50E+00	1.87E+02	3.00E+01
Vinyl Chloride	3.66E-01	2.50E-02	8.24E+01	2.40E+00
Zinc	5.98E+03	7.40E+03	2.52E+04	2.60E+04

Source:

USEPA. 2013a. National Recommended Water Quality Criteria: Human Health Criteria Table. Accessible via: http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm. Last updated: August 22.

Notes:

aAWQC = alternate ambient water quality criterion
MCL = Maximum Contaminant Level
NA = not available/not applicable
ug/L = micrograms per liter

[1] This chemical is regulated based on the MCL.
[2] Arsenic criteria is blank because in public forums the Washington Department of Ecology has stated they may consider an alternative approach for arsenic criteria.
[3] No bioconcentration factor (BCF) available; criteria are based on drinking water exposure only.

Attachment A

Development of a Fish Consumption Rate Distribution for Residents of the State of Washington

DEVELOPMENT OF A FISH CONSUMPTION RATE DISTRIBUTION FOR RESIDENTS OF THE STATE OF WASHINGTON

A fish consumption rate distribution representative of the entire population of Washington State residents was developed for use in calculating water quality criteria for the protection of human health using either probabilistic or deterministic methods. National fish consumption rate (FCR) data published by EPA (USEPA 2002, 2011) were used as the basis for estimating FCRs for the general population and tribal rate data published by Washington State Department of Ecology (WDOE 2011, 2013) were used to estimate tribal consumption rates. The general population distribution was adjusted to reflect: (1) consumption of fish and shellfish from freshwater and near-shore marine habitats only; and (2) the portion of salmon consumption accounting for contaminants acquired by salmon in waters of the state. The tribal distribution was only adjusted to account for contaminants acquired by salmon in waters of the state. The two distributions were then combined using weighting factors representing the relative populations of each group.

1. Development of a General Population Fish Consumption Rate

a. Use NCI-adjusted data from the 2003 to 2006 National Health and Nutrition Examination Survey (NHANES) to represent fish consumption rates of the general population of Washington State residents. EPA (USEPA 2011) analyzed these data and generated per capita and consumer-only intake rates for finfish, shellfish, and total fish and shellfish combined. These rates represent intake of all forms of seafood (e.g., purchased, self caught, marine, freshwater, estuarine) for individuals who provided data for two days of the survey.

The "consumers only" data were used for this analysis. Two day average fish intake rates were calculated for all individuals in the database for each of the food items/groups. If a person reported consuming fish on only one day of the survey, their two day average would be half the amount reported for the one day of consumption.

The short-term nature of the NHANES survey methodology has been found to overestimate long-term consumption rates of infrequently consumed foods such as fish (Polissar 2012). To address this problem, researchers at the National Cancer Institute (NCI) developed methodology for estimating the intake of such foods that better represents long-term consumption rates. This methodology addresses biases associated with the day-to-day variation in reported consumption as well as exclusion of fish consumers who did not report eating fish on either day of the survey. Table 1 shows the NCI-adjusted NHANES data as reported by Polissar et al. (2012).

Table 1. Summary of NCI-adjusted NHANES Whole Population Fish Consumption Distribution

Statistic	All Consumers Consumption Rate, All Fish (g/d)	Statistic	All Consumers Consumption Rate, All Fish (g/d)
Mean	18.8	75%	24.8
1%	0.9	80%	28.9
5%	2	85%	34.5
10%	3	90%	42.5
25%	6.2	95%	56.6
50%	12.7	99%	90.8

b. Adjust general population fish consumption data to reflect only freshwater and near-shore marine (estuarine) species. Because the NHANES data are based on total fish consumption, including offshore marine species such as tuna, and because EPA specifically recommends that data used to represent fish consumption for the purpose of developing human health water quality criteria be based on fish from freshwater and near-shore (estuarine) marine environments only, some means of adjusting the distribution in Table 1 is needed. To make this adjustment, data from US Department of Agriculture's (USDA) Continuing Survey of Food Intake by Individuals (CSFII) 1994 to 1996 were used. Adjustment of the NCI-adjusted NHANES distribution in this manner is based on the assumption that the relative proportions of fresh, near-shore marine, and off-shore marine fish in the American diet have not shifted dramatically in the period of time (about ten years) between the two surveys.

USDA's CSFII survey data (USEPA 2002, Section 5.1.1.1 Table 4) provide estimates of consumption rates of uncooked finfish and shellfish for the US population age 18 and older and were the basis of EPA's current national recommended default fish consumption rate of 17.5 g/day. The data are reproduced herein as Table 2. The reported mean consumption rates of freshwater/estuarine, marine, and all fish were 7.50, 12.41, and 19.91 g/day, respectively. The ratio between the mean freshwater and estuarine (F/E) rate and the all FCR was calculated (0.377) and used as an adjustment factor for the NCI-adjusted NHANES distribution. This ratio represents the average percentage (37.7%) of F/E fish in Americans' total fish diet. It also indicates that on average 62.3% of the fish consumed are from off-shore marine waters.

Table 2. Summary of EPA's Analysis of Uncooked Finfish and Shellfish Consumption Rates (g/person/day) for the CSFII Survey[a]

Habitat	Statistic	Estimate	90% Interval Lower Bound	90% Interval Upper Bound
Freshwater/Estuarine	Mean	7.50	6.75	8.25
	50th %	0.00	0.00	0.00
	90th %	17.37	14.32	21.58
	95th %	49.59	46.87	55.41
	99th %	143.35	125.27	156.84
Marine	Mean	12.41	11.46	13.37
	50th %	0.00	0.00	0.00
	90th %	48.92	47.10	51.17
	95th %	80.68	77.77	83.45
	99th %	150.77	139.66	164.34
All Fish	Mean	19.91	18.69	21.13
	50th %	0.00	0.00	0.00
	90th %	74.79	71.72	75.71
	95th %	111.35	110.03	114.02
	99th %	215.70	197.09	228.53

[a] USEPA 2002, Section 5.1.1.1 Table 4

Adjustment of the NCI-adjusted NHANES distribution was accomplished by multiplying the mean and each percentile by the F/E adjustment factor (0.377), based on the assumption that the average rate of fresh and estuarine fish consumption can be applied across the entire distribution. Note that ratios between F/E and total fish consumption in Table 2 are 0.232 and 0.445 at the 90th and 95th percentiles, respectively, suggesting that application of the mean ratio is in fact conservative for the majority of consumers (>90%). Table 3 summarizes the "all fish" NCI-adjusted NHANES data and the "fresh and estuarine adjusted" NCI-adjusted NHANES consumption rates.

Table 3. NCI-adjusted NHANES Data Adjusted to Reflect Freshwater and Estuarine Species Consumption Only

Distribution Statistic	All Fish (g/d)[a]	Fresh and Estuarine Species Only (g/d)[b]
Mean	18.8	7.09
1%	0.9	0.34
5%	2	0.75
10%	3	1.13
25%	6.2	2.34
50%	12.7	4.79
75%	24.8	9.35
80%	28.9	10.90
85%	34.5	13.01
90%	42.5	16.02
95%	56.6	21.34
99%	90.8	34.23

[a] from Polissar et al. 2012, Table 4
[b] component of all fish that are freshwater or estuarine fish [all fish x 0.377]

c. Adjust general population distribution to include salmon in proportion to their general population consumption rate and life history spent in fresh and estuarine waters. Scientific studies (e.g., Hope 2012) provide information indicating that some portion of highly bioaccumulative chemicals (e.g., PCBs) found in salmon consumed by Washington residents may be acquired in F/E environments. Thus, the distributions shown in Table 3 were adjusted upward to reflect this information. This was accomplished by adjusting the total salmon consumption rate to reflect only that portion of salmon life history that is spent in F/E waters and the fraction of salmon in the general population total fish diet, and then adding the adjusted salmon consumption rate to the NCI-adjusted NHANES "fresh and estuarine" rates shown in Table 3.

Life history factors (LHFs) were developed for each species of salmon based on information in the technical literature. Derivation of these LHFs is discussed in Appendix A, and Table 4 summarizes the final species-specific LHFs relevant to different waters of the state. As suggested by WDOE (2013), the species-specific LHFs used in this analysis were based on the amounts of time these fish spend in waters of the state from emergence to migration off-shore. For multiple reasons (see Appendix A), this approach probably overstates the accumulation of chemicals from waters of the state. For example, it assumes that accumulation occurs at a constant rate unrelated to growth or trophic level, and it ignores depuration of chemicals acquired in F/E waters.

Table 4. Life History Factors for Different Salmon Species and Different Waters Based on Residence Times in Waters of the State

	Life History Factors (LHFs)		
Species	Non-Puget Sound Waters	Puget Sound Waters Only	Statewide Composite
Chinook/King	0.15	0.40	0.30
Sockeye	0.50	0.60	0.56
Coho	NA	NA	0.19
Chum	0.13	0.28	0.22
Pink	NA	NA	0.24

A single composite salmon LHF for all waters of the state is computed by summing the species-specific (statewide composite) LHFs weighted by the relative amounts of each species consumed as given in EPA's *Exposure Factors Handbook* (USEPA 2011), Table 10-104, Adult Consumption Rate (g/kg-day) for Consumers Only. The information in the table is from an FCR survey conducted by the Suquamish Tribe. It was assumed that the relative amounts of salmon species consumed by the Suquamish tribe are representative of Washington consumers generally. The data from EPA's table are reproduced in part as Table 5 herein, which also shows generation of the final composite LHF for salmon (0.318). Salmon LHFs could be developed based on other information, as discussed in Appendix A.

Table 5. Relative Proportions of Salmon Species Consumed by the Suquamish Tribe and Derivation of Composite Life History Factor for All Salmon

	EPA Consumption Data				LHFs	
Species	n	Mean (g/d)	n x Mean (g/d)	Fraction at Mean	From Table 4	Consumption Weighted
Chinook/King	63	0.200	12.600	0.294	0.30	0.088
Sockeye	59	0.169	9.971	0.232	0.56	0.130
Coho	50	0.191	9.550	0.223	0.19	0.043
Chum	42	0.242	10.164	0.237	0.22	0.053
Pink	17	0.035	0.595	0.014	0.24	0.003
Final Composite LHF						0.318

An adjustment for salmon to the general population FCR distribution also requires an estimate of the fraction of the general population's total fish diet that is comprised of salmon. Information provided by EPA (USEPA 2002) and reproduced in EPA's *Exposure Factors Handbook* as Table 10-28 (USEPA 2011) was used for this purpose. The table, reproduced herein as Table 6, lists mean consumption rates for 64 species of fish from the 1994 to 1996 and 1998 combined CSFII survey data from USDA. Based on these data the fraction of total fish consumption that is comprised of salmon is 0.094 (9.4%).

Table 6. Uncooked Fish Consumption Estimates, US Population –
Mean Consumption by Species within Habitat, Individuals of Age 18 and Older

Habitat	Species	Estimated Mean (g/person/day)	Habitat	Species	Estimated Mean (g/person/day)
Estuarine			Marine		
	Shrimp	2.64686		Tuna	4.18375
	Flounder	0.69946		Salmon (marine)	1.77537
	Catfish (estuarine)	0.57463		Cod	1.65997
	Flatfish (estuarine)	0.40395		Clam (marine)	0.87021
	Crab (estuarine)	0.29953		Porgy	0.49466
	Perch (estuarine)	0.21256		Haddock	0.37374
	Herring	0.17937		Crab (marine)	0.34008
	Oyster	0.17395		Pollock	0.3321
	Croaker	0.16936		Whiting	0.30583
	Trout, mixed spp.	0.14568		Lobster	0.25919
	Salmon (estuarine)	0.08819		Scallop (marine)	0.23749
	Anchovy	0.05544		Squid	0.20948
	Rockfish	0.05162		Ocean perch	0.15663
	Mullet	0.04295		Mackerel	0.1456
	Clam (estuarine)	0.02332		Sardine	0.14375
	Smelts (estuarine)	0.00838		Swordfish	0.12595
	Eel	0.00444		Sea Bass	0.12543
	Scallop (estuarine)	0.0016		Pompano	0.11198
	Smelts, rainbow	0.00072		Mussels	0.09969
	Sturgeon (estuarine)	0.00017		Octopus	0.08819
Freshwater				Flatfish (marine)	0.07563
	Catfish (freshwater)	0.57463		Halibut	0.04224
	Trout	0.2414		Snapper	0.03624
	Perch (freshwater)	0.21256		Whitefish (marine)	0.01246
	Carp	0.18153		Smelts (marine)	0.00838
	Trout, mixed spp.	0.14568		Shark	0.00581
	Pike	0.03827		Conch	0.00284
	Whitefish (freshwater)	0.01246		Snails (marine)	0.00206
	Crayfish	0.01024		Roe	0.0014
	Snails (freshwater)	0.00206	Unknown		
	Cisco	0.0017		Fish	0.47575
	Salmon (freshwater)	0.00093		Seafood	0.00394
	Smelts, rainbow	0.00072			
	Sturgeon (freshwater)	0.00017			
All Fish		19.91037			
All Salmon		1.86449			
All Salmon as % of All Fish		9.4%			

[Source: USEPA 2002]

The portion of salmon to be added to the F/E NCI-adjusted NHANES distribution is determined by multiplying the salmon fraction in the total fish diet (.094) by the NCI-adjusted NHANES distribution for all fish and by the composite salmon LHF (0.318). The final general population FCR distribution is shown in column 5 of Table 7.

Table 7. General Population Fish Consumption Rate Distribution Adjusted for Fresh and Estuarine Species and for Salmon Life History

	(1)	(2) (1) * 0.377	(3) (1) * 0.094	(4) (3) * 0.318	(5) (2) + (4)
	NCI-Adjusted NHANES Consumption, All Fish (g/d)[a]	Fresh/ Estuarine Fish Only (g/d)[b]	Salmon Only (g/d)[c]	Fresh/Estuarine Life History Apportioned Salmon (g/d)[d]	Final General Population FCR (g/d)[e]
Mean	18.8	7.09	1.77	0.56	7.65
1%	0.9	0.34	0.08	0.03	0.37
5%	2	0.75	0.19	0.06	0.81
10%	3	1.13	0.28	0.09	1.22
25%	6.2	2.34	0.58	0.19	2.52
50%	12.7	4.79	1.19	0.38	5.17
75%	24.8	9.35	2.33	0.74	10.09
80%	28.9	10.90	2.72	0.86	11.76
85%	34.5	13.01	3.24	1.03	14.04
90%	42.5	16.02	4.00	1.27	17.29
95%	56.6	21.34	5.32	1.69	23.03
99%	90.8	34.23	8.54	2.71	36.95

[a] from Polissar et al. 2012, Table 4
[b] component of all fish that are freshwater or estuarine [all fish x 0.377]
[c] component of all fish that is salmon [all fish x 0.094]
[d] consumption of salmon associated with waters of state based on composite residence time LHF [salmon x 0.318]
[e] final general population FCR [F/E + apportioned salmon fraction]

2. Development of a Tribal Population Fish Consumption Rate

a. Use data from Washington tribal population surveys to represent fish consumption rates of the total tribal population of Washington State. Data from four tribal fish consumption surveys were used by WDOE to develop composite tribal distributions using different weighting schemes. Scheme No. 6 from *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*, version 1.0 (WDOE 2011), Table C-4 (tribal-specific distributions weighted according to relative population) was chosen to represent the fish consumption rates of Washington tribal members. The data are shown in Table 8, column 1.

b. Adjust tribal population distribution to include salmon in proportion to their tribal population consumption rate and life history spent in fresh and estuarine waters. The composite tribal distribution is adjusted to exclude the time salmon spend in the off-shore marine environment. To estimate the fraction of salmon consumed by these tribes, data provided in WDOE's *Fish Consumption Rate Technical Support Document*, version 2 (WDOE 2013) were used, reproduced here as Table 9. The amount of anadromous fish as a percentage of the total fish and shellfish diet for these tribes ranges from 23% for the Suquamish Tribe to about 66% for the Squaxin Island Tribe. The Tulalip Tribe seafood diet is about 46% anadromous fish. Data for the Columbia River Inter-Tribal Fish Commission (CRITFC) tribes are not directly comparable to the other tribal data because the survey did not reflect any consumption of shellfish. Nonetheless, CRITFC tribes ate anadromous fish equivalent to about 48% of all harvested fish from all sources. If one assumes that the CRITFC tribes consume only small amounts of shellfish relative to finfish, then 48% represents an approximate maximum value for the CRITFC tribes. A simple average of these percentage values for each of the four tribes (46% anadromous fish) was used to make this adjustment.

Table 8 shows adjustments to the composite tribal FCR distribution. Briefly, the total tribal fish consumption distribution was multiplied by the fraction of salmon in the tribal fish diet (0.46) and the composite salmon LHF (0.318). This "waters of the state" adjusted salmon consumption rate was then added to the non-salmon consumption rate to generate the final tribal FCR distribution.

Table 8. Composite Distribution of Washington Tribal Fish Consumption Rates Weighted Based on Relative Population

	(1)	(2) (1) * 0.46	(3) (1) * (1 - 0.46)	(4) (2) * 0.318	(5) (3) + (4)
	All Fish (g/d)[a]	Salmon (g/d)[b]	Non-Salmon (g/d)[c]	Fresh/Estuarine Apportioned Salmon (g/d)[d]	Final Washington Tribal Population FCR (g/d)[e]
mu	4.0083				
sigma	0.7158				
Mean	71.12	32.72	38.40	10.40	48.81
1%	10.41	4.79	5.62	1.52	7.14
5%	16.96	7.80	9.16	2.48	11.64
10%	22	10.12	11.88	3.22	15.10
25%	33.97	15.63	18.34	4.97	23.31
50%	55.05	25.32	29.73	8.05	37.78
75%	89.22	41.04	48.18	13.05	61.23
80%	100.55	46.25	54.30	14.71	69.01
85%	115.6	53.18	62.42	16.91	79.33
90%	137.77	63.37	74.40	20.15	94.55
95%	178.69	82.20	96.49	26.14	122.63
99%	291.03	133.87	157.16	42.57	199.73

[a] composite tribal distribution No. 6 from WDOE 2011, Table C-4, (tribal-specific distributions weighted according to relative population); assume 100% of tribal populations are consumers and all fish are from waters of the state
[b] component of all fish that is salmon [all fish x 0.46]
[c] component of all fish that is not salmon [all fish - salmon]
[d] consumption of salmon associated with waters of state based on composite residence time LHF [salmon x 0.318]
[e] final FCR [non-salmon + salmon fraction]

Table 9. Summary of Washington Tribal Fish Consumption Survey Data (g/day)

	Fish Source	50th %tile	Mean	75th %tile	90th %tile	95th %tile	% of All Fish at Mean
Tulalip Tribe							
All fish	All sources	44.5	82.2	94.2	193	268	100.0
Finfish	All sources	22.3	44.1	49.1	110	204	53.6
Shellfish	All sources	15.4	42.6	40.1	113	141	51.8
Non-anadromous	All sources	20.1	45.9	52.4	118	151	55.8
Anadromous	All sources	16.8	38.1	43.3	92.1	191	46.4
Squaxin Island Tribe							
All fish	All sources	44.5	83.7	94.4	206	280	100.0
Finfish	All sources	31.4	65.5	82.3	150	208	78.3
Shellfish	All sources	10.3	23.1	23.9	54	83.6	27.6
Non-anadromous	All sources	15.2	28.7	32.3	70.5	95.9	34.3
Anadromous	All sources	25.3	55.1	65.8	128	171	65.8
Suquamish Tribe							
All fish	All sources	132	214	284	489	797	100
Shellfish	All sources	64.7	134	145	363	615	63
Non-anadromous	All sources	102	169	219	377	615	79
Anadromous	All sources	27.6	48.8	79.1	133	172	23
CRITFC Tribes							
All finfish	All harvested	40.5	63.2	64.8	130	194	100
Non-anadromous	All harvested	20.9	32.6	33.4	67	99.9	52
Anadromous	All harvested	19.6	30.6	31.4	63.1	94.1	48

3. Development of an Overall Fish Consumption Rate Reflecting General Population and Tribal Fish Consumption

The general population and tribal population composite FCR distributions are combined to produce a single distribution for Washington. This is accomplished by weighting the two distributions according to the sizes of their respective populations. Population statistics reported in *Fish Consumption Rate Technical Support Document*, version 2 (WDOE 2013) were used for this purpose. The data are shown in Table 10, along with tribal and non-tribal weighting factors.

The final overall FCR distribution is shown in Table 11.

Table 10. Washington State Population Statistics (WDOE 2013)

Population	Numbers	Weighting Factors
Current total	6724540	
Adults	5143186	
Fish consuming adults	3805958	
Tribal	103869	
Adults (est. as 70%; assume 100% consumers)	73523	
Fish consuming non-tribal adults	3732435	0.981
Fish consuming tribal adults	73523	0.0193

Table 11. Final Overall Fish Consumption Rate Distribution for Washington State Including Consumption of Salmon Weighted to Reflect Bioaccumulation of Chemicals in Waters of the State Only Based on Salmon Life History Factors

Statistic	Tribal Population Composite FCR (g/d)[a]	General Population Composite FCR (g/d)[b]	Final Overall Washington FCR (g/d)[c]
mu			
sigma			
Mean	48.81	7.65	8.44
1%	7.14	0.37	0.50
5%	11.64	0.81	1.02
10%	15.10	1.22	1.49
25%	23.31	2.52	2.92
50%	37.78	5.17	5.80
75%	61.23	10.09	11.08
80%	69.01	11.76	12.87
90%	94.55	17.29	18.79
95%	122.63	23.03	24.95
99%	199.73	36.95	40.09

[a] final composite tribal distribution
[b] final general population distribution
[c] final composite distribution [(tribal x 0.019)+(gen pop x 0.981)]

Summary

A fish consumption rate distribution representative of the entire population of Washington State residents was developed. National FCR data published by EPA (USEPA 2002, 2011) were used as the basis for estimating FCRs for the general population, and tribal rate data published by WDOE (2011, 2013) were used for tribal consumption rates. The general population distribution was adjusted to reflect: (1) consumption of fish and shellfish from freshwater and near-shore marine habitats only; and (2) the portion of salmon consumed reflecting contaminants acquired by salmon in waters of the state. The tribal distribution was only adjusted to account for contaminants acquired by salmon in waters of the state. The two distributions were then combined using weighting factors representing the relative populations of each group. Table 12 provides a summary of the data and rationale used in developing this overall fish consumption rate distribution for Washington residents.

Table 12. Summary of Data and Rationale Used in Developing a Fish Consumption Rate Distribution for Residents of the State of Washington

	Fish Consumption Aspect	Data Source	Rationale	Comments
1a	Starting dataset for developing Washington-tailored general population FCR distribution	NHANES data from EPA's 2011 *Exposure Factors Handbook*, Table 10-12, Consumer-Only Intake of Total Finfish and Shellfish Combined (g/kg-day), Edible Portion, Uncooked Fish Weight, adjusted using NCI methodology	Used by EPA to establish default FCR rate, used by Florida to develop Florida-tailored FCR distribution; NCI methodology adjusts for short-term recall bias and bias associated with exclusion of fish consumers who did not report fish consumption on either of two survey events	There are no Washington-specific fish consumption data representing the entire population; this dataset reflects fish consumption rates nationally, consumers only, entire population
1b	Adjustment to exclude off-shore marine fish from NCI- NHANES distribution	USDA Continuing Survey of Food Intake by Individuals (CSFII)	Used by Florida to develop Florida-tailored FCR distribution	This adjustment is applied to entire NCI-NHANES distribution; adjusts distribution to reflect consumption of fish from freshwater and estuarine (near-shore marine) habitats only, per EPA guidance
1c	Adjustment to include portion of salmon consumed to account for contaminants acquired in waters of the state	See items 1c (i), (ii), and (iii) below	NHANES and CSFII survey data classify salmon as marine species; this adjustment 'adds back' a portion of salmon consumed based on (i) LHFs for each of five major species, (ii) relative fractions of each species consumed, and (iii) estimated fraction of salmon in total fish and shellfish diet of Washington residents	Adjustment is species-weighted composite salmon LHF multiplied by fraction of salmon in total fish and shellfish diet; value is multiplied by each percentile of the NCI-NHANES total fish consumption distribution; values are then added to NCI-NHANES freshwater and estuarine only distribution

	Fish Consumption Aspect	Data Source	Rationale	Comments
1c(i)	Salmon life history factor	Technical literature on species-specific behavior and life history	Development of LHFs for five major salmon species based on estimated time salmon spend in waters of the state as a fraction of total lifetime prior to return as adults for spawning	Approach may overestimate contaminant body burden acquired in waters of the state (e.g., salmon gain more than 95% of body mass in marine environment), so is believed to be conservative approach
1c(ii)	Salmon species relative consumption fractions	Suquamish tribal data as given in EPA's 2011 *Exposure Factors Handbook*, Table 10-104.	The only Washington-specific data on salmon species consumption rates; may not be representative of total state population	Relative rates for each salmon species used to weight LHFs to develop single composite LHF for all salmon
1c(iii)	Fraction of salmon in total <u>general population</u> fish and shellfish diet	EPA's 2011 *Exposure Factors Handbook*, Table 10-28, mean consumption rates for 64 species of fish from the 1994 to 1996; 1998 combined USDA CSFII survey data	Assumes data are representative of fish consumption for general population of Washington State	Based on these data, salmon fraction for general population consumer is 0.094 (9.4% of total fish and shellfish consumed)
2a	Starting dataset for developing Washington-tailored <u>tribal</u> <u>population</u> FCR distribution	*Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*, Ver. 1.0 (WDOE 2011), Table C-4, (tribal-specific distributions weighted according to relative population)	Represents all tribal fish consumption survey results	Individual tribal survey distributions were weighted according to relative populations of each surveyed tribe

	Fish Consumption Aspect	Data Source	Rationale	Comments
2b	Adjustment to include portion of salmon consumed to account for contaminants acquired in waters of the state	See items 1c (i), (ii) above and 2b(i) below	NHANES and CSFII survey data classify salmon as marine species; this adjustment 'adds back' a portion of salmon consumed based on (i) LHFs for each of five major species, (ii) relative fractions of each species consumed, and (iii) estimated fraction of salmon in total fish and shellfish diet of surveyed Washington tribes	Adjustment is species-weighted composite salmon LHF multiplied by fraction of salmon in total fish and shellfish diet; value is multiplied by each percentile of composite tribal total fish consumption distribution; values then added to composite tribal non-salmon consumption rate distribution
2b(i)	Fraction of salmon in total tribal fish and shellfish diet	Tribal data presented in *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*, Public Review Draft, ver. 2.0, August 27, 2012	The only Washington-specific tribal data on salmon consumption rates as a fraction of total fish and shellfish consumption	Simple average of four tribal FCR surveys used to represent whole tribal population of state; value is 0.46, meaning that 46% of average tribal fish consumption consists of salmon and other anadromous fish
3	Develop population-weighted overall Washington FCR based on general population and tribal composite FCR distributions and Washington population data	General population and tribal composite FCR distributions as described in 1 and 2 above; Washington population data from *Fish Consumption Rates Technical Support Document, A Review of Data and Information About Fish Consumption in Washington*, ver. 2 (WDOE 2013)	Population-based weighting schemes provide a way to combine general population and tribal FCR data into a single distribution that represents all fish consumers	

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APPENDIX A

LIFE HISTORY FACTORS FOR PACIFIC SALMON (01-13-2014)

1.0 INTRODUCTION

One of the primary factors to consider in deciding whether to include salmon in a fish consumption rate (FCR) used in deriving Clean Water Act (CWA) human health water quality criteria is when/where salmon accumulate their ultimate body burden of the relevant chemical(s). Traditionally, EPA has recommended against including salmon in these FCRs because it was accepted that, for bioaccumulative chemicals, the majority of a chemical-specific body burden in a returning adult salmon is acquired in the Pacific Ocean (in the case of Pacific Northwest salmon), and not in the fresh and/or estuarine waters under jurisdictional control of a state. However, this assumption has been challenged as part of the ongoing process in Washington State, and various stakeholders have argued that salmon must be included in the FCR for various reasons, including the cultural importance of salmon to tribal and other residents of the state.

A review of the technical literature shows that there are sufficient (albeit limited) data to conclude that the vast majority of the body burden of bioaccumulative chemicals in adult Chinook salmon is acquired during the marine phase of that species' life history. The data were developed by various researchers who measured chemical-specific body burdens in both out-migrating juvenile fish and returning adults belonging to the same runs. In all cases where these kinds of data have been developed, the researchers have concluded that >95% of the body burdens were acquired in the marine phase of the Chinook life history (Cullon et al. 2009; O'Neill and West 2009). However, these data are specific to Chinook salmon, and because each species of salmon has a unique life history it may not be appropriate to assume that what holds for Chinook also holds for coho, sockeye, chum, or pink salmon. Thus, there is some uncertainty regarding where these other species acquire their ultimate body burdens of bioaccumulative chemicals.

In response to this uncertainty, the Washington Department of Ecology (WDOE) has proposed use of what this report will call life history factors (LHFs) as a means of apportioning total body burden in adult salmon between different phases of a salmon's life history. As proposed, these LHFs reflect the relative amount of time salmon spend in different environments or geographic locations, and would be used to apportion the ultimate body burden in returning adults between these environments or geographic locations. Subsequently, the fraction of the burden acquired in waters of the state could be used to adjust the actual consumption rate for salmon included in the FCR.

The assumption inherent in this model is that the body burden of bioaccumulative chemicals in returning adult salmon is a linear function of time. This is the basis for the site-use factors WDOE has proposed as a means of accounting for salmon consumption when developing human health benchmarks for sediment cleanups (WDOE 2012). Thus, there is precedent in Washington for this kind of apportionment, and WDOE has prepared a Technical Issue Paper (TIP) summarizing information on the life-histories of Chinook, coho, sockeye, chum, and pink salmon as part of developing this concept (WDOE 2013). However, WDOE did not identify specific numeric LHFs for each species. This paper takes this next step using WDOE's TIP as the primary information resource; other sources of information were used only in instances where there were clear gaps in the TIP.

For the purposes of this exercise, consistent with scope of the CWA, LHFs were developed for waters of the state. In this context, waters of the state include all fresh and estuarine waters, Puget Sound, and all marine waters within three miles of the Washington coastline.

Section 2 addresses development of species-specific LHFs for Pacific Northwest salmon based on residence time. Section 3 offers some discussion supporting the position that LHFs based on residence time overstate the significance of bioaccumulation during the early stages of salmon life history. LHFs based on where body mass is acquired (i.e., where salmon grow) are likely to provide a more accurate measure of where salmon acquire their ultimate cumulative body burdens of bioaccumulative chemicals, and Section 4 addresses development of these alternative mass-based LHFs.

2.0 LIFE HISTORY FACTORS BASED ON RESIDENCE TIMES

2.1 Chinook Salmon

Table A1 summarizes LHFs for stream- and ocean-type Chinook salmon and resulting composite LHFs for all Chinook.

2.1.1 *Stream-Type Chinook Salmon Life History*

Excerpts from Ecology's TIP are quoted as the basis for developing the LHFs listed in Table A1.

Page 5. "After emergence, stream-type Chinook spend a year or more in the river before migrating downstream."

Different LHFs were calculated using one and two years residence in freshwater.

Page 5. "Once entering the marine environment, stream-type Chinook spend very little time in the estuaries before migrating towards coastal waters."

In this analysis, residence in estuarine waters prior to migration to coastal waters is approximated as 15 days. This decision was informed by the residence time of ocean-type Chinook, which WDOE cites as being a few weeks (which we interpret to mean three weeks); i.e., stream-type Chinook spend <21 days in estuarine environments, and 15 days was assumed.

Page 6. "Further, juvenile salmonids do not limit their use of estuarine habitats to their natal estuaries, as juvenile salmonids have also been found to enter and utilize non-natal estuaries during their marine near shore migration."

WDOE provided no indication of how much time juvenile Chinook salmon spend in these near-shore environments, so LHFs were calculated ignoring this behavior.

Page 6. "Salmonids mature in oceanic and coastal waters from 1 to 6 years, although 2 to 4 years is more typical, before returning to their natal streams to spawn."

LHFs were calculated using two, three, and four years.

2.1.2 *Ocean-Type Chinook Life History*

Excerpts from Ecology's TIP are quoted as the basis for developing the LHFs listed in Table A1.

Table A1. Life History Factors for Chinook Salmon[a]

Type	Residence Time (days) FW[b]	Est.[b]	Marine[b]	Age at Spawing (days)	(years)	LHFs FW+Est.[c]	Marine	Notes[d]
Stream-Type	365	15	730	1110	3.0	0.342	0.658	"a year or more in the river before migrating downstream"; "spend very little time in the estuaries"; "2 to 4 years is more typical"
	730	15	730	1475	4.0	0.505	0.495	
	365	15	1095	1475	4.0	0.258	0.742	
	730	15	1095	1840	5.0	0.405	0.595	
	365	15	1460	1840	5.0	0.207	0.793	
	730	15	1460	2205	6.0	0.338	0.662	
Ocean-Type (immediate)	50	21	730	801	2.2	0.089	0.911	"migrates to ocean soon after yolk resorption"; "a few weeks in the estuary"
	50	21	1095	1166	3.2	0.061	0.939	
	50	21	1460	1531	4.2	0.046	0.954	
Ocean-Type (most common)	105	21	730	856	2.3	0.147	0.853	"migrate to marine habitats at 60 to 150 days post hatching"; "a few weeks in the estuary"
	105	21	1095	1221	3.3	0.103	0.897	
	105	21	1460	1586	4.3	0.079	0.921	
Ocean-Type (poor conditions)	365	21	730	1116	3.1	0.346	0.654	"juveniles remain in fresh water for a year"
	365	21	1095	1481	4.1	0.261	0.739	
	365	21	1460	1846	5.1	0.209	0.791	
Average Stream-Type	547.5	15	1095	1657.5	4.5	0.339	0.661	average freshwater residence assuming 3 y in marine habitat
Average Ocean-Type	105	21	1095	1221	3.3	0.103	0.897	"most common" life history assuming 3 y in marine habitat
LHFs for non-Puget Sound waters →						0.15	0.85	LHFs assuming 80% of Chinook are ocean-type fish; Puget Sound residency not incorporated (Sec 2.3)
LHFs for Puget Sound Waters only →						0.40	0.60	LHFs for Puget Sound only Chinook incorporating residency and assuming 80% are ocean-type fish (Sec 2.3)
Composite LHFs for all waters of the state →						0.30	0.70	state-wide composite LHFs incorporating residency of Puget Sound Chinook assuming 60% Puget Sound fish (Sec 2.3)

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks

Page 5. WDOE (2012) describes three distinct behaviors (phases) for ocean-type Chinook fry:

1. The "immediate" phase – fish that migrate to the ocean "…soon after yolk resorption…"
2. The "most common" phase – the most common life history for ocean-type fry "…is to migrate to marine habitats at 60 to 150 days post hatching…"
3. The "poor conditions" phase – "During years of poor environmental conditions…ocean-type juveniles remaining in fresh water for a year, although this is relatively uncommon."

In this analysis, we assumed that the "immediate phase" spend 50 days in freshwater (an arbitrary number meant to include migration to the natal estuary), the "most common" phase spend 105 days (the average of the reported range) in freshwater, and the "poor conditions" phase spend 365 days in freshwater.

Page 5. "Once reaching the marine environment, they then spend a few weeks or longer rearing in the estuary."

An estuarine residence time of 21 days was used for all phases of ocean-type Chinook.

Page 6. "Salmonids mature in oceanic and coastal waters from 1 to 6 years, although 2 to 4 years is more typical, before returning to their natal streams to spawn."

LHFs were calculated using two, three, and four years.

2.1.3 *Discussion and Final LHF for Chinook Salmon*

As shown in Table A1, the LHFs for stream- and ocean-type Chinook differ. As a consequence, consumption of Chinook would, ideally, be broken out based on life history and the appropriate LHF applied to each type. Alternatively, if all Chinook are lumped together, composite LHFs are required. However, information on the relative fraction of the overall Chinook population that belong to each life history type are required to generate LHFs for lumped Chinook, and this information was not provided in the TIP.

According to Healey (1991), the ocean-type life history is "typical" of Pacific North American Chinook populations south of 56°N, which includes all of Washington and Oregon. More specifically, stream-type runs represent only 0 to 12% of Chinook runs in smaller rivers, and 14 to 48% of Chinook runs in larger rivers. However, Table 1 in Healey (1991) also indicates that 78% of Columbia River spawning runs and 88% of Sixes River (southern Oregon coast) runs are ocean-type. This information suggests that about 80% of Chinook salmon caught and consumed in Washington are ocean-type fishes. Thus, using the average stream- and ocean-type LHFs extracted from WDOE's TIP (Table 1), composite LHFs for Chinook salmon would be nominally 0.85 and 0.15 for marine and fresh plus estuarine waters, respectively, meaning that the LHF for waters of the state would be 0.15. However, this LHF does not account for a third life history not addressed by the TIP, which is Puget Sound residency throughout the full marine-phase of Chinook life history.

Puget Sound is known to support populations of resident Chinook and coho salmon (Chamberlin 2009; Rohde 2013). These fish spend the marine-phase of their life history in Puget Sound proper, meaning the LHF for waters of the state would be 1 for these specific fish. Based on information presented by WDOE (2013), 60% of the salmon harvested in Washington were caught in marine waters, and WDOE identified 60% of these as Puget Sound salmon. Of the 40% of salmon caught in freshwaters, WDOE estimated that 57% were harvested in Puget Sound streams. Thus, overall, approximately 60% ([0.6 x 0.6]+[0.4 x 0.57]) of the salmon harvested in Washington are estimated to originate from Puget Sound. Although not all these fish are Chinook, in this analysis we assume that this proportion applies to all salmon except pink salmon (100% of which are assumed to be Puget Sound fish); that is, we assume that 60% of the Chinook caught and consumed in Washington are from runs originating in Puget Sound. Regardless, not all Puget Sound Chinook exhibit full residency in Puget Sound.

Although full residency is a well known phenomenon, there is very little information indicating what fraction of Puget Sound Chinook exhibit this life history. Chamberlin (2009) studied the role of multiple factors on the tendency of Puget Sound Chinook to exhibit full residency (in Puget Sound) and concluded that 30% of Puget Sound Chinook salmon display this behavior (i.e., 30% of Puget Sound Chinook have a waters of the state LHF of 1). Chamberlin's conclusion is generally consistent with that of O'Neill and West (2009), who estimated that full residency was exhibited by between 29 and 45% of Puget Sound Chinook. Here, Chamberlin's estimate is used to calculate a composite waters of the state LHF of 0.40 ([0.7 x 0.15]+[0.3 x 1]) specific to Puget Sound Chinook.

This value is notably larger than the waters of the state LHF for non-Puget Sound Chinook (0.15) but is only applicable to Puget Sound Chinook. For other Chinook (e.g., Columbia River runs), the appropriate waters of the state LHF remains 0.15. Based on the same information, a composite waters of the state LHF for all Chinook would be 0.3 ([0.4 x 0.15]+[0.6 x 0.4]). This final value is the appropriate waters of the state LHF for use when considering Chinook on a statewide basis.

2.2 Coho Salmon

Table A2 summarizes LHFs for coho salmon.

2.2.1 *Coho Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs listed in Table A2.

Page 7. "For populations in and around Washington State, returning adult Coho salmon are generally 3-year-olds, and spend approximately 18 months in fresh water and 18 months in marine habitats."

Page 7. "After emerging, the fry generally remain within freshwater streams for a year or two before migrating downstream."

LHFs were calculated assuming one and two year periods.

Page 8. "Emergence has been detected from March to July."

In this analysis we assume emergence in mid-April.

Page 8. "Although some fry migrate to marine waters soon after emergence, the majority disperse both up- and downstream, remaining in streams to rear as juveniles for one to two years before migrating downstream."

LHFs were calculated assuming one and two year periods.

Page 8. "Within this region, Coho smolts typically leave fresh water and migrate to marine habitats to enter the smolting process in the spring (April to June). Once entering marine waters, Coho smelts spend little time rearing in estuaries, instead migrating toward coastal waters."

Migration was assumed to begin in mid-May.

Page 8. "Although some Coho salmon move to offshore waters, typically subadults continue to feed and mature in these coastal waters of the northeast Pacific."

Page 8. "The majority of Coho originating from Washington streams migrate to coastal waters off Oregon and Washington, with low numbers occurring in Oregon and British Columbia waters."

Table A2. Life History Factors for Coho Salmon[a]

Residence Time (days)			Age at Spawing		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	FW+Est.[c]	Marine	Notes[d]
547.5		547.5	1095	3.0	0.500	0.500	"18 months in fresh water and 18 months in marine habitats"
395		471	866	2.4	0.456	0.544	"1y" in FW (mid-April emergence and mid-May migration to saltwater = 13 months) followed by 1, 2, or 3 "summers" in marine water (15.5 months = 2 summers)
395		836	1231	3.4	0.321	0.679	
395		1201	1596	4.4	0.247	0.753	
760		471	1231	3.4	0.617	0.383	"2y" in FW (mid-April emergence and mid-May migration to saltwater = 25 months) followed by 1, 2, or 3 "summers" in marine water (15.5 months = 2 summers)
760		836	1596	4.4	0.476	0.524	
760		1201	1961	5.4	0.388	0.612	
					0.47	0.53	average LHFs for 3.4 year old fish excluding Puget Sound residency (Sec 3.2)
LHFs for non-Puget Sound waters →					0.50	0.50	LHFs based on 18 months in marine water, a 3 y life span, and excluding Puget Sound residency (Sec 3.2)
LHFs for Puget Sound Waters only →					0.60	0.40	LHFs for Puget Sound only coho incorporating residency (Sec 3.2)
Composite LHFs for all waters of the state →					0.56	0.44	state-wide composite LHFs incorporating residency of Puget Sound coho assuming 60% Puget Sound fish (Sec 3.2)

[a] all information extracted from WDOE’s TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks

Page 9. “While some adult male Coho salmon return after spending only one summer at sea, the majority of Coho return after spending two, and sometimes three, summers at sea. There are some run timing differences between coastal and inland Washington stocks of Coho salmon, but adults begin returning to estuaries and outlets of their natal streams from July to September.”

In this analysis, we assume return in September, and LHFs were calculated assuming two and three summers at sea.

2.2.2 *Discussion and Final LHF for Coho Salmon*

The timing of specific events in the life history of coho is variable at the scale of months. This level of variability is significant if it is accepted that the majority of returning adults are around three years old. This variability is reflected in the various LHFs shown in Table A2, which shows LHFs for marine residency ranging from 0.383 to 0.679 for 3.4 year old fish, depending on whether it is assumed they spent one or two years in freshwater. However, the average of these two marine LHFs is 0.53, which is essentially the same as obtained by assuming that coho split their life between fresh and estuarine waters, or near-shore waters vs. marine waters. Thus, the final LHFs for coho salmon are taken as 0.5 and 0.5 for marine and fresh plus estuarine waters, respectively, meaning that the final LHF for waters of the state would be 0.5.

However, similar to Chinook, some fraction of Puget Sound coho salmon also exhibit full residency in Puget Sound proper (e.g., Rohde 2013), and for these fish the waters of the state LHF would be 1. Following the work of Chamberlin (2009) on Chinook salmon, Rohde (2013) attempted to characterize the relative fraction of Puget Sound coho exhibiting this life history, and estimated that 3.4% are true residents, 61.3% migrate outside Puget Sound, and the behavior of the remaining 35.3% is ambiguous. Assuming 50% of the ambiguous fish are in fact residents means that approximately 21% of Puget Sound coho exhibit full residency, and the waters of the state LHF for these fish is 1. The associated composite waters of the state LHF for all Puget Sound coho is 0.6 ([0.79 x 0.5]+[0.21 x 1]). For other coho (e.g., Columbia River runs) the appropriate waters of the state LHF remains 0.5. Following the analysis for Chinook (i.e., assuming that 60% of the coho caught in Washington are from Puget Sound runs), the composite statewide waters of the state LHF for coho salmon is 0.56 ([0.4 x .5]+[0.6 x 0.6]).

2.3 Sockeye Salmon

Table A3 summarizes LHFs for sockeye salmon.

2.3.1 *Sockeye Salmon Life History*

Excerpts from WDOE’s TIP are quoted as the basis for developing the LHFs listed in Table A3.

Page 9. “Sockeye salmon have one of the most diverse patterns of life history among Pacific Northwest salmon species. For example, age at out-migration to marine systems from their natal streams not only varies between systems, and within systems, but can vary among related individuals.”

Page 10. “The hatched alevin then take an additional 24 to 60 days to emerge from the gravel as fry, with warmer temperatures reducing the time for emergence. Sockeye salmon emerge as fry generally in April or May, with some variability associated with temperature.”

In this analysis we assume emergence on May 1 (approximately 42 days post-hatch, meaning hatch in mid-March).

Table A3. Life History Factors for Sockeye Salmon[a]

Type	Residence Time (days) FW[b]	Est.[b]	Marine[b]	Age at Spawing (days)	(years)	LHFs FW+Est.[c]	Marine	Notes[d]
Stream-Type	457		730	1187	3.3	0.385	0.615	to marine water at age 1; assume hatch mid-March, emergence by May 1 (42 days post-hatch), 1 y residence, and then out-migration (50 days); "limited" use of estuary
Stream-Type	457		1095	1552	4.3	0.294	0.706	
Stream-Type	457		1460	1917	5.3	0.238	0.762	
						0.306	0.694	average of all age fish
Ocean-Type	92		730	822	2.3	0.112	0.888	to marine water first year (assume hatch mid-March, emergence by May 1 (42 days), and immediate out-migration (50 days); "limited" use of estuary
Ocean-Type	92		1095	1187	3.3	0.078	0.922	
Ocean-Type	92		1460	1552	4.3	0.059	0.941	
						0.083	0.917	average of all age fish
Ocean-Type	457		730	1187	3.3	0.385	0.615	to marine water at age 1
Ocean-Type	457		1095	1552	4.3	0.294	0.706	
Ocean-Type	457		1460	1917	5.3	0.238	0.762	
						0.306	0.694	average of all age fish
Composite LHFs for all waters of the state						0.19	0.81	composite LHFs assuming 50:50 split between stream- and ocean-type (92 days FW residence) (Sec 4.2)

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks

Page 10. "Regarding their entry into marine waters, two types of sockeye salmon occur: the ocean-type (or sea-type) that migrates to marine waters in the first year of their life, and the stream-type that may rear in rivers and lakes for a year or more before migrating to marine habitats."

LHFs were calculated for both scenarios. In all cases, it was assumed that out-migration peaks on May 1.

Page 10. "Juvenile sockeye in Washington generally migrate from their nursery lakes to marine habitats in March and continuing through June, with peak out-migration occurring in April and May. Upon entering marine waters, estuarine use by juvenile sockeye salmon (smolts at this point) is limited, although some ocean-type sockeye may use these habitats before migrating toward coastal waters."

Here we assume peak migration occurs on May 1 for both ocean- and stream-type, and we assume this migration takes 50 days.

Page 10. "Sockeye spend 2 to 4 years at sea before returning to their natal systems to spawn."

In this analysis, LHFs were calculated using two, three, and four years.

2.3.2 *Discussion and Final LHF for Sockeye Salmon*

LHFs for stream-type and ocean-type sockeye differ only if it is assumed that ocean-type fish out-migrate immediately following emergence. If these ocean-type fish rear in freshwater for a full year after emergence, they effectively become stream-type fish with respect to their LHF. However, WDOE gives no information indicating what fraction of these ocean-type fish exhibit this life history. As a consequence, this life history for ocean-type fish is ignored.

WDOE's TIP is also mute on what fraction of sockeye salmon exhibit stream- vs. ocean-type life histories. Likewise, no information regarding what fraction of each type spends two, three, or four years at sea was provided in the TIP. As a consequence, LHFs for each life history type were calculated as the average of the LHFs for fish spending two, three, and four years at sea. Subsequently, composite LHFs were calculated assuming a 50:50 split between stream- and ocean-type fish. The resulting composite LHFs are 0.81 and 0.19 for marine and fresh plus estuarine waters, respectively, meaning that the final statewide composite waters of the state LHF is 0.19.

2.4 Chum Salmon

Table A4 summarizes LHFs for chum salmon.

2.4.1 *Chum Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs listed in Table A4.

Page 11. "Similar to pink salmon or ocean-type Chinook, juvenile chum migrate from their freshwater redds to marine waters almost immediately after emergence."

Page 11. "The alevins remain in the gravel another 30 to 50 days, until their yolk sac is absorbed."

Here we assume 40 days.

Table A4. Life History Factors for Chum Salmon[a]

Residence Time (days)			Age at Spawing		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	FW+Est.[c]	Marine	Notes[d]
121	42	932	1095	3.0	0.149	0.851	fish migrate to ocean after minimal residence in estuarine waters
121	42	1297	1460	4.0	0.112	0.888	
					0.130	0.870	average of 3 and 4 year old fish
121	426.5	547.5	1095	3.0	0.500	0.500	fish stay in Hood Canal/Puget Sound until age 1.5 y (this time in coastal marine water assigned to "Est")
121	426.5	912.5	1460	4.0	0.375	0.625	
					0.438	0.563	average of 3 and 4 year old fish
LHFs for non-Puget Sound waters →					0.13	0.87	LHFs for non-Puget Sound chum based on average age fish (Sec 5.2)
LHFs for Puget Sound waters only →					0.28	0.72	LHFs for Puget Sound only chum using average age fish and assuming 50:50 split between two life histories (Sec 5.2)
Composite LHFs for all waters of the state →					0.22	0.78	statewide composite LHFs assuming 60% Puget Sound fish (Sec 5.2)

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks

Page 11. "Most chum salmon fry spend only a few days to a few weeks rearing in fresh water before migrating toward marine habitats from March to May. A much smaller number of fry may rear in freshwater streams but migrate to marine waters by the end of their first summer."

This "much smaller number" of fry is excluded from this analysis, and the post-hatch time in freshwater prior to out-migration is assumed to be 21 days ("a few weeks"). Out-migration is assumed to peak on April 1.

Page 11. "Chum salmon utilize estuarine habitats for a few more weeks before migrating to coastal, then offshore waters."

This suggests estuarine residence is ≈21 days.

Page 12. "Most chum fry enter estuaries by June and leave them by mid to late summer."

This appears to conflict with the statement (page 11) that chum utilize estuarine habitats for a "few more weeks." Thus, this analysis assumes arrival in June and a six week (42 days) residence in estuarine waters (i.e., fish leave natal estuaries in mid-July). This means that migration time to the natal estuary is assumed to be two months (60 days).

Page 12. "The Hood Canal shoreline is said to serve as a nursery and rearing habitat for a significant portion of all chum salmon originating from Washington State rivers."

WDOE gives no information on the amount of time these fish spend in this habitat. However, the indication that a significant portion of chum salmon manifest this life history means they should be accounted for in any LHFs, and our analysis assumes that 50% of Puget Sound chum exhibit this behavior.

Page 12. "A number of age 2 chum salmon do occur within Puget Sound waters, although the absence of age 3 chum suggests that all chum salmon spend some time rearing in the Pacific Ocean."

It is not clear what age 2 means (e.g., in the second year of life, i.e., 1.01 years; over 2 years old, i.e., in the third year of life). In this analysis, it is assumed that these fish move out of Puget Sound at age 1.5 years (547.5 days old). This assumption concerning residence time is also meant to encompass Puget Sound fish that utilize Hood Canal for rearing.

Page 12. "In general, chum salmon originating from Washington streams and rivers, and rearing in the open ocean, do not return as mature adults until age 3 or 4."

LHFs were calculated assuming both three and four years.

2.4.2 *Discussion and Final LHF for Chum Salmon*

Table A4 gives LHFs for three and four year old chum assumed to migrate to marine waters after minimal residence in estuarine waters (assumed as 42 days) following 121 days in freshwater. These LHFs are relevant to chum originating outside of Puget Sound/Hood Canal. For these fish, the waters of the state LHF is estimated to be 0.13 (average of three and four year old fish).

For Puget Sound/Hood Canal chum, one important unknown is the fraction of the total population spending "additional" time rearing in Hood Canal/Puget Sound prior to migrating to the Pacific Ocean proper, and just exactly how much time they spend in these waters prior to this final out-migration. As noted, we assume these fish migrate to the Pacific Ocean at age 1.5 years (547.5 days). This corresponds to 121 days in freshwater followed by 426.5 days in estuarine waters and Hood Canal/Puget Sound combined, and Table A4 gives LHFs for age three and four year old Puget Sound chum according to these assumptions. However, not all Puget Sound chum exhibit this life history. Because the TIP gives no information indicating what fraction of Puget Sound fish follow this life history, we have arbitrarily assumed 50%. Thus, the final LHF for Puget Sound chum is a composite of the two life histories equally weighted. The resulting LHFs are 0.72 and 0.28 for marine and fresh plus estuarine waters, respectively, meaning that the waters of the state LHF for Puget Sound chum is 0.28 ([0.5 x 0.13]+[0.5 x 0.438]).

Composite LHFs for statewide use were calculated assuming that 60% of the chum salmon harvested in Washington are Puget Sound fishes. The resulting values are 0.78 and 0.22 for marine and fresh plus estuarine waters, respectively, meaning that the statewide composite waters of the state LHF for chum salmon is 0.22 ([0.4 x 0.13]+[0.6 x 0.28]).

2.5 Pink Salmon

Table A5 summarizes LHFs for pink salmon derived from the information provided by WDOE (2013).

2.5.1 *Pink Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs listed in Table A5.

Page 13. "Pink salmon only live for 2 years, with very little variability."

Page 13. "As pink salmon adults spawn near river mouths, and fry migrate downstream immediately after emergence, this salmon species spends the least amount of time in fresh water."

The fact that pink salmon spawn near the mouth of their natal river suggests that the time required for migration to estuarine waters is minimal. This analysis assumes migration takes 10 days.

Page 13. "Although some smaller coastal and Columbia River runs occur, within Washington State two of the rivers supporting the largest pink salmon runs are the Snohomish and Puyallup."

This statement is consistent with essentially all pink salmon in Washington State originating from Puget Sound.

Page 14. "Once the yolk sac is depleted, the alevins emerge as fry some 41 to 64 days (average 52 days) post hatching."

The 52 day average is used herein.

Page 14. "There is little or no fresh water rearing as pink salmon fry migrate seaward upon emergence from the gravel, and so their downstream migration also occurs in March and April."

Based on this and other statements in WDOE's TIP, migration was assumed to begin immediately following emergence.

Page 14. "Pink salmon originating from Puget Sound and Hood Canal streams and rivers appear to use near shore areas extensively for early rearing during their first few weeks of entry into marine habitats."

This suggests nominally 21 days (a "few weeks") in estuarine waters.

Page 14. "While little is known about their behavior as the fry are exiting Puget Sound proper, Hiss (1994, as cited in Hard et al 1996) found that fry occurrence in Dungeness Bay (near Sequim) peaked in April and they were gone by late May."

Assuming that peak migration manifests on April 1, the observation that fry are no longer present in Dungeness Bay by late May suggests two months (60 days) residence in near-shore waters of Hood Canal/Puget Sound prior to out-migration to the Pacific Ocean.

Table A5. Life History Factors for Pink Salmon[a]

Residence Time (days)			Age at Spawing		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	FW+Est.[c]	Marine	Notes[d]
62	106.5	561.5	730	2	0.231	0.769	fry emerge 52 days post-hatch; estimate 10 days to migrate to estuary for a total of 62 days in FW; 3.5 months in estuary/near-shore waters prior to migration to marine waters; 2 y total life span
183		547	730	2	0.251	0.749	based on 18 months rearing in marine water and 24 month life span
LHFs for all waters of the state[e]					0.24	0.76	average LHFs

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] FW+Est. = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] all pink salmon assumed to be Puget Sound fish

Page 14. "Findings suggest that most out-migrating pink salmon enter the open ocean by late summer or early fall."

This suggests residence in estuarine waters for more than two months.

Page 14. "However, like some Chinook, and Coho, a small portion of the pink salmon population appears to adopt residency in Puget Sound for the marine phase of the life cycle."

WDOE gives no information on what fraction of pink salmon exhibit this behavior.

Page 14. "Once reaching estuarine and marine habitats, pink salmon migrate towards the open ocean within the first couple of months. By September the majority of pink salmon migrate hundreds of miles out in the open sea to grow and mature."

Assuming migration from freshwater to estuarine water peaks on April 1 suggests that pink salmon spend anywhere from two to five months in estuarine (near-shore) waters of Hood Canal/Puget Sound prior to out-migration to the Pacific Ocean. In this analysis, we assume an average of 3.5 months (106.5 days).

Page 14. "They spend approximately eighteen months rearing in the open ocean before their eastward migration to their natal streams and rivers."

LHFs were calculated assuming 18 months in marine waters and a 24 month total life span.

2.5.2 *Discussion and Final LHF for Pink Salmon*

Table A5 gives two sets of LHFs based on the information presented by WDOE (2013). The difference between these two estimates is minimal, and the final LHFs are taken as the mean of the two. Thus, the resulting LHFs for pink salmon are 0.76 and 0.24 for marine and fresh plus estuarine waters, respectively. The final LHF for pink salmon reflecting time spent in waters of the state is 0.24.

For pink salmon that spend their marine phase in Puget Sound, the resulting LHF reflecting time in waters of the state would be 1. However, no information on what fraction of pink salmon manifest this life history was found, while WDOE (2013) noted that only a "small portion" of the overall pink salmon population exhibit Puget Sound residency. As a consequence, this full residency life history is not accounted for in the final waters of the state LHF.

2.6 Composite Residency-Based LHF for all Washington Salmon

Sections 2.1 through 2.5 address development of LHFs for individual salmon species based on residence times. However, there may be circumstances in which a single composite LHF for all Washington salmon will be required. One approach to developing such a composite LHF is to sum the species-specific LHFs after weighting each by a factor reflecting species-specific consumption rates of Washington consumers. One source of these consumption rates is EPA's Exposure Factor Handbook (USEPA 2011), which gives species-specific consumption rates for adult members (consumers only) of the Suquamish Tribe in Table 10-104. Although this tribe consumes more shellfish than other tribal data would suggest, it was assumed that the relative amounts of the different salmon species consumed are representative of Washington consumers generally, including high-end tribal consumers. The data from EPA's table is reproduced in part as Table A6 herein, which also shows generation of a single composite LHF for salmon in general (0.32) based on the species-specific LHFs.

A composite salmon LHF could be developed based on other information such as commercial landings, but such data do not necessarily reflect consumption habits of Washington residents.

Table A6. Derivation of Composite Residency-Based Life History Factor for All Salmon Species based on Tribal Consumption Pattern

	Tribal Consumption Data[a]				Species-Specific LHFs	
Species	N	Mean (g/d)	n x Mean (g/d)	Diet Fraction at Mean[b]	LHF[c]	Consumption Weighted
Chinook (King)	63	0.200	12.6	0.294	0.300	0.088
Sockeye	59	0.169	9.971	0.233	0.560	0.130
Coho	50	0.191	9.55	0.223	0.194	0.043
Chum	42	0.242	10.164	0.237	0.222	0.053
Pink	17	0.035	0.595	0.014	0.241	0.003
			composite LHF for salmon		→	0.318

[a] consumption data for Suquamish Tribe from Table 10-104 in USEPA 2011
[b] fraction of overall salmon consumption attributable to each species
[c] species-specific LHFs from Sections 2.1 to 2.5, Tables A1 to A5

3.0 DISCUSSION OF LIFE HISTORY FACTORS BASED ON RESIDENCE TIMES

As seen in Section 2, LHFs for Washington salmon can be developed based on residence time. However, in addition to uncertainty regarding residence times of different salmon species (or specific runs) in different environments or geographic locations, the available data also manifest a high degree of variability. Thus, the resulting LHFs must be considered gross approximations. Despite this, there are factors that inform the potential for bias in the residence time LHFs presented in Section 2, and these factors suggest that, in general, residence time LHFs overstate the magnitude of bioaccumulation in early life stages of salmon life history.

One such factor is, ironically, time. This results because bioaccumulation is a reversible process, meaning that organisms are accumulating and depurating bioaccumulative chemicals simultaneously. Indeed, it is the ratio (accumulation rate/depuration rate) that underpins chemical- and organism-specific bioaccumulation factors. Once an organism moves from one environment (geographic location) to another, the probability that the specific molecules of a chemical acquired in the first environment/location will depurate increases with the time spent in the second environment/location. This probability increases when the first environment/location is more contaminated than the second, which is the exact scenario relevant to Puget Sound salmon that spend time in the Pacific Ocean proper. Apportioning body burdens based on residence time thus tend to overstate the contribution of accumulation during the early life stages to the ultimate body burden in returning adult Puget Sound salmon.

Beyond this, the assumption that an organism acquires bioaccumulative chemicals at a constant rate is analogous to assuming a fixed bioaccumulation factor. This assumption might hold for an organism that is static, that is, an organism that is not undergoing any physiological changes, feeds at a fixed trophic level, and exhibits either no growth or a constant rate of growth, but it is clearly a gross oversimplification for salmon, which exhibit extremely complex life histories. Thus, a more appropriate basis for apportioning when/where bioaccumulative chemicals are acquired might be relative growth, that is, when/where salmon acquire body mass. Section 4 describes an initial attempt to develop such LHFs.

4.0 LIFE HISTORY FACTORS BASED ON GROWTH

The literature contains many statements (e.g., Quinn 2005) to the effect that salmon acquire the majority of their body mass during the marine phase of their life cycle; that is, while feeding in the ocean (or Puget Sound for true resident fish). For this analysis, the generalized summary of body mass presented by Quinn (2005) is taken as representative; these data are summarized in Table A7, which also gives nominal mass-based LHFs reflecting the relative body masses of out-migrating smolt and returning adult salmon.

Table A7. Generalized Weights of Salmon as they Enter the Ocean and as Returning Adults[a]

	Chinook	Coho	Sockeye	Chum	Pink
Smolt weight (g)	5-18	18	10	0.4	0.22
Adult weight (kg)	7.22	3.02	2.69	3.73	1.63
LHF[b]	0.00249	0.00596	0.00372	0.00011	0.00013

[a] from Quinn 2005, Table 16.3
[b] calculated as simple ration (smolt/adult)

By definition (Quinn 2005), smolts are the final stage in salmon development prior to migration to true marine waters. This means the difference in body mass between smolt and adult fish reflects growth in marine waters, and the information provided in Table A7 indicates that all five species of Pacific Northwest salmon acquire >99% of their adult body mass during the marine phase of their life history. Thus, if it is assumed that these fish spend this portion (the marine phase) of their life outside waters of the state, the mass-based LHFs given in Table A7 are the relevant waters of the state LHF. However, some salmon spend a portion of their marine life history in waters of the state. Unfortunately, as noted (Section 3), residence time cannot be used to apportion growth among different habitats or geographic locations. Thus, without higher resolution mass data (i.e., measured mass of fish at multiple ages corresponding to species-specific shifts in habitat usage), the only distinction that can be made is between those fish that exhibit nominally full residency in waters of the state (i.e., Puget Sound) during their marine phase and those that exhibit full residency in the Pacific Ocean during this phase. Adjustments to the mass-based LHF given in Table A7 reflecting this life history (full residency in Puget Sound) are discussed on a species-specific basis.

4.1 Chinook Salmon

Based on the analysis presented in Section 2.1.3, approximately 60% of the salmon, including Chinook, are caught and consumed in Washington are Puget Sound fish. Of these Puget Sound Chinook, about 30% are resident fish. Thus, 18% of all Chinook (0.6 x 0.3) are Puget Sound residents which, by definition, have an LHF equal to 1. For the remaining 82%, the default mass-based LHF is that given in Table A7. Thus, the single composite mass-based LHF for Chinook salmon reflecting waters of the state is 0.182 ([0.82 x 0.00249]+[0.18 x 1]).

4.2 Coho Salmon

Following the analysis for Chinook, 60%of coho salmon are considered to be Puget Sound fish, and 21% of these are assumed to be full time residents of Puget Sound (Section 2.2.2). Thus, 13% (0.6 x 0.21) of all coho are Puget Sound residents which, by definition, have a waters of the state LHF equal to 1. For the remaining 87%, the default mass-based LHF is that given in Table A7. Thus, the single composite mass-based LHF for coho reflecting waters of the state is 0.135 ([0.87 x 0.00596]+[0.13 x 1]).

4.3 Sockeye Salmon

WDOE's TIP gives no information on what fraction of Puget Sound sockeye salmon exhibit full residency in Puget Sound, so there is no basis for parsing sockeye as Puget Sound or non-Puget Sound fish. This means that the only mass-based LHF for sockeye is that given in Table A7. Thus, the single mass-based LHF for Sockeye salmon reflecting waters of the state is 0.00372.

4.4 Chum Salmon

As discussed in Section 2.4.2, some chum spend some time rearing in Hood Canal/Puget Sound prior to migrating to the Pacific Ocean. However, as also discussed (Section 4.0), without data there is no way to identify the fraction of ultimate adult body mass chum acquire during this period. Beyond this, the TIP provides no information suggesting any chum salmon take up full residency in Puget Sound. Thus, there is no basis for modifying the mass-based LHF for chum given in Table A7, meaning that the final mass-based LHF for chum salmon reflecting waters of the state is 0.00011.

4.5 Pink Salmon

As noted in WDOE's TIP (Section 2.5.1 herein), some pink salmon spend some time in near-shore marine waters rearing prior to completing migration to the Pacific Ocean. However, as discussed (Section 4.0), without data there is no way to identify the fraction of ultimate adult body mass these fish acquire during this period. Beyond this, the TIP states that only "a small portion of the pink salmon population appears to adopt residency in Puget Sound for the marine phase of the life cycle." Thus, there is no basis for modifying the mass-based LHF for pink salmon given in Table A7, meaning that the final mass-based LHF for pink salmon reflecting waters of the state is 0.00013.

4.6 Composite Mass-Based LHF for all Washington Salmon

Table A8 summarizes calculation of a single composite mass-based LHF for all Washington Salmon according to Section 2.6.

Table A8. Derivation of Composite Mass-Based Life History Factor for All Salmon Species based on Tribal Consumption Pattern

	Tribal Consumption Data[a]				Species-Specific LHFs	
Species	N	Mean (g/d)	n x Mean (g/d)	Diet Fraction at Mean[b]	LHF[c]	Consumption Weighted
Chinook (King)	63	0.200	12.6	0.294	0.182	0.053
Sockeye	59	0.169	9.971	0.233	0.135	0.031
Coho	50	0.191	9.55	0.223	3.72×10^{-3}	8.28×10^{-4}
Chum	42	0.242	10.164	0.237	1.10×10^{-4}	2.61×10^{-5}
Pink	17	0.035	0.595	0.014	1.30×10^{-4}	1.80×10^{-6}
			composite mass-based LHF for salmon			0.086

[a] consumption data for Suquamish Tribe from Table 10-104 in USEPA 2011
[b] fraction of overall salmon consumption attributable to each species
[c] species-specific LHFs from Sections 4.1 to 4.5

5.0 REFERENCES

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From: Niemi, Cheryl (ECY)
Sent: Wednesday, November 20, 2013 11:30 AM
To: Susewind, Kelly (ECY); Gildersleeve, Melissa (ECY)
Subject: FW: Slide: Fish Consumption Alternatives for Consideration

Kelly and Melissa,

I think the summary slide below is important, and will probably be referenced by many people. I am concerned that in the process of making the alternative simpler to understand, the descriptions have picked up inaccuracies.

Below are recommendations for your consideration regarding the summary slide:

1. 225 g/day.

The description of the 225 g/day alternative in the slide below is inaccurate: 225 is not the" Mean of highest highly exposed fish consumption study and recreation fish consumption."

My recommendation is that the text be modified to improve accuracy as follows: "Representative of highly exposed populations. Encompasses the means and most 90th percentiles of tribal and recreational fish consumption surveys in Washington."

2. 175 g/day.

The description of the 175 g/day currently reads: Negotiated value used in Oregon's updated Human Health Criteria. Based on 90-95th percentile of Oregon Fish Consuming populations.*

ODEQ characterizes the 175 g/day as: "*...This rate matches the 95th percentile value from the CRITFC study...*" (ODEQ 5/24/2011). The CRITFIC study includes the Umatilla (Oregon), Nez Perce (Idaho), Yakima (Washington), and Warm Springs (Oregon) tribes.

My recommendation is that the text be modified to improve accuracy to read as follows: "Representative of highly exposed populations. Value with written endorsement by many tribes and EPA. Basis is the FCR chosen by Oregon for CWA human health criteria rule-making (2011).

Thanks,

Cheryl

Cheryl A. Niemi
Surface Water Quality Standards Specialist
Department of Ecology
P.O. Box 47600
Olympia WA 98504
360.407.6440
cheryl.niemi@ecy.wa.gov

From: Conklin, Becca (ECY)
Sent: Wednesday, November 20, 2013 10:03 AM
To: Niemi, Cheryl (ECY)
Subject: Slide: Fish Consumption Alternatives for Consideration

Hi Cheryl,

Here is the table you requested. Please email any edits to Kelly and Melissa.

Thanks,
Becca

	Current	Alternative 1	Alternative 2
Fish Consumption Rate	**6.5** grams/day	**125** grams/day	**175** grams/day
Approximate conversion to standard units	¼ ounce per day	¼ pound per day	**1/3** pound per day
	½ pound per month	**8** pounds per month	**12** pounds per month
	5 pounds per year	**100** pounds per year	**140** pounds per year
Basis	Mean of the per capita national data set.	Mean of the fish consumption rate surveys of 3 Puget Sound tribes	Negotiated value used in Oregon's updated Human Health Criteria. Based on 9(95th percentile of Oregon Fi Consuming populations.*

Deliberative Process Draft Document

Decision Factors in development of Human Health Criteria

Deterministic or probabilistic approach- This approach relies on choosing one value (usually average or high end) to use in the human health criteria equation.	
Advantages – can be done quickly using default values (plug and play). This is the traditional approach that has been used by most states and EPA	Disadvantages – does not use all the variability in the data sets, so the certainty of the level of protection is not as representative of the data accurate
Probabilistic approach - This approach relies on using a range of values (distribution) in the human health criteria equation and then modeling for criteria based on the population to protect and the statistic (mean, 90th percentile, etc.)	
Advantages – uses all information including variability and uncertainty, provides a complete assessment of risk	Disadvantages – more complex calculations, difficult to explain to public and will require us to change out outreach strategy... does not clearly define 1 fish consumption rate.

How salmon are treated. Current federal guidelines do not use salmon in the fish consumption rate because most do not reside for their full life in water regulated by the Clean water Act. Salmon are an iconic fish species for Washingtonians and most spend time in the state waters (regulated under CWA) and part of their life outside state waters. Human health criteria development options center around how to address this situation. Ecology is looking at scientific data to determine if there is support for using a multiplier to determine salmon percentage of toxics picked up in Washington's regulated waters.
Geographic Area The data sets and distribution of fish consumption in Washington are variable. This is especially true where marine shellfish are so prevalent in Washingtonian diets. The fish consumption studies performed for Washington might be better aligned by fish consumption patterns. Those patterns, such as consumption of shellfish, might better support a different HHC for the Puget Sound vs. non-Puget Sound areas. Fish consumption studies that represent the Puget Sound could be used to develop Puget Sound HHC while the non-Puget Sound studies could be used to develop HHC the rest of the state.
Whether to use the same population to protect assumptions for cancerous vs. noncancerous chemicals. Washington currently protects the mean of the general population at 10^{-6} cancer risk rate. We protect a mean of the general population at a hazard quotient of 1 for the noncarcinogens. Some options recommend a different level of protection for these different chemicals. EPA does not provide guidelines for the risk acceptable for noncarcinogens
Risk level for cancerous chemicals. The EPA has said that each state can decide their cancerous risk rates but are required to provide a risk

level no less protective than 10^{-4} for all high consumers. Washington currently protects for a 10^{-6} cancer risk rate for a mean of the general population. Should that rate be retained for cancer causing chemicals?
Target population. Identifies the population of consumers that the criteria are designed to protect. The current NTR protects the mean of the general population. Other options could be the mean of the highly exposed population (HEP), the 90th or 95th percentile of the HEP, the mean of the HEP, etc....
Hazard Quotient for noncarcinogens – the ratio of potential exposure to the substance and the level at which no adverse effects are expected. If the hazard quotient is equal to or less than 1 then no adverse health effects are expected.
Relative Source Contribution for noncarcinogens This is the percentage of the pollutant that comes from other sources than fish/shellfish. EPA has just written guidance on what they think states should use for this part of the equation. Currently, the National Toxics rule uses a value of 1. The new EPA guidance articulates a lower range to be used for development of new criteria. EPA itself has only used a value different than 1 for 17 of the national recommended criteria.

All other parts of the equation remain constant for the following parts of the human health equation:

Body weight	70 kg
Duration of exposure	70 years
Drinking water intake	2 L/day

ncasi

NATIONAL COUNCIL FOR AIR AND STREAM IMPROVEMENT, INC.
West Coast Regional Center
Mailing address: PO Box 458, Corvallis OR 97339
Street address: 720 SW Fourth Street, Corvallis OR 97333
Phone: (541)752-8801 Fax: (541)752-8806

Steve Stratton
Regional Manager
sstratton@ncasi.org

January 11, 2012

Washington State Department of Ecology
PO Box 47600
Olympia, Washington 98504-7600

RE: Comments on Publication No. 11-09-050, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*

The National Council for Air and Stream Improvement, Inc. (NCASI) is an independent, nonprofit membership organization that provides technical support to the forest products industry on a wide range of environmental issues. An important part of our mission is to ensure that regulatory decision making is based on sound science. In this capacity, NCASI reviewed the September 2011 document titled: *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington* (Publication No. 11-09-050), and offers the attached comments.

Overall, NCASI finds that Ecology has not made a compelling case for increasing statewide default fish consumption rates (FCRs). Ecology should clearly explain the level of protection afforded by existing environmental standards for protection of human health, and the incremental benefit to public health that would result from making these standards up to 41 times more stringent. We also have serious concerns that the fish consumption data used to develop the proposal are not representative of the general population, and that these data have been interpreted in an arbitrary manner that leads to an extreme conclusion.

Sincerely,

Jeffrey Louch, PhD.
Senior Scientist, NCASI

Steve Stratton
West Coast Regional Manager, NCASI

ec: Christian McCabe, Northwest Pulp & Paper Association
Paul Wiegand, NCASI

NCASI COMMENTS ON WASHINGTON'S PROPOSAL TO REVISE STATEWIDE DEFAULT FISH CONSUMPTION RATES

In September 2011 Washington State Department of Ecology (Ecology) issued Publication No. 11-09-050, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*. This technical support document (TSD) summarizes available fish consumption studies and proposes that the state adopt default fish consumption rates (FCR) of between 157 and 267 grams per day (g/day). One or more default rates would be used to establish regulatory requirements under the following programs:

- Sediment Management Standards (SMS) rule, which establishes standards for cleanup of contaminated sediments in fresh and marine waters; this rule is currently being revised and a default FCR will be part of the revisions
- Model Toxics Control Act (MTCA), which regulates cleanup of contaminated soils and sediments
- Clean Water Act water quality standards (WQS) established by states and tribes to limit the effects of contaminants ingested with fish and water on human health.

Current default FCRs are 6.5 g/day for WQS and 54 g/day for MTCA cleanup standards. Thus, Ecology is proposing to make human health WQS more stringent by a factor of between 24 and 41, and to make MTCA cleanup standards more stringent by a factor of between 2.9 and 4.9. Ecology is currently working to revise the SMS rule and anticipates establishing a default FCR for sediment cleanups. Ecology also intends to update Washington's WQS and has stated that the information contained in the TSD and the SMS rule revision "will likely strongly influence the rates included in future human health-based water quality criteria."

Ecology has requested comments on the TSD and the proposed range of default FCRs. NCASI offers the following general comments and answers to questions posed in the TSD.

General Comments

1. <u>Any decision to change the current default FCRs should be justified in terms of overall benefit to public health</u>. The underlying premise of the report is that use of the current default FCRs result in water quality or sediment management standards that are not sufficiently protective. However, the TSD provides no perspective on the degree to which public health is protected under the existing FCRs. More importantly, the TSD provides no basis for gauging the overall benefit to public health that might result from changing these FCRs. Ecology should present a coherent assessment of health risks to the general population of the state represented by the current default FCRs and contrast them with the health risks that would result if the default FCRs were increased as recommended in the TSD. This assessment is imperative as there is currently no viable comparator for the costs that would be borne by both Ecology and the regulated community in responding to lowered sediment and water quality criteria as a result of increased FCRs. Without knowledge of what the benefit might be, it is impossible to determine if these costs would be justified.

Understanding what benefit to public health might result from increasing the FCRs is critically important in this context because the current risk assessment paradigm already results in highly protective environmental standards as a result of multiple conservative assumptions. For example, the calculation of risks resulting from consuming contaminants in fish generally assumes that fish are consumed at the default rate for 70 years, that all fish consumed are contaminated to the same degree (which is functionally equivalent to assuming all fish are from the same body of water), and that there are no losses of contaminants during preparation. Beyond this, the maximum dose of a chemical considered to be safe is always adjusted downward from the level indicated by the toxicological data. In the case of non-cancer endpoints, the product of the multiple safety factors (termed uncertainty or modifying factors) used to develop a reference dose (RfD) can approach well over 1000, meaning that the dose used in a risk assessment could be 1000 times lower than the dose directly indicated by the toxicological data. For carcinogens, this safety factor is typically 10, and the acceptable risk level is typically set at one hypothetical additional cancer case per million lifetimes. This is an exceedingly small incremental risk in light of a current lifetime cancer incident rate due to all causes of about 40% (400,000 in one million)[1]. Finally, the paradigm completely discounts any health benefits attributable to consuming fish.

All this supports the current water and sediment quality standards as being highly protective of the residents of Washington, and any proposal to revise these standards should be based on an analysis of the public health benefit to be gained.

2. <u>The proposed range of default FCRs overstates the fish consumption rates for the vast majority of residents of the state.</u> The proposed range is based on high-end statistical consumption rates (e.g., 80th to 95th percentile values) developed from five fish consumption rate studies of known high fish consuming subpopulations. Four of the studies are of tribal groups and the fifth is a study of the King County Asian and Pacific Islander (API) subpopulation. Notwithstanding the methodological concerns we have about Ecology's interpretation of some of these studies (see general comment no. 3), the FCRs recommended in the TSD have the effect of establishing protections for the general population of Washington residents using consumption rates derived from a total surveyed population of 996 individuals reflecting the behaviors of an estimated 0.2-0.9% of the total population of the state.

   Studies that apply to general populations suggest that fish consumption rates are considerably lower than Ecology's proposed range. For example, EPA[2] indicates that for US adults, the 90th and 95th percentile consumption rates of freshwater and estuarine finfish and shellfish are 17.4 and 49.6 g/day, respectively. These values suggest that Ecology's proposed FCR range is not representative of fish consumption rates for the general population statewide.

3. <u>Ecology's analysis of the data from the fish consumption studies used to develop the proposed FCRs is significantly flawed.</u> First, the API study is dominated by first-generation residents (89% of respondents), who are known to consume more fish than later generations.

[1] See, for example, the American Chemical Society at http://www.cancer.org/Cancer/CancerBasics/lifetime-probability-of-developing-or-dying-from-cancer
[2] USEPA. 2002. *Estimated Per Capita Fish Consumption in the United States*.

This known bias in the results casts considerable doubt on the representativeness of the results to describe the fish consumption rates of the broader API population.

Another significant issue with the API study is that the consumption rates used in the TSD to generate a proposed range of FCRs for adoption are not corrected for cooking losses, non-local harvest, or API population demographics. EPA Region 10 reanalyzed these data[3], adjusted for these biases, and determined the reasonable maximum exposure (RME, the 95th percentile value) to be 51.1 g/day not including anadromous fish, or 57 g/d including anadromous fish (see table on pg. 61 of TSD). Contrast this with the unadjusted data in the TSD, where the 95th percentile value is shown as 306 g/day (e.g., Table A-1 in TSD). It is unclear why Ecology believes that consumption data biased high by inclusion of non-locally harvested fish should be the basis of its FCR proposal when more scientifically defensible estimates are available. To be clear, any default FCRs should reflect consumption of locally harvested fish only.

It appears that the data from the Tulalip and Suquamish Island tribes also need to be adjusted to remove non-locally harvested fish, as EPA Region 10 did in developing its guidance for site-specific cleanup levels[4]. In addition, Pacific salmon comprised a significant fraction of the fish diet for all the Native American fish consumption studies. For reasons discussed in Appendix A, inclusion of salmon in a statewide default FCR is clearly not appropriate.

Because the actual data from most of the fish consumption surveys are not publically available, Ecology used descriptive statistics to develop composite log-normal distributions based on seven different weighting schemes. (As noted above, these datasets should be adjusted (per EPA Region 10 guidance) to eliminate fish that are not locally harvested before developing composite distributions). Ecology ultimately chose to use a scheme in which each of the five surveys was given equal weight to develop a composite distribution from which the proposed range (80th to 95th percentiles) of FCRs was developed. Given that these data represent only known high fish consuming subpopulations, the use of statistics that characterize the upper extremes (e.g., 80th to 95th percentile values) of a composite distribution that intentionally excludes the vast majority of fish consumers and, more importantly, the vast majority of the general population, would be inappropriate for establishing default FCRs for statewide application. Beyond this, assigning equal weights to each of the five surveys is arbitrary, giving a proposed FCR that is driven by survey results from as few as 50 people (95th percentile of 996 surveyed adults). It would be more defensible to weigh each of these studies according to the estimated total adult populations represented by the underlying data (e.g., per weighing scheme #2 in Appendix C of the TSD), and this process should include the total population of Washington State (with consumption rates taken from EPA[5,6] or other appropriate studies).

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[3] Kissinger, L. 2005. *Application of data from an Asian and Pacific Islander (API) seafood consumption study to derive fish and shellfish consumption rates for risk assessment*.

[4] USEPA. 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*.

[5] USEPA. 2002. *Estimated Per Capita Fish Consumption in the United States*.

[6] USEPA. 2011. *Exposure Factors Handbook: 2011 Edition*.

In addition to these general comments, responses to specific questions posed by Ecology in the TSD are provided below. Note that some of these responses draw on information presented in Appendix A, which provides a brief review of what is known about the accumulation of persistent, bioaccumulative, and toxic (PBT) chemicals by salmon.

Responses to Questions Posed by Ecology in the TSD

1. <u>How should default rates take into account the consumption of fish species like salmon that spend much of their life outside of Washington waters?</u>

The consumption of salmon should be excluded from any statewide default FCR. This conclusion is based on review of the scientific literature (Appendix A), which indicates that different species of salmon and different runs of the same species of salmon will accumulate PBT chemicals to differing degrees. In addition, the literature supports the contention that the major fraction of any PBT burden carried by returning adult salmon (i.e., salmon that will be harvested and consumed) is acquired in the open ocean. The fact that resident Puget Sound salmon generally exhibit higher burdens than true open ocean salmon is not inconsistent with this, and simply points out that Puget Sound is a unique habitat (i.e., Puget Sound is not the open ocean).

Because of this, it might be appropriate to assess risk to select Puget Sound residents as a separate activity, and inclusion of salmon in an FCR used in such a risk assessment may well be warranted. However, given that Chinook, Coho, sockeye, pink, and chum salmon are predicted to accumulate different body burdens of PBT chemicals even when they share a common migration corridor, salmon consumption should be apportioned between species, and not simply lumped together as "salmon." In addition, only salmon harvested directly from Puget Sound should be included in an FCR used for this purpose: ideally, only truly resident salmon (i.e., "blackmouth" salmon) would be included.

2. <u>How should the complex life cycle and biology of the different salmon species be considered when making regulatory decisions?</u>

As noted above, the complexities of salmon biology and/or ecology require that:

- salmon be excluded from any default FCR,
- a site-specific FCR include only "resident" salmon, and only when there are data showing that these salmon are impacted by local sources of chemical contaminants,
- whenever salmon are included in a site-specific FCR, consumption must be broken out on a species-specific basis, and the associated risk assessment must use species-specific chemical concentrations and, when necessary, bioaccumulation factors (BAFs).

3. <u>What is the status of resources pertaining to the harvest of fish and shellfish in Washington?</u>

This question seems irrelevant to the issue at hand.

4. How many people in Washington consume fish? How many people in Washington can be considered high-end fish consumers?

NCASI suggests that assigning individuals to a "consumer" or "non-consumer" category is a false dichotomy, and that it would be more correct to consider fish consumption on a continuum having, essentially, no non-consumers (there are likely to be very few individuals that consume no fish over the course of a lifetime). Thus, according to the TSD, there are 5,143,186 adult consumers of fish in Washington State currently. Beyond this, any categorization of what constitutes "high-end" consumption is unavoidably arbitrary in the sense that it will always be a matter of subjective opinion. This is, and will remain true regardless of statistical categorizations or the overall accuracy or completeness of associated fish consumption data.

5. What are scientifically defensible methods for characterizing fish consumption rates?

A variety of survey methods have been used to generate fish consumption data, as the TSD discusses; each method has both strengths and weaknesses. Regardless, the more important issue is whether the method used accurately captures the consumption habits of the targeted population which, for purposes of establishing default statewide FCRs, should be the population of the entire State of Washington.

Clearly, Ecology has a large body of data characterizing the fish consumption habits of four Puget Sound tribal communities, certain Columbia Basin tribes and the API population residing in King County. Ecology apparently does not have data sufficient to characterize fish consumption by the general population of Washington State to anywhere near the same level of confidence as it has for these very specific subpopulations. This is a critical information gap that must be filled in order to fully understand the risks to public health resulting from the consumption of fish.

6. What is currently known about the fish consumption habits and rates for different fish-consuming populations in Washington?

What is known are the consumption patterns of a few Native American tribes and the API population residing in King County. As a whole, the sampled population represents approximately 311,300 adults (from Table C-2 in the TSD). This number is equivalent to approximately 11% of the adult consumers of purchased fresh fish (as estimated by Washington's Department of Health, Table 5 in the TSD), approximately 8% of the adult consumers of store-bought fish, and approximately 6% of the general adult population. The TSD provides no details relevant to the consumption habits of the remaining population besides that taken from DOH (e.g., 74% of the general adult population consumes store-bought fish).

7. Would establishing a statewide default fish consumption rate (or rates) be a useful step toward consistency among regulatory programs (for example, MTCA cleanups and water quality-based permitting)?

NCASI notes that statewide default fish consumption rates are already in place for the development of water quality standards (6.5 g/d) and for MTCA cleanups (54 g/d), and Ecology has stated that it intends to adopt a default FCR for sediment management standards (SMS). Thus, any questions regarding the utility of intra-program default FCRs appear to be moot, and the real question is whether there is a benefit to be had from adopting a single default FCR applicable to all programs. NCASI suggests that the answer to that question is no.

Given the distinctly different scopes and missions of Ecology's different programs (e.g., the MCTA program focuses on cleanup of geographically limited sites posing risk to very specific populations and known to be contaminated with specific chemicals, while the Clean Water Act applies to the whole state regardless of any known source of contamination by any single chemical), it is hard to image that adopting a single default FCR for all programs would actually provide any benefit beyond conceptual simplicity. The validity of this conclusion is best illustrated by the range of FCRs exhibited across different subpopulations and the degree to which these FCRs clearly reflect geographic location. With this last point in mind, the only defensible statewide default FCR for any regulatory program is an FCR reflecting mean consumption by the statewide general population. In situations where subpopulations are believed to be subject to significantly greater risks than the general population (e.g., a subpopulation taking fish from near a MCTA site), an appropriate, risk-based response would be to conduct a population- or site-specific risk assessment[7] to determine if actual risk (in this case due to a greater than average FCR) for that subpopulation exceeds target values considering all aspects of exposure including, in this case, the health benefits of eating fish[8].

8. <u>What is an appropriate statewide default fish consumption rate (or rates) given available data, uncertainties and variability in fish consumption habits, and current statutes, regulations, and policies?</u>

As noted, the only defensible statewide default FCR is one that reflects consumption by the general population as a whole (i.e., without attempting to discriminate "consumers" from "non-consumers").

Consistent with this, if Ecology is driven to adopt a single default FCR for use statewide and has no data characterizing fish consumption by the general population of Washington State, it should draw from EPA's data for the general US population[6]. Based on these data, EPA[9] has concluded that the mean consumption rate of freshwater and estuarine finfish and shellfish by adults (18 and older) is 7.50 g/day. The associated 90th and 95th percentile consumption rates are 17.4 and 49.6 g/d, respectively. Although these FCRs are almost certainly high-biased (i.e., conservative) estimates for the general US population, they provide a much better measure of fish consumption by the general population of Washington State than the range of FCRs proposed by Ecology, which clearly reflects high-end consumers exclusively, and so are preferable for use as default values meant to apply statewide. Using the flexibility afforded under different regulatory programs (MTCA, etc.), adjustments to a "general population" default FCR can then be made using site-specific information, meaning that Ecology can decide to make site-specific standards more protective when circumstances clearly warrant.

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[7] USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000).*
[8] Washington Department of Health. 2006. *Human Health Evaluation of Contaminants in Puget Sound Fish.*
[9] USEPA. 2002. *Estimated Per Capita Fish Consumption in the United States*.

APPENDIX A

A BRIEF REVIEW OF ISSUES RELEVANT TO THE ACCUMULATION OF PERSISTANT, BIOACCUMULATIVE, AND TOXIC (PBT) CHEMICALS BY SALMON

INTRODUCTION

In September 2011 Washington State Department of Ecology (WDOE) issued Publication No. 11-09-050, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*. This technical support document (TSD) was generated to support decision making regarding how to obtain an appropriate fish consumption rate (FCR) for use in calculating water quality standards for protecting human health (HHWQS). One of the issues WDOE raised in this TSD was whether consumption of salmon should be included in whatever FCR is ultimately used in these calculations, and if it is concluded that salmon should be included in an FCR, how to do so.

The driver behind this is human exposure to toxic chemicals, specifically via consumption of fish (or aquatic tissue in general). The greatest risk to human health from consumption of fish is generally understood to result from the presence of persistent, bioaccumulative, and toxic (PBT) chemicals. Thus the primary factor in determining the appropriateness of including consumption of salmon in an FCR is where salmon actually pick up these contaminants. A brief review of what is known about this subject is presented herein.

WHERE SALMON ACCUMULATE PBT CHEMICALS

As discussed by NOAA (2005), different runs of salmon exhibit different life histories. More specifically, NOAA described stream-type and ocean-type life histories. Behavioral attributes of these two general types of salmon are summarized in Table 1.

Table 1. A Summary of the Juvenile Characteristics of Stream and Ocean Life History Types

Stream-Type Fish	Ocean-Type Fish
Species	
Coho salmon	Coho salmon
Some Chinook populations	Some Chinook populations
Steelhead	Chum
Sockeye	Pink
Attributes	
Long period of freshwater rearing (>1 yr)	Short period of freshwater rearing
Shorter ocean residence	Longer ocean residence
Short period of estuarine residence	Longer period of estuarine residence
Larger size at time of estuarine entry	Smaller size at time of estuarine entry
Mostly use deeper, main channel estuarine habitats	Mostly use shallow water estuarine habitats, especially vegetated ones

[SOURCE: NOAA 2005]

From Table 1, different species of salmon and different runs of the same species can exhibit distinctly different life histories, including how much time is spent in freshwater and where in freshwater systems this time is spent. These differences are potentially significant in that they may lead to differences in the mass (burden) of chemical contaminants (e.g., PBT chemicals) ultimately accumulated by the salmon, and in the fraction of this ultimate burden accumulated in freshwater vs. saltwater. Although the latter may not be relevant when assessing the risk to human health resulting from eating contaminated fish in general, it is relevant when considering what fraction of this overall risk results from accumulation of contaminants in freshwater systems vs. saltwater systems.

This last point is directly relevant to the question of whether there is any utility in including consumption of salmon in an FCR that will be used to drive remedial action(s) on the geographically limited scale of a single state. If a significant fraction of the contaminant burden found in salmon is accumulated in true freshwater systems it makes sense that the consumption of salmon be included in an FCR. However, if accumulation in the open ocean dominates, inclusion of salmon in an FCR makes no sense because there is no action the state can take that will have a significant effect on the contaminant burden found in returning adult salmon.

Exclusion of salmon from an FCR does not imply that human exposure to contaminants due to consumption of salmon should not be accounted for when assessing overall risks to human health. Instead, these issues should be weighed when deciding whether salmon are accounted for when assessing the risks resulting from consumption of freshwater fish (by including consumption of salmon in an FCR) or when assessing the risks resulting from consumption of saltwater or marine fish (salmon would be backed out of the risk assessment for deriving a freshwater HHWQS via the relative source contribution or RSC). Ultimately, the issue of where the risks from consumption of salmon are counted appears to be an academic question. The more important factor (from the perspective of characterizing risk) is to ensure that consumption of salmon is not double counted by including it in both an FCR **and** as a component of the RSC.

In any case, the issue of salmon (or anadromous fish in general) is unique in that it is quite likely that a generic salmon will accumulate contaminants in both freshwater and saltwater habitats, and that the relative fraction accumulated in one habitat vs. the other will vary with species, run, and even individual. Taken to the extreme, this implies that each run needs to be evaluated independently to determine where contaminants are accumulated. However, much of the scientific literature supports accumulation in the open ocean as the dominant pathway for uptake of PBT chemicals by salmon, with the work of O'Neill, West, and Hoeman (1998), West and O'Neill (2007), and O'Neill and West (2009) providing perhaps the most through examination of the issue.

Figure 1 is taken from O'Neill and West (2009) and shows that levels of polychlorinated biphenyls (PCBs) in adult Chinook salmon (fillets) collected from a wide range of geographic locations are relatively uniform except for fish taken from Puget Sound, which show three to five times higher levels of PCBs than fish taken from other locations. As discussed by the authors, these data can be interpreted as indicating accumulation of PCBs in Puget Sound and/or along the migratory routes of these fish, which, depending on the specific runs, can pass through some highly contaminated Superfund sites (e.g., Duwamish Waterway). However, O'Neill and West (2009) concluded that, on average, >96% of the total body burden (mass) of PCBs in these Puget Sound Chinook was accumulated in the Sound and not in natal river(s).

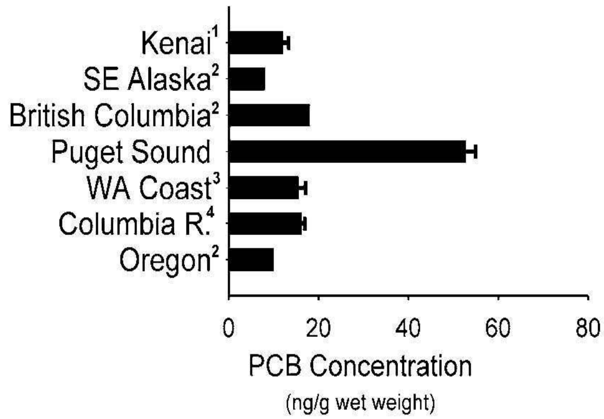

Figure 1. Average (±SE) PCB Concentration in Chinook Salmon Fillets
Data for Puget Sound were based on 204 samples collected by the Washington Department of Fish and Wildlife from 1992 to 1996; data for other locations were taken from the following (indicated by superscript numbers): [1]Rice and Moles (2006), [2]Hites et al. (2004; estimated from publication), [3]Missildine et al. (2005), and [4]United States Environmental Protection Agency (USEPA 2002)
[SOURCE: O'Neill and West 2009]

The basis for this conclusion is presented in Table 2, which compares PCB concentrations and body burdens in out migrating Chinook smolts collected from the Duwamish River and adults returning to the Duwamish.

TABLE 2.—Concentration of PCBs (ng/g) and body burden of PCBs (total ng/fish) in out-migrating Chinook salmon smolts and returning adults from the contaminated Duwamish River, Washington.

Variable	Smolts	Adults
Number of samples	80	34
Mean fish weight (g)	10	6,000
Whole body PCB concentration (ng/g)[a]		
Mean	170	57
95th percentile	860	88
PCB body burden (ng/fish)[a]		
Mean	2,100	350,000
95th percentile	9,200	800,000
Mean % of PCB body burden from the most contaminated smolts[b]	—	3.8

[a] Values for smolts are from J. P. Meador (National Oceanic and Atmospheric Administration Fisheries, Northwest Fisheries Science Center, personal communication); values for adults were estimated from measured muscle tissue concentration using the fillet–whole-body regression (see Methods) for PCBs.
[b] Contaminant data were only available for out-migrating subyearling smolts, so only samples with adults that went to sea as subyearlings were included in the analysis.

[SOURCE: O'Neill and West 2009]

These data show that even the most contaminated out migrating smolts contained no more than 4% of the body burden (mass) of PCBs found in returning adults. Thus, >96% of the PCB mass (burden) found in the returning adults was accumulated in Puget Sound. Even allowing for an order of magnitude underestimate in the body burden of out migrating smolts, O'Neill and West (2009) concluded that accumulation in freshwater would account for <10% of the average PCB burden ultimately found in adults returning to the Duwamish. By extension, this analysis supports the conclusion that Chinook salmon passing through uncontaminated estuaries during out migration accumulate a dominant fraction of their ultimate PCB body burdens in the open ocean. Other researchers have also reached this conclusion using their own data (e.g., Johnson et al. 2007; Cullon et al. 2009).

However, this analysis does not explain why Chinook salmon collected in Puget Sound exhibit higher concentrations of PCBs than Chinook salmon collected from other locations (Figure 1). Ultimately, O'Neill and West (2009) attributed this to a combination of factors, specifically PCB contamination of the Puget Sound food web (e.g., West, O'Neill, and Ylitalo 2008) combined with a high percentage of Chinook displaying resident behavior. That is, a large fraction of out migrating Chinook smolts take up permanent residence in the Sound, where they feed from a more contaminated food web than found in the open ocean. These factors would not affect Chinook runs or runs of any other species associated with natal rivers that discharge to saltwater outside Puget Sound.

Overall, these data support the position that, as a general rule, the predominant fraction of the ultimate PCB burden found in harvested adult fish is accumulated while in the ocean-phase of their life cycle (e.g., Cullon et al. 2009; Johnson et al. 2007; O'Neill and West 2009). Although this conclusion is specific to PCBs, there is no reason to suppose that it would not also hold for other legacy PBTs (e.g., DDT, dioxins) or globally ubiquitous PBTs (e.g., PBDEs, methylmercury) in general (e.g., Cullon et al. 2009). Because concerns about human consumption of fish are driven by risks from exposure to PBTs, driving the FCR higher by including salmon would thus appear to be of limited utility from the perspective of protecting human health simply because these contaminants are accumulated in the ocean.

With that said, there are sufficient data to conclude that the food web in Puget Sound is contaminated with PCBs to a greater degree than the food web in the open ocean. To the extent that this is a result of true local sources (e.g., sediment hotspots), there may in fact be some "local" action that can be taken to reduce PCBs, or potentially other PBTs, in Puget Sound salmon. However, this is totally dependent on identification of localized sources amenable to remediation, and not simply a conclusion that the food web is contaminated (e.g., West and O'Neill 2007).

Again, simply increasing the FCR by including salmon will have essentially no positive effect on human health given that the dominant fraction of PBT body burdens in salmon appears to be accumulated in the open ocean, and not in waters immediately subject to in-state loadings.

PBT ACCUMULATION BY DIFFERENT SALMON SPECIES

As discussed, there is ample evidence that the body burdens of PBTs found in returning adult Chinook salmon depend to a significant extent on the life history of the specific run. Beyond this, there are interspecies differences in migratory and feeding behavior that suggest Coho, sockeye, pink, and chum salmon will not accumulate PBTs to the same extent as Chinook salmon under similar exposure scenarios (Groot and Margolis 1991; Higgs et al. 1995). Perhaps the most significant factor differentiating Chinook from the other salmon species is that Chinook tend to eat more fish (Higgs et al. 1995). Thus they effectively feed at a higher trophic level than the other species of salmon, and would be expected to accumulate greater burdens of PBT chemicals even when sharing the same habitat. This is in fact observable. For example, when looking at adult Chinook and Coho returning to the same rivers, O'Neill, West, and Hoeman (1998) found that Chinook muscle contained, on average, almost twice the total PCB concentrations found in Coho muscle. This was also true for adults collected in Puget Sound proper (O'Neill, West, and Hoeman 1998).

Differences between species can also manifest in sub-adults. For example, Johnson et al. (2007) reported ΣPCB concentrations in juvenile wild Coho collected from five different estuaries ranging from 5.9 to 27 ng/g (wet weight; whole body minus stomach contents). The corresponding range for wild Chinook juveniles collected from the same estuaries was 11 to 46 ng/g (wet weight; whole body minus stomach contents). Overall, PCB concentrations in juvenile Coho were, on average, equivalent to nominally 50% of those found in the paired Chinook juveniles. This is essentially the same ratio observed by O'Neill, West, and Hoeman (1998) in adult fish.

All this indicates that PBT residues in salmon will vary within species depending on the specific run, and between species regardless (i.e., even when different species share the same general habitat). Thus, grouping all salmon together does not provide an accurate assessment of PBT doses delivered to human consumers due to consumption of salmon. This suggests that human health risk assessments should, as a general rule, incorporate salmon on a species-specific basis, if not a run-specific basis.

Certainly, none of this is supportive of adopting a single default value for the dose of any contaminant received by humans via consumption of salmon. Thus adoption of a single default FCR for salmon is also not supported.

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ncasi

NATIONAL COUNCIL FOR AIR AND STREAM IMPROVEMENT, INC.
West Coast Regional Center
Mailing address: PO Box 458, Corvallis OR 97339
Street address: 720 SW Fourth Street, Corvallis OR 97333
Phone: (541)752-8801 Fax: (541)752-8806

Steve Stratton
Regional Manager
SStratton@ncasi.org

March 4, 2015

D R A F T

Washington State Department of Ecology
PO Box 47600
Olympia, Washington 98504-7600

RE: Comments on Proposed Human Health Criteria and Implementation Tools Rule Proposal dated January 12, 2015

The National Council for Air and Stream Improvement, Inc. (NCASI) is an independent, nonprofit membership organization that provides technical support to the forest products industry on a wide range of environmental issues. An important part of our mission is to help ensure that regulatory decision making is based on sound science. In this capacity, NCASI reviewed the January 2015 Proposed Human Health Criteria and Implementation Tools Rule Proposal, and offers the following comments.

After review of Ecology's proposal, we find that while the decision to select a fish consumption rate (FCR) is a policy choice, the value selected (175 g/day) grossly overstates consumption by the general population as well as the vast majority of Washington tribal members. NCASI's analysis of publically available tribal fish consumption summary data indicates that Ecology's claim that 175 g/day is "*representative of average FCRs*" for highly exposed populations is incorrect as it pertains to tribal populations specifically. Rather, as discussed below, it represents approximately the 95th percentile of tribal fish consumption based on Washington-specific tribal studies. Thus, Ecology is proposing criteria based on the consumption patterns of a few of the highest consuming individuals in the state. Coupled with Ecology's selected values for other risk management factors (1×10^{-5} excess lifetime cancer risk for carcinogens and a hazard quotient equal to 1.0 for non-carcinogens) that are intended to apply to general populations (per EPA guidance), an FCR of 175 g/day yields water quality criteria that are protective in the extreme. Consequently, we believe that Ecology needs to provide technical justification for its FCR selection.

The attached analysis performed by NCASI using data provided by Ecology (Table 1 in Attachment A) shows that the mean consumption rate based on Washington tribal studies is approximately 71 g/day and that 175 g/day is approximately equivalent to the 95th percentile tribal consumption rate. These rates are based on tribal data only and include consumption of all fish, including salmon. Thus, if Ecology intended to select an FCR reflecting "average" consumption of all fish (including salmon and store-bought fish) by tribal populations, 71 g/day would be the appropriate statistic.

However, as NCASI has noted previously, we believe it is not appropriate to include all salmon in the FCR because the vast majority of the contaminants found in these fish are accumulated in marine waters outside of state jurisdiction. NCASI has developed an alternative tribal FCR distribution including salmon at a rate nominally reflecting accumulation of pollutants by salmon in waters of the state only (Table 1 in Attachment A). The resulting distribution has a mean of approximately 49 g/day. As discussed in the attachment (Sections 3 and 4), we believe that this value still overstates human exposure to accumulation of contaminants sourced within Washington State, but believe it is at least scientifically defensible. It is also worth noting that 49 g/day is very conservative compared to EPA's default recommendation for the general population of 17.5 g/day, which is a 90th percentile statistic.

NCASI also notes that Ecology's use of deterministic calculations using such extreme (conservative) values for the FCR and other exposure factors yields water quality criteria whose actual level of protection greatly exceeds that needed to adequately protect all residents of the state. Use of probabilistic risk assessment (PRA) using data representing the entire population avoids this problem, which is known as compounded conservatism. Compounded conservatism results when single point estimates for fish consumption, drinking water consumption, and other risk management and exposure factors, each of which represents a conservative selection, are multiplied together to calculate water quality criteria. The resulting criteria can be so stringent that they protect against human exposure scenarios that would never occur. In contrast, PRA uses data distributions that represent the exposure behaviors of all residents. Given that the computational tools needed to perform a PRA analysis are readily available and easy to use, and that data for fish consumption rates and other human exposure factors representing all Washington residents have already been compiled, Ecology should use a probabilistic approach to develop its water quality criteria. Attachment B is a peer-reviewed article approved for publication in *Integrated Environmental Assessment and Management* that expounds on the problem of compounded conservatism.

Finally, despite the concerns outlined herein, we would like to express our appreciation to Ecology for its sustained efforts to carry out this rule making in a thorough and transparent manner.

Sincerely,

Steve Stratton	Jeffrey Louch, PhD.
West Coast Regional Manager, NCASI	Senior Scientist, NCASI

Copy: Christian McCabe, Northwest Pulp & Paper Association
Dirk Krouskop, NCASI
Paul Wiegand, NCASI

ATTACHMENT A

DEVELOPMENT OF A FISH CONSUMPTION RATE DISTRIBUTION FOR WASHINGTON'S GENERAL TRIBAL POPULATION

Washington State Department of Ecology (WDOE) has presented results from surveys characterizing fish consumption by the Tulalip, Squaxin, Suquamish, and Columbia River (Nez Perce, Umatilla, Warm Springs, and Yakama) tribes. WDOE used these data to develop a composite fish consumption rate (FCR) distribution by weighting the individual (tribal-specific) distributions based on relative populations. The resulting composite distribution was presented as Scheme 6 in Table C-4 of *Fish Consumption Rates Technical Support Document: A Review of Data and Information about Fish Consumption in Washington*, ver. 1.0 (WDOE 2011). This distribution, shown in Column 1 in Table 1, represents all fish consumption by the general tribal population of Washington State.

Table 1. Derivation of Fish Consumption Rate (FCR) Distribution for the General Tribal Population of Washington State (g/d)

	[1]	[2] [1] * 0.46	[3] [1] * (1 - 0.46)	[4] [2] * 0.314	[5] [3] + [4]
	All Fish[a]	Salmon[b]	Non-Salmon[c]	Fresh/Estuarine Apportioned Salmon[d]	Final Washington Tribal Population FCR[e]
mu	4.0083				
sigma	0.7158				
Mean	71.12	32.72	38.40	10.27	48.68
1%	10.41	4.79	5.62	1.50	7.13
5%	16.96	7.80	9.16	2.45	11.61
10%	22	10.12	11.88	3.18	15.06
25%	33.97	15.63	18.34	4.91	23.25
50%	55.05	25.32	29.73	7.95	37.68
75%	89.22	41.04	48.18	12.89	61.07
80%	100.55	46.25	54.30	14.52	68.82
85%	115.6	53.18	62.42	16.70	79.12
90%	137.77	63.37	74.40	19.90	94.30
95%	178.69	82.20	96.49	25.81	122.30
99%	291.03	133.87	157.16	42.04	199.19

[a] composite tribal distribution No. 6 from WDOE 2011, Table C-4 (tribal-specific distributions weighted according to relative population); assumes 100% of tribal populations are consumers and all fish are from waters of the state
[b] component of all fish that is salmon (all fish x 0.46)
[c] component of all fish that is not salmon (all fish – salmon)
[d] consumption of salmon associated with waters of state based on composite residence time life history factor (salmon x 0.314)
[e] final FCR (non-salmon + salmon fraction)

The distribution in Column 1 of Table 1 reflects consumption of all fish (including salmon) and seafood reported by the surveyed populations regardless of source. Under these conditions, the mean tribal FCR specific to Washington's tribal population is 71 g/d and the 95th percentile FCR is 179 g/d (Table 1). However, even though all surveyed tribal populations reported that a high percentage (62-96%) of total consumption was of locally harvested organisms (e.g., WDOE 2013), these consumption rates may include store-bought fish and so may overstate consumption of organisms harvested from waters of the state.

Inclusion of salmon in this FCR distribution (Table 1, column 1) is controversial because the majority of the body burden of bioaccumulative chemicals found in returning (adult) salmon is accumulated in the oceans, not in freshwater. Thus inclusion of salmon in any FCR overstates exposure to pollutants sourced within Washington State, and the effect of including salmon in an FCR used to calculate human health water quality criteria represent goals that are unattainable by actions that Washington State can take on its own.

WDOE (2013) has provided data sufficient to estimate the fraction of tribal-specific FCRs contributed by consumption of salmon (summarized in Table 2). The amount of salmon (anadromous fish) as a percentage of the total fish and shellfish diet for these tribes ranges from 23% for the Suquamish Tribe to about 66% for the Squaxin Island Tribe, with an arithmetic mean of 46%. As summarized in Columns 2 and 3 of Table 1, this mean value was used to back out consumption of salmon from the general FCR distribution given in Column 1 of that table; that is, Column 3 in Table 1 gives the general tribal FCR distribution excluding all salmon.

Table 2. Summary of Washington Tribal Fish Consumption Survey Data (g/day)

	Fish Source	50th %tile	Mean	75th %tile	90th %tile	95th %tile	% of All Fish at Mean
Tulalip Tribe[a]							
All fish	All sources	44.5	82.2	94.2	193	268	100.0
Finfish	All sources	22.3	44.1	49.1	110	204	53.6
Shellfish	All sources	15.4	42.6	40.1	113	141	51.8
Non-anadromous	All sources	20.1	45.9	52.4	118	151	55.8
Anadromous	All sources	16.8	38.1	43.3	92.1	191	46.4
Squaxin Island Tribe[b]							
All fish	All sources	44.5	83.7	94.4	206	280	100.0
Finfish	All sources	31.4	65.5	82.3	150	208	78.3
Shellfish	All sources	10.3	23.1	23.9	54	83.6	27.6
Non-anadromous	All sources	15.2	28.7	32.3	70.5	95.9	34.3
Anadromous	All sources	25.3	55.1	65.8	128	171	65.8
Suquamish Tribe[c]							
All fish	All sources	132	214	284	489	797	100
Shellfish	All sources	64.7	134	145	363	615	63
Non-anadromous	All sources	102	169	219	377	615	79
Anadromous	All sources	27.6	48.8	79.1	133	172	23
CRITFC Tribes[d]							
All finfish	All harvested	40.5	63.2	64.8	130	194	100
Non-anadromous	All harvested	20.9	32.6	33.4	67	99.9	52
Anadromous	All harvested	19.6	30.6	31.4	63.1	94.1	48

[a] WDOE 2013 Table 23
[b] WDOE 2013 Table 24
[c] WDOE 2013 Table 26
[d] WDOE 2013 Table 21

The FCR distribution in Column 3 of Table 1 does not include consumption of any salmon, and so does not account for tribal exposure to whatever fraction of the ultimate pollutant body burden in returning adult fish might have been acquired as juveniles in fresh and/or estuarine (F/E) waters of the state (e.g., Hope 2012). WDOE anticipated this issue and proposed use of site-use factors based on residence time as a means of apportioning the fraction that might be accumulated in F/E vs. offshore waters (WDOE 2011, 2013). To this end, NCASI undertook a detailed analysis of salmon life histories (Appendix A), which resulted in species-specific life-history factors (LHFs, Table 3) representing the fraction of total pollutant body burden in returning adult fish acquired in F/E waters of Washington State.

Table 3. Life History Factors for Different Salmon Species and Different Waters Based on Residence Times in Waters of the State[a]

Species	Non-Puget Sound Waters	Puget Sound Waters Only	Statewide Composite
Chinook/King	0.15	0.40	0.30
Coho	0.50	0.60	0.56
Sockeye	NA	NA	0.19
Chum	0.13	0.28	0.22
Pink	NA	NA	0.24

[a] see Appendix A

To obtain a single composite LHF for salmon in general, the species-specific statewide composite LHFs in Table 3 were combined after weighting based on the amounts of each species consumed by members of the Suquamish Tribe (USEPA 2011). This derivation is summarized in Table 4, and resulted in a single statewide LHF of 0.314. The composite LHF was then used to estimate the fraction of the pollutant body burden present in returning (adult) salmon that might have been acquired during time spent in waters of the state. This fraction was added back to the non-salmon FCRs to obtain a final FCR distribution for the general tribal population of Washington State (Column 5 in Table 1) reflecting exposure to contaminants acquired by fish from waters of the state.

Table 4. Relative Proportions of Salmon Species Consumed by the Suquamish Tribe and Derivation of Composite Life History Factor for All Salmon

	EPA Consumption Data[a]				LHFs	
Species	n	Mean (g/d)	n x Mean (g/d)	Fraction at Mean	From Table 4	Consumptio n Weighted
Chinook/King	63	0.200	12.600	0.294	0.30	0.088
Coho	50	0.191	9.550	0.223	0.56	0.125
Sockeye	59	0.169	9.971	0.233	0.19	0.045
Chum	42	0.242	10.164	0.237	0.22	0.053
Pink	17	0.035	0.595	0.014	0.24	0.003
Final composite LHF						0.314

[a] EPA 2011

As discussed in Appendix A, Section 3, LHFs based on residence time almost certainly overstate the relative magnitude of bioaccumulation during the early life stages of salmon life history. That is, LHFs based on residence time almost certainly overstate human exposure to pollutants acquired from waters of the state. As discussed in Appendix A, a more appropriate basis for apportioning when/where bioaccumulative chemicals are acquired by salmon might be relative growth; that is, when/where salmon acquire body mass. Appendix A, Section 4, describes derivation of a single composite, consumption-weighted, LHF for salmon based on where salmon acquire biomass. The result was 0.086 (Appendix A, Table A8), which is ≈3.5 times smaller than the single composite (consumption-weighted) LHF based on residence time. Thus, use of LHFs based on residence times should be considered conservative.

Summary

An FCR distribution representative of the general tribal population of Washington State residents was developed. An initial composite distribution was taken from WDOE (2011), and was adjusted to reflect the portion of salmon consumed by tribal members reflecting contaminants acquired by salmon in waters of the state. Table 5 provides a summary of the data and rationale used in developing the final FCR distribution for Washington tribal members, which is given in Column 5 of Table 1. Ultimately, this final distribution should be considered conservative in that it almost certainly overstates human exposure to pollutants sourced from waters of the state because 1) it potentially includes consumption of organisms not sourced from waters of the state and 2) it relies on residence time LHFs instead of growth rate-based LHFs to apportion bioaccumulation of pollutants by salmon in waters of the state.

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Table 5. Summary of Data and Rationale Used in Developing Fish Consumption Rate Distribution for Tribal Residents of the State of Washington (presented in Table 1)

Table 1 Column	Description/Purpose	Data Source	Rationale	Comments
[1]	Starting dataset for developing Washington-specific tribal population FCR distribution	WDOE 2011, Table C-4; tribal-specific distributions weighted according to relative population	Represents all tribal fish consumption survey results reflecting Washington tribes	Individual tribal survey distributions weighted according to relative populations of each surveyed tribe
[2] and [3]	Adjustment to exclude all salmon	WDOE 2013, Tables 21, 23, 24, and 26; tribal-specific consumption rates of salmon as relative percent of total consumption	Same dataset used to develop composite FCR distribution	Adjustment applied to entire tribal distribution; adjusts distribution to reflect consumption of all fish except salmon
[4]	Adjustment to add back portion of salmon reflecting bioaccumulation from waters of the state	See items [4](i), [4](ii) below	Consistent with WDOE 2013 proposal	Adjustment is species-weighted composite salmon LHF multiplied by salmon-specific consumption rate (added back to consumption rate excluding salmon)
[4](i)	Salmon LHF	Technical literature on species-specific behavior and life history (primarily from WDOE 2013); see Appendix A	Development of LHFs for five major salmon species based on time salmon spend in waters of the state as a fraction of total lifetime prior to return as adults for spawning (residence time as proxy for bioaccumulation)	Approach may overestimate contaminant body burden acquired in waters of the state (e.g., salmon gain more than 95% of body mass in marine environment), so is believed to be conservative approach
[4](ii)	Relative consumption of different salmon species	Suquamish tribal data from USEPA 2011, Table 10-104	Washington-specific data on tribal consumption of different salmon species	Relative consumption rates for each salmon species used to weight LHFs to develop single composite LHF for all salmon

(Continued on next page.)

Table 1 Column	Description/Purpose	Data Source	Rationale	Comments
[5]	Final tribal-specific FCR distribution including fraction of total salmon consumption reflecting bioaccumulation from waters of the state	Table 1 columns [3] and [4] summed		Final distribution includes consumption of all fish but only the fraction of salmon reflecting bioaccumulation in waters of the state

APPENDIX A

LIFE HISTORY FACTORS FOR PACIFIC SALMON
(02-13-2015)

1.0 INTRODUCTION

One of the primary factors to consider in deciding whether to include salmon in a fish consumption rate (FCR) used in deriving Clean Water Act human health water quality criteria is when/where salmon accumulate their ultimate body burden of relevant chemicals. Traditionally, EPA has recommended against including salmon in these FCRs because it was accepted that for bioaccumulative chemicals a majority of the chemical-specific body burden in a returning adult salmon is acquired in the Pacific Ocean (in the case of Pacific Northwest salmon), and not in the fresh and/or estuarine (F/E) waters under jurisdictional control of a state. However, this assumption has been challenged as part of the ongoing process in Washington State, and various stakeholders have argued that salmon must be included in the FCR for various reasons, including the cultural importance of salmon to tribal and other residents of the state.

A review of the technical literature shows that there are sufficient (albeit limited) data to conclude that the vast majority of the body burden of bioaccumulative chemicals in adult Chinook salmon is acquired during the marine phase of that species' life history. The data were developed by various researchers who measured chemical-specific body burdens in both out-migrating juvenile fish and returning adults belonging to the same runs. In all cases where these kinds of data have been developed, the researchers have concluded that >95% of the body burdens were acquired in the marine phase of the Chinook life history (Cullon et al. 2009; O'Neill and West 2009). However, these data are specific to Chinook salmon, and because each species of salmon has a unique life history it may not be appropriate to assume that what holds for Chinook also holds for coho, sockeye, chum, or pink salmon. Thus, there is some uncertainty regarding where these other species acquire their ultimate body burdens of bioaccumulative chemicals.

In response to this uncertainty, the Washington State Department of Ecology (WDOE) has proposed use of what this report will call life history factors (LHFs) as a means of apportioning total body burden in adult salmon between different phases of a salmon's life history. As proposed, these LHFs reflect the relative amount of time salmon spend in different environments or geographic locations, and would be used to apportion the ultimate body burden in returning adults between these environments or geographic locations. Subsequently, the fraction of the burden acquired in waters of the state could be used to adjust the actual consumption rate for salmon included in the FCR.

The assumption inherent in this model is that the body burden of bioaccumulative chemicals in returning adult salmon is a linear function of time. This is the basis for the site-use factors WDOE has proposed as a means of accounting for salmon consumption when developing human health benchmarks for sediment cleanups (WDOE 2012). Thus, there is precedent in Washington for this kind of apportionment, and WDOE has prepared a technical issue paper (TIP) summarizing information on the life histories of Chinook, coho, sockeye, chum, and pink salmon as part of developing this concept (WDOE 2013).

However, WDOE did not identify specific numeric LHFs for each species. This paper takes the next step using WDOE's TIP as the primary information resource; other sources of information were used only in instances where there were clear gaps in the TIP.

For the purposes of this exercise and consistent with scope of the Clean Water Act, LHFs were developed for waters of the state. In this context, waters of the state include all F/E waters, Puget Sound, and all marine waters within three miles of the Washington coastline.

Section 2 addresses development of species-specific LHFs for Pacific Northwest salmon based on residence time. Section 3 offers some discussion supporting the position that LHFs based on residence time overstate the significance of bioaccumulation during the early stages of salmon life history. LHFs based on where body mass is acquired (i.e., where salmon grow) are likely to provide a more accurate measure of where salmon acquire their ultimate cumulative body burdens of bioaccumulative chemicals, and Section 4 addresses development of these alternative mass-based LHFs.

2.0 LIFE HISTORY FACTORS BASED ON RESIDENCE TIMES

2.1 Chinook Salmon

Table A1 summarizes LHFs for stream- and ocean-type Chinook salmon and resulting composite LHFs for all Chinook (all tables are in Section 6 herein).

2.1.1 *Stream-Type Chinook Salmon Life History*

Excerpts from Ecology's TIP are quoted as the basis for developing the LHFs in Table A1.

Page 5. "After emergence, stream-type Chinook spend a year or more in the river before migrating downstream."

- Different LHFs were calculated using one and two years residence in freshwater.

Page 5. "Once entering the marine environment, stream-type Chinook spend very little time in the estuaries before migrating towards coastal waters."

- In this analysis, residence in estuarine waters prior to migration to coastal waters is approximated as 15 days. This was informed by the residence time of ocean-type Chinook, which WDOE cites as being a few weeks (we interpret this to mean three weeks); i.e., stream-type Chinook spend <21 days in estuarine environments, and 15 days was assumed.

Page 6. "Further, juvenile salmonids do not limit their use of estuarine habitats to their natal estuaries, as juvenile salmonids have also been found to enter and utilize non-natal estuaries during their marine near shore migration."

- WDOE provided no indication of how much time juvenile Chinook salmon spend in these near-shore environments, so LHFs were calculated ignoring this behavior.

Page 6. "Salmonids mature in oceanic and coastal waters from 1 to 6 years, although 2 to 4 years is more typical, before returning to their natal streams to spawn."

- LHFs were calculated using two, three, and four years.

2.1.2 *Ocean-Type Chinook Life History*

Excerpts from Ecology's TIP are quoted as the basis for developing the LHFs in Table A1.

Page 5. WDOE (2012) describes three distinct behaviors (phases) for ocean-type Chinook fry:

1. The "immediate" phase – fish that migrate to the ocean "…soon after yolk resorption…"
2. The "most common" phase – the most common life history for ocean-type fry "…is to migrate to marine habitats at 60 to 150 days post hatching…"
3. The "poor conditions" phase – "During years of poor environmental conditions…ocean-type juveniles remaining in fresh water for a year, although this is relatively uncommon."

- In this analysis, we assumed that the "immediate phase" spend 50 days in freshwater (an arbitrary number meant to include migration to the natal estuary), the "most common" phase spend 105 days (average of the reported range) in freshwater, and the "poor conditions" phase spend 365 days in freshwater.

Page 5. "Once reaching the marine environment, they then spend a few weeks or longer rearing in the estuary."

- An estuarine residence time of 21 days was used for all phases of ocean-type Chinook.

Page 6. "Salmonids mature in oceanic and coastal waters from 1 to 6 years, although 2 to 4 years is more typical, before returning to their natal streams to spawn."

- LHFs were calculated using two, three, and four years.

2.1.3 *Discussion and Final LHF for Chinook Salmon*

As shown in Table A1, LHFs for stream- and ocean-type Chinook differ. As a consequence, consumption of Chinook would, ideally, be broken out based on life history and the appropriate LHF would be applied to each type. Alternatively, if all Chinook are lumped together composite LHFs are required. However, information on the relative fraction of the overall Chinook population that belong to each life history type are required to generate LHFs for lumped Chinook, and this information was not provided in the TIP.

According to Healey (1991), the ocean-type life history is "typical" of Pacific North American Chinook populations south of 56°N, which includes all of Washington and Oregon. More specifically, stream-type runs represent only 0 to 12% of Chinook runs in smaller rivers and 14 to 48% of Chinook runs in larger rivers. However, Table 1 in Healey (1991) also indicates that 78% of Columbia River spawning runs and 88% of Sixes River (southern Oregon coast) runs are ocean-type. This suggests that about 80% of Chinook salmon caught and consumed in Washington are ocean-type fishes. Using the average stream- and ocean-type LHFs extracted from WDOE's TIP (Table 1), composite LHFs for Chinook salmon would be nominally 0.85 and 0.15 for marine and F/E waters, respectively, so the LHF for waters of the state would be 0.15. However, this does not account for a third life history not addressed by the TIP, which is Puget Sound residency throughout the full marine phase of Chinook life history.

Puget Sound is known to support populations of resident Chinook and coho salmon (Chamberlin 2009; Rohde 2013). These fish spend the marine phase of their life history in Puget Sound proper, so the LHF for waters of the state would be 1 for these fish. Based on information presented by WDOE (2013), 60% of the salmon harvested in Washington were caught in marine waters, and WDOE identified 60% of these as Puget Sound salmon. Of the 40% of salmon caught in freshwaters, WDOE estimated that 57% were harvested in Puget Sound streams. Thus, overall, approximately 60% ([0.6 x 0.6]+[0.4 x 0.57]) of the salmon harvested in Washington are estimated to originate from Puget Sound. Although not all these fish are Chinook, in this analysis we assume that this proportion applies to all salmon except pink salmon (100% of which are assumed to be Puget Sound fish); that is, we assume that 60% of the Chinook caught and consumed in Washington are from runs originating in Puget Sound. Regardless, not all Puget Sound Chinook exhibit full residency in Puget Sound.

Although full residency is a well known phenomenon, there is very little information indicating what fraction of Puget Sound Chinook exhibit this life history. Chamberlin (2009) studied the role of multiple factors in the tendency of Puget Sound Chinook to exhibit full residency and concluded that 30% of Puget Sound Chinook salmon display this behavior (i.e., 30% of Puget Sound Chinook have a waters of the state LHF of 1). Chamberlin's conclusion is generally consistent with that of O'Neill and West (2009), who estimated that full residency was exhibited by between 29 and 45% of Puget Sound Chinook. Here, Chamberlin's estimate is used to calculate a composite waters of the state LHF of 0.40 ([0.7 x 0.15]+[0.3 x 1]) specific to Puget Sound Chinook salmon.

This value is notably larger than the waters of the state LHF for non-Puget Sound Chinook (0.15) but is only applicable to Puget Sound Chinook. For other Chinook (e.g., Columbia River runs) the appropriate waters of the state LHF remains 0.15. Based on the same information, a composite waters of the state LHF for all Chinook would be 0.3 ([0.4 x 0.15]+[0.6 x 0.4]). This is the appropriate waters of the state LHF for use when considering Chinook on a statewide basis.

2.2 Coho Salmon

Table A2 summarizes LHFs for coho salmon.

2.2.1 *Coho Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs in Table A2.

Page 7. "For populations in and around Washington State, returning adult Coho salmon are generally 3-year-olds, and spend approximately 18 months in fresh water and 18 months in marine habitats."

Page 7. "After emerging, the fry generally remain within freshwater streams for a year or two before migrating downstream."

- LHFs were calculated assuming one and two year periods.

Page 8. "Emergence has been detected from March to July." In this analysis we assume emergence in mid-April.

Page 8. "Although some fry migrate to marine waters soon after emergence, the majority disperse both up- and downstream, remaining in streams to rear as juveniles for one to two years before migrating downstream."

- LHFs were calculated assuming one and two year periods.

Page 8. "Within this region, Coho smolts typically leave fresh water and migrate to marine habitats to enter the smolting process in the spring (April to June). Once entering marine waters, Coho smelts spend little time rearing in estuaries, instead migrating toward coastal waters."

- Migration was assumed to begin in mid-May.

Page 8. "Although some Coho salmon move to offshore waters, typically subadults continue to feed and mature in these coastal waters of the northeast Pacific."

Page 8. "The majority of Coho originating from Washington streams migrate to coastal waters off Oregon and Washington, with low numbers occurring in Oregon and British Columbia waters."

Page 9. "While some adult male Coho salmon return after spending only one summer at sea, the majority of Coho return after spending two, and sometimes three, summers at sea. There are some run timing differences between coastal and inland Washington stocks of Coho salmon, but adults begin returning to estuaries and outlets of their natal streams from July to September."

- In this analysis we assume return in September, and LHFs were calculated assuming two and three summers at sea.

2.2.2 *Discussion and Final LHF for Coho Salmon*

The timing of specific events in the life history of coho is variable at the scale of months. This is significant if it is accepted that the majority of returning adults are around three years old. This variability is reflected in the various LHFs shown in Table A2, which shows LHFs for marine residency ranging from 0.383 to 0.679 for 3.4 year old fish, depending on whether it is assumed they spent one or two years in freshwater. However, the average of these two marine LHFs is 0.53, which is essentially the same as obtained by assuming that coho split their life between fresh and estuarine waters, or near-shore waters vs. marine waters. Thus, the final LHFs for coho salmon are taken as 0.5 and 0.5 for marine and F/E waters, respectively, meaning that the final LHF for waters of the state would be 0.5.

However, as with Chinook salmon, some fraction of Puget Sound coho salmon exhibit full residency in Puget Sound proper (e.g., Rohde 2013), and for these fish the waters of the state LHF would be 1. Following the work of Chamberlin (2009) on Chinook salmon, Rohde (2013) attempted to characterize the relative fraction of Puget Sound coho exhibiting this life history, and estimated that 3.4% are true residents, 61.3% migrate outside Puget Sound, and the behavior of the remaining 35.3% is ambiguous. Assuming 50% of the ambiguous fish are in fact residents means that approximately 21% of Puget Sound coho exhibit full residency, and the waters of the state LHF for these fish is 1. The associated composite waters of the state LHF for all Puget Sound coho is 0.6 ([0.79 x 0.5]+[0.21 x 1]). For other coho (e.g., Columbia River runs) the appropriate waters of the state LHF remains 0.5. Following the analysis for Chinook (i.e., assuming that 60% of coho caught in Washington are from Puget Sound runs), the composite statewide waters of the state LHF for coho salmon is 0.56 ([0.4 x 0.5]+[0.6 x 0.6]).

2.3 Sockeye Salmon

Table A3 summarizes LHFs for sockeye salmon.

2.3.1 *Sockeye Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs in Table A3.

Page 9. "Sockeye salmon have one of the most diverse patterns of life history among Pacific Northwest salmon species. For example, age at out-migration to marine systems from their natal streams not only varies between systems, and within systems, but can vary among related individuals."

Page 10. "The hatched alevin then take an additional 24 to 60 days to emerge from the gravel as fry, with warmer temperatures reducing the time for emergence. Sockeye salmon emerge as fry generally in April or May, with some variability associated with temperature."

- In this analysis we assume emergence on May 1 (approximately 42 days post-hatch, hatch in mid-March).

Page 10. "Regarding their entry into marine waters, two types of sockeye salmon occur: the ocean-type (or sea-type) that migrates to marine waters in the first year of their life, and the stream-type that may rear in rivers and lakes for a year or more before migrating to marine habitats."

- LHFs were calculated for both scenarios. In all cases, it was assumed that out-migration peaks on May 1.

Page 10. "Juvenile sockeye in Washington generally migrate from their nursery lakes to marine habitats in March and continuing through June, with peak out-migration occurring in April and May. Upon entering marine waters, estuarine use by juvenile sockeye salmon (smolts at this point) is limited, although some ocean-type sockeye may use these habitats before migrating toward coastal waters."

- Here we assume peak migration occurs on May 1 for both ocean- and stream-type, and we assume migration takes 50 days.

Page 10. "Sockeye spend 2 to 4 years at sea before returning to their natal systems to spawn."

- In this analysis, LHFs were calculated using two, three, and four years.

2.3.2 *Discussion and Final LHF for Sockeye Salmon*

LHFs for stream-type and ocean-type sockeye differ only if it is assumed that ocean-type fish out-migrate immediately following emergence. If these ocean-type fish rear in freshwater for a full year after emergence, they effectively become stream-type fish with respect to their LHF. However, WDOE gives no information indicating what fraction of these ocean-type fish exhibit this life history. As a consequence, this life history for ocean-type fish is ignored.

WDOE's TIP is also mute on what fraction of sockeye salmon exhibit stream- vs. ocean-type life histories. Likewise, no information regarding what fraction of each type spends two, three, or four years at sea was provided in the TIP. As a consequence, LHFs for each life history type were calculated as the average of the LHFs for fish spending two, three, and four years at sea. Composite LHFs were then calculated assuming a 50:50 split between stream- and ocean-type fish. The resulting composite LHFs are 0.81 and 0.19 for marine and F/E waters, respectively; the final statewide composite waters of the state LHF is 0.19.

2.4 Chum Salmon

Table A4 summarizes LHFs for chum salmon.

2.4.1 *Chum Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs in Table A4.

Page 11. "Similar to pink salmon or ocean-type Chinook, juvenile chum migrate from their freshwater redds to marine waters almost immediately after emergence."

Page 11. "The alevins remain in the gravel another 30 to 50 days, until their yolk sac is absorbed."

- Here we assume 40 days.

Page 11. "Most chum salmon fry spend only a few days to a few weeks rearing in fresh water before migrating toward marine habitats from March to May. A much smaller number of fry may rear in freshwater streams but migrate to marine waters by the end of their first summer."

- This "much smaller number" of fry is excluded from this analysis, and the post-hatch time in freshwater prior to out-migration is assumed to be 21 days ("a few weeks"). Out-migration is assumed to peak on April 1.

Page 11. "Chum salmon utilize estuarine habitats for a few more weeks before migrating to coastal, then offshore waters."

- This suggests estuarine residence is ≈21 days.

Page 12. "Most chum fry enter estuaries by June and leave them by mid to late summer."

- This appears to conflict with the statement (page 11) that chum utilize estuarine habitats for a "few more weeks." Thus, this analysis assumes arrival in June and a six week (42 days) residence in estuarine waters (i.e., fish leave natal estuaries in mid-July). Migration time to the natal estuary is assumed to be two months (60 days).

Page 12. "The Hood Canal shoreline is said to serve as a nursery and rearing habitat for a significant portion of all chum salmon originating from Washington State rivers."

- WDOE gives no information on the amount of time these fish spend in this habitat. However, the indication that a significant portion of chum salmon manifest this life history means they should be

- accounted for in any LHFs, and our analysis assumes that 50% of Puget Sound chum exhibit this behavior.

Page 12. "A number of age 2 chum salmon do occur within Puget Sound waters, although the absence of age 3 chum suggests that all chum salmon spend some time rearing in the Pacific Ocean."

- It is not clear what age 2 means (e.g., in the second year of life, i.e., 1.01 years; over 2 years old, i.e., in the third year of life). In this analysis, it is assumed that these fish move out of Puget Sound at age 1.5 years (547.5 days). This assumption concerning residence time also includes Puget Sound fish that utilize Hood Canal for rearing.

Page 12. "In general, chum salmon originating from Washington streams and rivers, and rearing in the open ocean, do not return as mature adults until age 3 or 4."

- LHFs were calculated assuming both three and four years.

2.4.2 *Discussion and Final LHF for Chum Salmon*

Table A4 gives LHFs for three and four year old chum assumed to migrate to marine waters after minimal residence in estuarine waters (assumed as 42 days) following 121 days in freshwater. These LHFs are relevant to chum originating outside of Puget Sound/Hood Canal. For these fish, the waters of the state LHF is estimated to be 0.13 (average of three and four year old fish).

For Puget Sound/Hood Canal chum, one important unknown is the fraction of the total population spending "additional" time rearing in Hood Canal/Puget Sound prior to migrating to the Pacific Ocean proper, and just exactly how much time they spend in these waters prior to this final out-migration. As noted, we assume these fish migrate to the Pacific Ocean at age 1.5 years (547.5 days). This corresponds to 121 days in freshwater followed by 426.5 days in estuarine waters and Hood Canal/Puget Sound combined, and Table A4 gives LHFs for three and four year old Puget Sound chum according to these assumptions. However, not all Puget Sound chum exhibit this life history. Because the TIP gives no information indicating what fraction of Puget Sound fish follow this life history, we have arbitrarily assumed 50%. Thus, the final LHF for Puget Sound chum is a composite of the two life histories equally weighted. The resulting LHFs are 0.72 and 0.28 for marine and F/E waters, respectively, meaning that the waters of the state LHF for Puget Sound chum is 0.28 ([0.5 x 0.13]+[0.5 x 0.438]).

Composite LHFs for statewide use were calculated assuming that 60% of the chum salmon harvested in Washington are Puget Sound fishes. The resulting values are 0.78 and 0.22 for marine and F/E waters, respectively, meaning that the statewide composite waters of the state LHF for chum salmon is 0.22 ([0.4 x 0.13]+[0.6 x 0.28]).

2.5 Pink Salmon

Table A5 summarizes LHFs for pink salmon derived from the information provided by WDOE (2013).

2.5.1 *Pink Salmon Life History*

Excerpts from WDOE's TIP are quoted as the basis for developing the LHFs in Table A5.

Page 13. "Pink salmon only live for 2 years, with very little variability."

Page 13. "As pink salmon adults spawn near river mouths, and fry migrate downstream immediately after emergence, this salmon species spends the least amount of time in fresh water."

- The fact that pink salmon spawn near the mouth of their natal rivers suggests that the time required for migration to estuarine waters is minimal. This analysis assumes migration takes 10 days.

Page 13. "Although some smaller coastal and Columbia River runs occur, within Washington State two of the rivers supporting the largest pink salmon runs are the Snohomish and Puyallup."

- This statement is consistent with essentially all pink salmon in Washington State originating from Puget Sound.

Page 14. "Once the yolk sac is depleted, the alevins emerge as fry some 41 to 64 days (average 52 days) post hatching."

- The 52 day average is used herein.

Page 14. "There is little or no fresh water rearing as pink salmon fry migrate seaward upon emergence from the gravel, and so their downstream migration also occurs in March and April."

- Based on this and other statements in WDOE's TIP, migration was assumed to begin immediately following emergence.

Page 14. "Pink salmon originating from Puget Sound and Hood Canal streams and rivers appear to use near shore areas extensively for early rearing during their first few weeks of entry into marine habitats."

- This suggests nominally 21 days (a "few weeks") in estuarine waters.

Page 14. "While little is known about their behavior as the fry are exiting Puget Sound proper, Hiss (1994, as cited in Hard et al 1996) found that fry occurrence in Dungeness Bay (near Sequim) peaked in April and they were gone by late May."

- Assuming that peak migration manifests on April 1, the observation that fry are no longer present in Dungeness Bay by late May suggests two months (60 days) residence in near-shore waters of Hood Canal/Puget Sound prior to out-migration to the Pacific Ocean.

Page 14. "Findings suggest that most out-migrating pink salmon enter the open ocean by late summer or early fall."

- This suggests residence in estuarine waters for more than two months.

Page 14. "However, like some Chinook, and Coho, a small portion of the pink salmon population appears to adopt residency in Puget Sound for the marine phase of the life cycle."

- WDOE gives no information on what fraction of pink salmon exhibit this behavior.

Page 14. "Once reaching estuarine and marine habitats, pink salmon migrate towards the open ocean within the first couple of months. By September the majority of pink salmon migrate hundreds of miles out in the open sea to grow and mature."

- Assuming that migration from freshwater to estuarine water peaks on April 1 suggests that pink salmon spend anywhere from two to five months in estuarine (near-shore) waters of Hood Canal/Puget Sound prior to out-migration to the Pacific Ocean. In this analysis, we assume an average of 3.5 months (106.5 days).

Page 14. "They spend approximately eighteen months rearing in the open ocean before their eastward migration to their natal streams and rivers."

- LHFs were calculated assuming 18 months in marine waters and a 24 month total life span.

2.5.2 *Discussion and Final LHF for Pink Salmon*

Table A5 gives two sets of LHFs based on the information presented by WDOE (2013). The difference between these estimates is minimal, and the final LHFs are taken as the mean of the two. Thus, the resulting LHFs for pink salmon are 0.76 and 0.24 for marine and F/E waters, respectively. The final LHF for pink salmon reflecting time spent in waters of the state is 0.24.

For pink salmon that spend their marine phase in Puget Sound, the LHF reflecting time in waters of the state would be 1. However, no information on what fraction of pink salmon manifest this life history was found, while WDOE (2013) noted that only a "small portion" of the overall pink salmon population exhibit Puget Sound residency. As a consequence, this full residency life history is not accounted for in the final waters of the state LHF.

2.6 Composite Residency-Based LHF for all Washington Salmon

Sections 2.1 through 2.5 address development of LHFs for individual salmon species based on residence times. However, there may be circumstances in which a single composite LHF for all Washington salmon will be required. One approach to developing such a composite LHF is to sum the species-specific LHFs after weighting each by a factor reflecting species-specific consumption rates of Washington consumers. One source of these consumption rates is EPA's *Exposure Factor Handbook* (USEPA 2011), which gives species-specific consumption rates for adult members (consumers only) of the Suquamish Tribe in Table 10-104. Although this tribe consumes more shellfish than other tribal data would suggest, it was assumed that the relative amounts of the different salmon species consumed are representative of Washington consumers generally, including high-end tribal consumers. The data from EPA's table is reproduced in part as Table A6 herein, which also shows generation of a single composite LHF for salmon in general (0.32) based on the species-specific LHFs.

A composite salmon LHF could be developed based on other information such as commercial landings, but such data do not necessarily reflect consumption habits of Washington residents.

3.0 DISCUSSION OF LIFE HISTORY FACTORS BASED ON RESIDENCE TIMES

As seen in Section 2, LHFs for Washington salmon can be developed based on residence time. However, in addition to uncertainty regarding residence times of different salmon species (or specific runs) in different environments or geographic locations, the available data also manifest a high degree of variability. Thus, the resulting LHFs must be considered gross approximations. Despite this, there are factors that inform the potential for bias in the residence time LHFs presented in Section 2, and these factors suggest that, in general, residence time LHFs overstate the magnitude of bioaccumulation in early life stages of salmon life history.

One such factor is, ironically, time. This is because bioaccumulation is a reversible process, such that organisms are accumulating and depurating bioaccumulative chemicals simultaneously. Indeed, it is the ratio (accumulation rate/depuration rate) that underpins chemical- and organism-specific bioaccumulation factors. Once an organism moves from one environment (geographic location) to another, the probability that the specific molecules of a chemical acquired in the first environment/location will depurate increases with the time spent in the second environment/location.

This probability increases when the first environment/location is more contaminated than the second, which is the exact scenario relevant to Puget Sound salmon that spend time in the Pacific Ocean proper. Apportioning body burdens based on residence time thus tend to overstate the contribution of accumulation during the early life stages to the ultimate body burden in returning adult Puget Sound salmon.

Beyond this, the assumption that an organism acquires bioaccumulative chemicals at a constant rate is analogous to assuming a fixed bioaccumulation factor. This assumption might hold for an organism that is static, that is, an organism that is not undergoing any physiological changes, feeds at a fixed trophic level, and exhibits either no growth or a constant rate of growth, but it is clearly a gross oversimplification for salmon, which exhibit extremely complex life histories. Thus, a more appropriate basis for apportioning when/where bioaccumulative chemicals are acquired might be relative growth, that is, when/where salmon acquire body mass. Section 4 describes an initial attempt to develop such LHFs.

4.0 LIFE HISTORY FACTORS BASED ON GROWTH

The literature contains many statements (e.g., Quinn 2005) to the effect that salmon acquire the majority of their body mass during the marine phase of their life cycle; that is, while feeding in the ocean (or Puget Sound for true resident fish). For this analysis, the generalized summary of body mass presented by Quinn (2005) is taken as representative. These data are summarized in Table A7, which also gives nominal mass-based LHFs reflecting the relative body masses of out-migrating smolt and returning adult salmon.

By definition (Quinn 2005), smolts are the final stage in salmon development prior to migration to true marine waters. This means the difference in body mass between smolt and adult fish reflects growth in marine waters, and the information provided in Table A7 indicates that all five species of Pacific Northwest salmon acquire >99% of their adult body mass during the marine phase of their life history. Thus, if it is assumed that these fish spend this portion (the marine phase) of their life outside waters of the state, the mass-based LHFs given in Table A7 are the relevant waters of the state LHF. However, some salmon spend a portion of their marine life history in waters of the state. Unfortunately, as noted in Section 3, residence time cannot be used to apportion growth among different habitats or geographic locations. Thus, without higher resolution mass data (i.e., measured mass of fish at multiple ages corresponding to species-specific shifts in habitat usage), the only distinction that can be made is between those fish that exhibit nominally full residency in waters of the state (i.e., Puget Sound) during their marine phase and those that exhibit full residency in the Pacific Ocean during this phase. Adjustments to the mass-based LHFs given in Table A7 reflecting this life history (full residency in Puget Sound) are discussed on a species-specific basis.

4.1 Chinook Salmon

Based on the analysis presented in Section 2.1.3, approximately 60% of the salmon, including Chinook, caught and consumed in Washington are Puget Sound fish. Of these Puget Sound Chinook, about 30% are resident fish. Thus, 18% of all Chinook (0.6 x 0.3) are Puget Sound residents which, by definition, have an LHF equal to 1. For the remaining 82%, the default mass-based LHF is that given in Table A7. Thus, the single composite mass-based LHF for Chinook salmon reflecting waters of the state is 0.182 ([0.82 x 0.00249]+[0.18 x 1]).

4.2 Coho Salmon

Following the analysis for Chinook, 60%of coho salmon are considered to be Puget Sound fish, and 21% of these are assumed to be full time residents of Puget Sound (Section 2.2.2). Thus, 13% (0.6 x 0.21) of all coho are Puget Sound residents which, by definition, have a waters of the state LHF equal to 1. For the remaining 87%, the default mass-based LHF is that given in Table A7. Thus, the single composite mass-based LHF for coho reflecting waters of the state is 0.135 ([0.87 x 0.00596]+[0.13 x 1]).

4.3 Sockeye Salmon

WDOE's TIP gives no information on what fraction of Puget Sound sockeye salmon exhibit full residency in Puget Sound, so there is no basis for parsing sockeye as Puget Sound or non-Puget Sound fish. This means that the only mass-based LHF for sockeye is that given in Table A7. Thus, the single mass-based LHF for Sockeye salmon reflecting waters of the state is 0.00372.

4.4 Chum Salmon

As discussed in Section 2.4.2, some chum spend some time rearing in Hood Canal/Puget Sound prior to migrating to the Pacific Ocean. However, as discussed in Section 4.0, without data there is no way to identify the fraction of ultimate adult body mass chum acquire during this period. Beyond this, the TIP provides no information suggesting that any chum salmon take up full residency in Puget Sound. Thus, there is no basis for modifying the mass-based LHF for chum given in Table A7, so the final mass-based LHF for chum salmon reflecting waters of the state is 0.00011.

4.5 Pink Salmon

As noted in WDOE's TIP (Section 2.5.1 herein), some pink salmon spend time in near-shore marine waters rearing prior to completing migration to the Pacific Ocean. However, as discussed in Section 4.0, without data there is no way to identify the fraction of ultimate adult body mass these fish acquire during this period. Beyond this, the TIP states that only "a small portion of the pink salmon population appears to adopt residency in Puget Sound for the marine phase of the life cycle." Thus, there is no basis for modifying the mass-based LHF for pink salmon given in Table A7, so the final mass-based LHF for pink salmon reflecting waters of the state is 0.00013.

4.6 Composite Mass-Based LHF for all Washington Salmon

Table A8 summarizes calculation of a single composite mass-based LHF for all Washington salmon according to Section 2.6.

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6.0 TABLES

Table A1. Life History Factors (LHFs) for Chinook Salmon[a]

Type	Residence Time (days)			Age at Spawning		LHFs		Notes[d]
	FW[b]	Est.[b]	Marine[b]	(days)	(years)	F/E[c]	Marine	
Stream-Type	365	15	730	1110	30.	0.342	0.658	"a year or more in the river before migrating downstream"; "spend very little time in the estuaries"; "2 to 4 years is more typical"
	730	15	730	1475	4.0	0.505	0.495	
	365	15	1095	1475	4.0	0.258	0.742	
	730	15	1095	1840	5.0	0.405	0.595	
	365	15	1460	1840	5.0	0.207	0.793	
	730	15	1460	2205	6.0	0.338	0.662	
Ocean-Type (immediate)	50	21	730	801	2.2	0.089	0.911	"migrates to ocean soon after yolk resorption"; "a few weeks in the estuary"
	50	21	1095	1166	3.2	0.061	0.939	
	50	21	1460	1531	4.2	0.046	0.954	
Ocean-Type (most common)	105	21	730	856	2.3	0.147	0.853	"migrate to marine habitats at 60 to 150 days post hatching"; "a few weeks in the estuary"
	105	21	1095	1221	3.3	0.103	0.897	
	105	21	1460	1586	4.3	0.079	0.921	
Ocean-Type (poor conditions)	365	21	730	1116	3.1	0.346	0.654	"juveniles remain in fresh water for a year"
	365	21	1095	1481	4.1	0.261	0.739	
	365	21	1460	1846	5.1	0.209	0.791	
Stream-Type average	547.5	15	1095	1657.5	4.5	0.339	0.661	average freshwater residence assuming 3 y in marine habitat
Ocean-Type average	105	21	1095	1221	3.3	0.103	0.897	"most common" life history assuming 3 y in marine habitat
LHFs for non-Puget Sound waters ⇨						0.15	0.85	LHFs assuming 80% of Chinook are ocean-type fish; Puget Sound residency not incorporated[e]
LHFs for Puget Sound waters only ⇨						0.40	0.60	LHFs for Puget Sound only Chinook incorporating residency and assuming 80% are ocean-type fish[e]
Composite LHFs for all waters of the state ⇨						0.30	0.70	statewide composite LHFs incorporating residency of Puget Sound Chinook assuming 60% Puget Sound fish[e]

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] see Section 2.1.3

Table A2. Life History Factors (LHFs) for Coho Salmon[a]

Residence Time (days)			Age at Spawning		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	F/E[c]	Marine	Notes[d]
547.5		547.5	1095	3.0	0.500	0.500	"18 months in fresh water and 18 months in marine habitats"
395		471	866	2.4	0.456	0.544	"1y" in FW (mid-April emergence and mid-May migration to saltwater = 13 mon) followed by 1, 2, or 3 "summers" in marine water (15.5 mon = 2 summers)
395		836	1231	3.4	0.321	0.679	
395		1201	1596	4.4	0.247	0.753	
760		471	1231	3.4	0.617	0.383	"2y" in FW (mid-April emergence and mid-May migration to saltwater = 25 mon) followed by 1, 2, or 3 "summers" in marine water (15.5 mon = 2 summers)
760		836	1596	4.4	0.476	0.524	
760		1201	1961	5.4	0.388	0.612	
					0.47	0.53	average LHFs for 3.4 y old fish excluding Puget Sound residency[e]
LHFs for non-Puget Sound waters →					0.50	0.50	LHFs based on 18 mon in marine water, a 3 y life span, and excluding Puget Sound residency[e]
LHFs for Puget Sound waters only →					0.60	0.40	LHFs for Puget Sound only coho incorporating residency[e]
Composite LHFs for all waters of the state →					0.56	0.44	statewide composite LHFs incorporating residency of Puget Sound coho assuming 60% Puget Sound fish[e]

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] see Section 2.2.2

Table A3. Life History Factors (LHFs) for Sockeye Salmon[a]

Type	Residence Time (days) FW[b]	Est.[b]	Marine[b]	Age at Spawning (days)	(years)	LHFs F/E[c]	Marine	Notes[d]
Stream-Type	457		730	1187	3.3	0.385	0.615	to marine water at age 1; assume hatch mid-March,
Stream-Type	457		1095	1552	4.3	0.294	0.706	emergence by May 1 (42 d post-hatch), 1 y
Stream-Type	457		1460	1917	5.3	0.238	0.762	residence, then out-migration (50 d); "limited" use of estuary
						0.306	0.694	average of all age fish
Ocean-Type	92		730	822	2.3	0.112	0.888	to marine water first year; assume hatch mid-March,
Ocean-Type	92		1095	1187	3.3	0.078	0.922	emergence by May 1 (42 d), and immediate out-
Ocean-Type	92		1460	1552	4.3	0.059	0.941	migration (50 d); "limited" use of estuary
						0.083	0.917	average of all age fish
Ocean-Type	457		730	1187	3.3	0.385	0.615	to marine water at age 1
Ocean-Type	457		1095	1552	4.3	0.294	0.706	
Ocean-Type	457		1460	1917	5.3	0.238	0.762	
						0.306	0.694	average of all age fish
Composite LHFs for all waters of the state →						0.19	0.81	statewide composite LHFs assuming 50:50 split between stream- and ocean-type (92 days FW residence[e]

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] see Section 2.3.2

Table A4. Life History Factors (LHFs) for Chum Salmon[a]

Residence Time (days)			Age at Spawning		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	F/E[c]	Marine	Notes[d]
121	42	932	1095	3.0	0.149	0.851	fish migrate to ocean after minimal residence in estuarine waters
121	42	1297	1460	4.0	0.112	0.888	
					0.130	0.870	average of 3 and 4 y old fish
121	426.5	547.5	1095	3.0	0.500	0.500	fish stay in Hood Canal/Puget Sound until age 1.5 y (this time is in coastal marine water assigned to 'Est.')
121	426.5	912.5	1460	4.0	0.375	0.625	
					0.438	0.563	average of 3 and 4 y old fish
LHFs for non-Puget Sound waters →					0.13	0.87	LHFs for non-Puget Sound chum based on average age fish[e]
LHFs for Puget Sound waters only →					0.28	0.72	LHFs for Puget Sound only chum using average age fish and assuming 50:50 split between two life histories[e]
Composite LHFs for all waters of the state →					0.22	0.78	statewide composite LHFs assuming 60% Puget Sound fish[e]

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] see Section 2.4.2

Table A5. Life History Factors (LHFs) for Chum Salmon[a]

Residence Time (days)			Age at Spawning		LHFs		
FW[b]	Est.[b]	Marine[b]	(days)	(years)	F/E[c]	Marine	Notes[d]
62	106.5	561.5	730	2	0.231	0.769	fry emerge 52 d post-hatch; estimate 10 d to migrate to estuary, total of 62 d in FW; 3.5 mon in estuary/near-shore waters prior to migration to marine waters; 2 y total life span
	183	547	730	2	0.251	0.749	based on 18 mon rearing in marine water and 24 mon life span
LHFs for all waters of the state[e] →					0.24	0.76	average LHFs

[a] all information extracted from WDOE's TIP (WDOE 2013)
[b] FW = freshwater; Est. = estuarine water; marine = marine water
[c] F/E = time spent in waters of the state (combined time spent in freshwater plus estuarine water only)
[d] excerpts from WDOE's TIP in quotation marks
[e] all pink salmon assumed to be Puget Sound fish

Table A6. Derivation of Composite Residency-Based Life History Factor (LHF) for All Salmon Species based on Tribal Consumption Pattern

	Tribal Consumption Data[a]				Species-Specific LHFs	
Species	n	Mean (g/d)	n x Mean (g/d)	Diet Fraction at Mean[b]	LHF[c]	Consumption Weighted
Chinook (King)	63	0.200	12.6	0.294	0.300	0.088
Coho	50	0.191	9.55	0.223	0.560	0.125
Sockeye	59	0.169	9.971	0.233	0.194	0.045
Chum	42	0.242	10.164	0.237	0.222	0.053
Pink	17	0.035	0.595	0.014	0.241	0.003
		Composite residency-based LHF for salmon			→	0.314

[a] consumption data for Suquamish Tribe from USEPA 2011, Table 10-104
[b] fraction of overall salmon consumption attributable to each species
[c] species-specific LHFs from Sections 2.1 to 2.5, Tables A1 to A5

Table A7. Generalized Weights of Salmon as they Enter the Ocean and as Returning Adults[a]

	Chinook	Coho	Sockeye	Chum	Pink
Smolt weight (g)	5 – 18	18	10	0.4	0.22
Adult weight (kg)	7.22	3.02	2.69	3.73	1.63
LHF[b]	0.00249	0.00596	0.00372	0.00011	0.00013

[a] from Quinn 2005, Table 16.3
[b] calculated as simple ratio (smolt/adult)

Table A8. Derivation of Composite Mass-Based Life History Factor (LHF) for All Salmon Species based on Tribal Consumption Pattern

	Tribal Consumption Data[a]				Species-Specific LHFs	
Species	n	Mean (g/d)	n x Mean (g/d)	Diet Fraction at Mean[b]	LHF[c]	Consumption Weighted
Chinook (King)	63	0.200	12.6	0.294	0.182	0.053
Coho	50	0.191	9.55	0.223	0.135	0.030
Sockeye	59	0.169	9.971	0.233	3.72×10^{-3}	8.65×10^{-4}
Chum	42	0.242	10.164	0.237	1.10×10^{-4}	2.61×10^{-5}
Pink	17	0.035	0.595	0.014	1.30×10^{-4}	1.80×10^{-6}
		Composite mass-based LHF for salmon			→	0.084

[a] consumption data for Suquamish Tribe from USEPA 2011, Table 10-104
[b] fraction of overall salmon consumption attributable to each species
[c] species-specific LHFs from Sections 4.1 to 4.5

ATTACHMENT B

823/Z-92-001

Tuesday
December 22, 1992

federal register

Part II

Environmental Protection Agency

40 CFR Part 131
Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4660-9]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance

AGENCY: Environmental Protection Agency.

ACTION: Correction notice; final rule.

SUMMARY: EPA is correcting typographical errors in the final rule for water quality standards for priority toxic pollutants which appeared in the Federal Register on December 22, 1992, 57 FR 60848.

FOR FURTHER INFORMATION CONTACT: David K. Sabock, Chief, Water Quality Standards Branch (WH-585), Office of Water, Environmental Protection Agency, 401-M Street, SW, Washington, DC 20460. Telephone number is 202-260-1318.

SUPPLEMENTARY INFORMATION: EPA promulgated a final rule to establish numeric water quality criteria for priority toxic pollutants applicable to State water quality standards under section 303(c) of the Clean Water Act on December 22, 1992 (57 FR 60848). These criteria became the enforceable criteria for all purposes under the Clean Water Act for the 12 States and 2 territories listed in the rule on February 5, 1993.

Description of Errors and Corrections

On Page 60911, EPA has been advised that the legibility of the matrix on some of the printed notices is such that it is not clear that Arsenic is identified as number 2 on the table and Silver is number 11. In addition, pollutant number 12 is Thallium.

On page 60917, middle column, line 49, the phrase "* * * the lethal concentration of * * *" is incorrect. It should read "* * * the concentration lethal to * * *."

On page 60919, in the middle column dealing with paragraph (6) Florida, in subparagraph (ii), the applicable criteria for Class II and Class III (marine) were inadvertently omitted from the text. The applicable criteria for both Class II and Class III (marine) should read: "This classification is assigned the criteria in: Column D2-#16."

On page 60920, dealing with paragraph (10) California, in subparagraph (ii), the applicable criteria for "Waters of the Sacramento-San Joaquin Delta" should also include pollutant #67 in Column D1; this pollutant was inadvertently omitted from the list.

On page 60921 dealing with paragraph (10) California, in subparagraph (ii), the fifth paragraph beginning "All enclosed bays and estuaries" under the heading "Water and Use Classification", the words "that do not include an MUN designation" were omitted from the first line. The correct wording is: "All enclosed bays and estuaries that are waters of the United States *that do not include an MUN designation* and that the State has. . ."

On page 60922, dealing with paragraph (12) Alaska, in subparagraph (ii), the applicable criteria assigned to use classification (1)(A)(ii) is incorrectly printed as Column D1. The correct reference should be to Column D2.

Dated: May 25, 1993.

Tudor Davies,

Acting Assistant Administrator for Water.

[FR Doc. 93-12845 Filed 5-28-93; 8:45 am]

BILLING CODE 6560-50-M

Corrections

Federal Register
Vol. 58, No. 121
Friday, June 25, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4660-9]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; State's Compliance

Correction

In rule document 93-12845 beginning on page 31177 in the issue of Tuesday, June 1, 1993, make the following correction:

On page 31178, in the first column, in the fifth full paragraph, in the fourth line, "(1)(A)(ii)" should read "(1)(A)(iii)".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY-930-4210-06; WYW 128871]

Proposed Withdrawal and Opportunity for Public Meeting; Wyoming

Correction

In notice document 93-13009, appearing on page 31538 in the issue of Thursday, June 3, 1993 in land description T.41 N., R. 117 W., "34 and 25" should read "34 and 35".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4658-1]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; State's Compliance

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is amending a rule issued on December 22, 1992, to withdraw a portion of that rule as it applies to the State of Washington. The aquatic life criteria for arsenic and selenium adopted by Washington and approved by EPA make the Federally promulgated criteria for these pollutants unnecessary.

EFFECTIVE DATE: This amendment is effective July 6, 1993.

ADDRESSES: The administrative record for the consideration of Washington's revised standards is available for public inspection from the Environmental Protection Agency, Region X Office, Water Division, 1200 Sixth Avenue, Seattle, WA, 98101, during normal business hours of 8 a.m. until 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: David K. Sabock, Chief, Water Quality Standards Branch (WH-585), Office of Water, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. The telephone number is 202-260-1315.

SUPPLEMENTARY INFORMATION: A final rule to establish numeric water quality criteria for those States and Territories that failed to comply fully with section 303(c)(2)(B) of the Clean Water Act was published in the Federal Register on December 22, 1992 (57 FR 60848). Federal criteria were promulgated for 12 States and 2 Territories, and these criteria became the legally enforceable water quality standards in the named States and Territories for all purposes and programs under the Clean Water Act on February 5, 1993.

As indicated in the preamble to the final rule, EPA would amend the rule to withdraw criteria from the rule when a State adopted and EPA approved criteria that met the requirements of the Clean Water Act (see 57 FR 60860). On November 25, 1992, the State of Washington adopted revisions to the State's surface water quality standards, Chapter 173-201A of the Washington Administrative Code, regarding aquatic life criteria for arsenic and selenium. The State adopted criteria identical to those promulgated by EPA for both fresh and marine waters. These criteria were approved by EPA on March 25, 1993.

EPA's promulgated criteria for arsenic and selenium are now duplicative of EPA-approved State criteria and are no longer needed to meet the requirements of the Act. It is EPA's policy to withdraw promulgated water quality standards when the State adopts new or revised standards which meet the requirements of the Act (57 FR 60848). Accordingly, EPA is amending its rule promulgated December 22, 1992, to withdraw the criteria for arsenic and selenium for the protection of aquatic life for Washington. Other criteria

promulgated by EPA for Washington remain in force.

Washington complied with the public participation requirements in its adoption of State standards. Additionally, because Washington adopted, and EPA approved, water quality criteria for arsenic and selenium for the protection of fresh and marine aquatic life identical to those being withdrawn in today's rule, EPA has determined that additional public participation in this action is unnecessary and constitutes good cause for issuing this final rule without notice and comment. For the same reasons, the Agency has determined that good cause exists to waive the requirement for a 30-day period before the amendment becomes effective and therefore the amendments will be immediately effective.

This action imposes no new regulatory requirements but merely withdraws a Federal regulation. Therefore, this rule imposes no costs and does not require a regulatory impact analysis under Executive Order 12291. The Agency has determined that this action will have no significant impact on a substantial number of small entities. The rule also does not impose any requirements subject to the Paperwork Reduction Act.

List of Subjects in 40 CFR Part 131

Water pollution control, Water quality standards, Toxic pollutants.

Dated: June 8, 1993.

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 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. Section 131.36(d)(14)(ii) is amended in "Fish and Shellfish; Fish" use classification, under the listing of applicable criteria, by removing the entries "Column B1 and B(2)—#2, 10" and "Column C1—#2, 10" in their entirety and by removing "#2" and "#10" from the entry for Column C2.

[FR Doc. 93-15862 Filed 7-2-93; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[WH-FRL-4543-9]

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This rule promulgates for 14 States, the chemical-specific, numeric criteria for priority toxic pollutants necessary to bring all States into compliance with the requirements of section 303(c)(2)(B) of the Clean Water Act (CWA). States determined by EPA to fully comply with section 303(c)(2)(B) requirements are not affected by this rule.

The rule addresses two situations. For a few States, EPA is promulgating a limited number of criteria which were previously identified as necessary in disapproval letters to such States, and which the State has failed to address. For other States, Federal criteria are necessary for all priority toxic pollutants for which EPA has issued section 304(a) water quality criteria guidance and that are not the subject of approved State criteria.

When these standards take effect, they will be the legally enforceable standards in the named States for all purposes and programs under the Clean Water Act, including planning, monitoring, NPDES permitting, enforcement and compliance.

EPA is also withdrawing today the human health criteria published in the 1980 Ambient Water Quality Criteria documents for: Beryllium, Cadmium, Chromium, Lead, Methyl Chloride, Selenium, Silver, and 1,1,1 Trichloroethane. A summary of the criteria recommendation and the notice of availability of each criteria document were published at 45 FR 79318, November 28, 1980.

EFFECTIVE DATE: This rule shall be effective February 5, 1993.

ADDRESSES: The public may inspect the administrative record for this rulemaking, including documentation supporting the aquatic life and human health criteria, and all public comments received on the proposed rule at the Environmental Protection Agency, Standards and Applied Science Division, Office of Science and Technology, room 919 East Tower, Waterside Mall, 401 M Street, SW., Washington, DC 20460 (Telephone: 202-260-1315) on weekdays during the Agency's normal business hours of 8 a.m. to 4:30 p.m. A reasonable fee will be charged for photocopies. Inquiries can be made by calling 202-260-1315.

FOR FURTHER INFORMATION CONTACT: David K. Sabock or R. Kent Ballentine, Telephone 202-260-1315.

SUPPLEMENTARY INFORMATION:

This preamble is organized according to the following outline:

A. Introduction and Overview
1. Introduction
2. Overview
B. Statutory and Regulatory Background
1. Pre-Water Quality Act Amendments of 1987 (Pub. L. 100-4)
2. The Water Quality Act Amendments of 1987 (Pub. L. 100-4)
a. Description of the New Requirements
b. EPA's Initial Implementing Actions for sections 303(c) and 304(l)
3. EPA's Program Guidance for section 303(c)(2)(B)
C. State Actions Pursuant to section 303(c)(2)(B)
D. Determining State Compliance with section 303(c)(2)(B)
1. EPA's Review of State Water Quality Standards for Toxics
2. Determining Current Compliance Status
E. Rationale and Approach For Developing the Final Rule
1. Legal Basis
2. Approach for Developing the Final Rule
3. Approach for States that Fully Comply Subsequent to Issuance of this Final Rule
F. Derivation of Criteria
1. Section 304(a) Criteria Process
2. Aquatic Life Criteria
3. Criteria for Human Health
4. Section 304(a) Human Health Criteria Excluded
5. Cancer Risk Level
6. Applying EPA's Nationally Derived Criteria to State Waters
7. Application of Metals Criteria
G. Description of the Final Rule and Changes from Proposal
1. Changes from Proposal
2. Scope
3. EPA Criteria for Priority Toxic Pollutants
4. Applicability
H. (Reserved)
I. Response to Public Comments
1. Legal Authority
2. Science
3. Economics
4. Implementation
5. Timing and Process
6. State Issues
J. Executive Order 12291
K. Regulatory Flexibility Act
L. Paperwork Reduction Act

A. Introduction and Overview

1. Introduction

This section of the Preamble introduces the topics which are addressed subsequently and provides a brief overview of EPA's basis and rationale for promulgating Federal criteria for priority toxic pollutants. Section B of this Preamble presents a description of the evolution of the Federal Government's efforts to control toxic pollutants beginning with a discussion of the authorities in the Federal Water Pollution Control Act Amendments of 1972. Also described in some detail is the development of the water quality standards review and revision process which provides for establishing both narrative goals and enforceable numeric requirements for controlling toxic pollutants. This discussion includes the changes enacted in the 1987 Clean Water Act Amendments which are the basis for this rule. Section C summarizes State efforts since 1987 to comply with the requirements of section 303(c)(2)(B). Section D describes EPA's procedure for determining whether a State has fully complied with section 303(c)(2)(B). Section E sets out the rationale and approach for developing the final rule, including a discussion of EPA's legal basis. Section F describes the development of the criteria included in this rule. Section G summarizes the provisions of the final rule. (Section H is reserved.) Section I contains the response to major public comments received on the proposal. Sections J, K, and L address the requirements of Executive Order 12291, the Regulatory Flexibility Act, and the Paperwork Reduction Act, respectively. Section M provides a list of subjects covered in this rule.

A public hearing on the proposed rule was held on December 19, 1991, in Washington, DC. A total of 26 non-EPA people registered at the hearing. The public comment period closed on December 19, 1991. EPA received a total of 153 written comments on the proposed rule.

2. Overview

This rule, which establishes Federal criteria for certain priority toxic pollutants in a number of States, is important for several environmental, programmatic and legal reasons.

First, control of toxic pollutants in surface waters is an important priority to achieve the Clean Water Act's goals and objectives. The most recent National Water Quality Inventory indicates that one-third of monitored river miles, lake acres, and coastal waters have elevated levels of toxics. Forty-seven States and Territories have reported elevated levels of toxic pollutants in fish tissues. States have issued a total of 586 fishing advisories and 135 bans, attributed mostly to industrial discharges and land disposal.

The absence of State water quality standards for toxic pollutants undermines State and EPA toxic control efforts to address these problems. Without clearly established water quality goals, the effectiveness of many of EPA's water programs is jeopardized. Permitting, enforcement, coastal water quality improvement, fish tissue quality protection, certain nonpoint source controls, drinking water quality protection, and ecological protection all depend to a significant extent on complete and adequate water quality standards. Numeric criteria for toxics are essential to the process of controlling toxics because they allow States and EPA to evaluate the adequacy of existing and potential control measures to protect aquatic ecosystems and human health. Formally adopted standards are the legal basis for including water quality-based effluent limitations in NPDES permits to control toxic pollutant discharges. The critical importance of controlling toxic pollutants has been recognized by Congress and is reflected, in part, by the addition of section 303(c)(2)(B) to the Act. Congressional impatience with the pace of State toxics control programs is well documented in the legislative history of the 1987 CWA amendments. In order to protect human health, aquatic ecosystems, and successfully implement toxics controls, EPA believes that all actions which are available to the Agency must be taken to ensure that all necessary numeric criteria for priority toxic pollutants are established in a timely manner.

Second, as States and EPA continue the transition from an era of primarily technology-based controls to an era in which technology-based controls are integrated with water quality-based controls, it is important that EPA ensures timely compliance with CWA requirements. An active Federal role is essential to assist States in getting in place complete toxics criteria as part of their pollution control programs. While most States recognize the need for enforceable water quality standards for toxic pollutants, their recent adoption efforts have often been stymied by a variety of factors including limited resources, competing environmental priorities, and difficult scientific, policy and legal challenges. Most water quality criteria for toxic pollutants have been available since 1980. Section 303 of the CWA requires States to review, revise, and adopt updated water quality standards every three years as part of a continuing triennial review process. The water quality standards regulation has required State adoption of numeric criteria for toxic pollutants since 1983 (see 40 CFR 131.11). Despite the availability of scientific guidance documents and clear statutory and regulatory requirements, a preliminary assessment of the water quality standards for all States in February of 1990 showed that only six States had established fully acceptable criteria for toxic pollutants. This rate of toxics criteria adoption is contrary to the CWA requirements and is a reflection of the difficulties faced by States. In such circumstances, it is EPA's responsibility to exercise its CWA authorities to move forward the toxic control program in concert with the statutory scheme.

EPA's action will also help restore equity among the States. The CWA is designed to ensure all waters are sufficiently clean to protect public health and the environment. The CWA allows some flexibility and differences among States in their adopted and approved water quality standards, but it was not designed to reward inaction and inability to meet statutory requirements.

Although most States have made important progress toward satisfying CWA requirements, some have still failed to fully comply with section 303(c)(2)(B). The CWA authorizes EPA to promulgate standards where necessary to meet the requirements of the Act. Where States have not satisfied the CWA requirement to adopt water quality standards for toxic pollutants, which was reemphasized by Congress in 1987, it is imperative that EPA take action.

EPA's ability to oversee State standards-setting activities and to correct deficiencies in State water quality standards is critical to the effective implementation of section 303(c)(2)(B). This rule is a necessary and important component of EPA's implementation of section 303(c)(2)(B) as well as EPA's overall efforts to control toxic pollutants in surface waters.

On February 26, 1992, EPA's Deputy Administrator issued "Guidance on Risk Characterization for Risk Managers and Risk Assessors" which addresses a problem that affects public perception regarding the reliability of EPA's scientific assessments and related regulatory decisions. The guidance noted that "when risk information is presented to the * * * public, the results have been boiled down to a point estimate of risk * * * which do not fully convey the range of information considered and used in developing the assessment." The guidance lays out principles and implementation procedures to address risk assessments in future EPA presentations, reports and decision packages. The guidance specifically notes, *"However, we do not expect risk assessment documents that are close to completion to be rewritten."*

The proposal for this final rule was published in November, 1991, three months prior to the risk assessment guidance being issued. Since the Agency was striving to meet a mid-February statutory deadline for final publication, when the risk guidance was issued the rulemaking package was essentially complete. The specifics of the aquatic life and human health guidelines are discussed in the preamble and in the response to public comments. The actual methodology and criteria documents describe in detail the risk assessment process involved in deriving a water quality criteria and the water quality standards contained in this rule and the resulting risk characterization. The water quality criteria methodology and individual criteria documents are part of the record for this rule. Therefore, while all the specifics of the new risk characterization guidance were not followed in this preamble, the spirit of the guidance is reflected.

Moreover, EPA has initiated a review and update of these criteria methodologies. These updates will be conducted in conformance with the risk characterization guidance and include public involvement and review.

B. Statutory and Regulatory Background

1. Pre-Water Quality Act Amendments of 1987 (Pub. L. 100-4)

Section 303(c) of the 1972 Federal Water Pollution Control Act Amendments (FWPCA) (33 U.S.C. 1313(c)) established the statutory basis for the current water quality standards program. It completed the transition from the previously established program of water quality standards for interstate waters to one requiring standards for all surface waters of the United States.

Although the major innovation of the 1972 FWPCA was technology-based controls, Congress maintained the concept of water quality standards both as a mechanism to establish goals for the Nation's waters and as a regulatory requirement when standardized technology controls for point source discharges and/or nonpoint source controls were inadequate. In recent years, these so-called water quality-based controls have received new emphasis by Congress and EPA in the continuing quest to enhance and maintain water quality to protect the public health and welfare.

Briefly stated, the key elements of section 303(c) are:

(a) A water quality standard is defined as the designated beneficial uses of a water segment and the water quality criteria necessary to support those uses;

(b) The minimum beneficial uses to be considered by States in establishing water quality standards are specified as public water supplies, propagation of fish and wildlife, recreation, agricultural uses, industrial uses and navigation;

(c) A requirement that State standards must protect public health or welfare, enhance the quality of water and serve the purposes of the Clean Water Act;

(d) A requirement that States must review their standards at least once each three year period using a process that includes public participation;

(e) The process for EPA review of State standards which may ultimately result in the promulgation of a superseding Federal rule in cases where a State's standards are not consistent with the applicable requirements of the CWA, or in situations where the Agency determines Federal standards are necessary to meet the requirements of the Act.

Another major innovation in the 1972 FWPCA was the establishment of the National Pollutant Discharge Elimination System (NPDES) which requires point source discharges to obtain a permit before legally discharging to the waters of the United States. In addition to the permit limits established on the basis of technology (e.g. effluent limitations guidelines), the Act requires discharges to meet instream water quality standards. (See section 301(b)(1)(C), 33 U.S.C. 1311(b)(1)(C)).

The water quality standards serve a dual function under the Clean Water Act regulatory scheme. Standards establish narrative and numeric definitions and quantification of the Act's goals and policies (see section 101, 33 U.S.C. 1251) which provide a basis for identifying impaired waters. Water quality standards also establish regulatory requirements which are translated into specific discharge requirements. In order to fulfill this critical function, adopted State criteria must contain sufficient parametric coverage to protect both human health and aquatic life.

In its initial efforts to control toxic pollutants, the FWPCA, pursuant to section 307, required EPA to designate a list of toxic pollutants and to establish toxic pollutant effluent standards based on a formal rulemaking record. Such rulemaking required formal hearings, including cross-examination of witnesses. EPA struggled with this unwieldy process and ultimately promulgated effluent standards for six toxic pollutants, pollutant families or mixtures. (See 40 CFR part 129.) Congress amended section 307 in the 1977 Clean Water Act Amendments by endorsing the Agency's alternative procedure of regulating toxic pollutants by use of effluent limitations guidelines, by amending the procedure for establishing toxic pollutant effluent standards to provide for more flexibility in the hearing process for establishing a record, and by directing the Agency to include sixty-five specific pollutants or classes of pollutants on the toxic pollutant list. EPA published the required list on January 31, 1978 (43 FR 4109). This toxic pollutant list was the basis on which EPA's efforts on criteria development for toxics was focused.

During planning efforts to develop effluent limitations guidelines and water quality criteria, the list of sixty-five toxic pollutants was judged too broad as some of the pollutants were, in fact, general families or classes of organic compounds consisting of many individual chemicals. EPA selected key chemicals of concern within the 65 families of pollutants and identified a more specific list of 129 priority toxic pollutants. Two volatile chemicals and one water unstable chemical were removed from the list (see 46 FR 2266, January 8, 1981; 46 FR 10723, February 4, 1981) so that at present there are 126 priority toxic pollutants. This list is published as appendix A to 40 CFR part 423.

Another critical section of the 1972 FWPCA was section 304(a) (33 U.S.C. 1314(a)). Section 304(a)(1) provides, in pertinent part, that EPA

> * * * shall develop and publish * * * criteria for water quality accurately reflecting the latest scientific knowledge (A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, * * * and (C) on the effects of pollutants on biological community diversity, productivity, and stability, * * *

In order to avoid confusion, it must be recognized that the Clean Water Act uses the term "criteria" in two separate ways. In section 303(c), which is discussed above, the term is part of the definition of a water quality standard. That is, a water quality standard is comprised of designated uses and the criteria necessary to protect those uses. Thus, States are required to adopt regulations or statutes which contain legally achievable criteria. However, in section 304(a), the term criteria is used in a scientific sense and EPA develops recommendations which States consider in adopting regulatory criteria.

In response to this legislative mandate and an earlier similar statutory requirement, EPA and a predecessor agency have produced a series of scientific water quality criteria guidance documents. Early Federal efforts were Water Quality Criteria (1968 "Green Book") and Quality Criteria for Water (1976 "Red Book"). EPA also sponsored a contract effort with the National Academy of Science—National Academy of Engineering which resulted in Water Quality Criteria, 1972 (1973 "Blue Book"). These early efforts were premised on the use of literature reviews and the collective scientific judgment of Agency and advisory panels. However, when faced with the list of 65 toxic pollutants and the need to develop criteria for human health as well as aquatic life, the Agency determined that new procedures were necessary. Continued reliance solely on existing scientific literature was deemed inadequate, since for many pollutants essential information was not available. EPA scientists developed formal methodologies for establishing scientifically defensible criteria. These were subjected to review by the Agency's Science Advisory Board of outside experts and the public. This effort culminated on November 28, 1980, when the Agency published criteria development guidelines for aquatic life and for human health, along with criteria for 64 toxic pollutants. (See 45 FR 79318.) Since that initial publication, the aquatic life methodology was slightly amended (50 FR 30784, July 29, 1985) and additional criteria was proposed for public comment and finalized as Agency criteria guidance. EPA summarized the available criteria information in Quality Criteria for Water 1986 (1986 "Gold Book") which is updated from time-to-time. However, the individual criteria documents, as updated, are the official guidance documents.

EPA's criteria documents provide a comprehensive toxicological evaluation of each chemical. For toxic pollutants, the documents tabulate the relevant acute and chronic toxicity information for aquatic life and derive the criteria maximum concentrations (acute criteria) and criteria continuous concentrations (chronic criteria) which the Agency recommends to protect aquatic life resources. For human health criteria, the document provides the appropriate reference doses, and if appropriate, the carcinogenic slope factors, and derives recommend criteria. The details of this process are described more fully in a later part of this Preamble.

Programmatically, EPA's initial efforts were aimed at converting a program focused on interstate waters into one addressing all interstate and intrastate surface waters of the United States. Guidance was aimed at the inclusion of traditional water quality parameters to protect aquatic life (e.g., pH, temperature, dissolved oxygen and a narrative "free from toxicity" provision), recreation (e.g., bacteriological criteria) and general aesthetics (e.g., narrative "free from nuisance" provisions). EPA also required State adoption of an antidegradation policy to maintain existing high quality or ecologically unique waters as well as maintain improvements in water quality as they occur.

The initial water quality standards regulation was actually a part of EPA's water quality management regulations implementing section 303(e) (33 U.S.C. 1313(e)) of the Act. It was not comprehensive and did not address toxics or any other criteria specifically. Rather, it simply required States to adopt appropriate water quality criteria necessary to support designated uses. (See 40 CFR 130.17 as promulgated in 40 FR 55334, November 28, 1975).

After several years of effort and faced with increasing public and Congressional concerns about toxic pollutants, EPA realized that proceeding under section 307 of the Act would not comprehensively address in a timely manner the control of toxics through either toxic pollutant effluent standards or effluent limitations guidelines because these controls are only applicable to specific types of discharges. EPA sought a broader, more generally applicable mechanism and decided to vigorously pursue the alternative approach of EPA issuance of scientific water quality criteria documents which States could use to adopt enforceable water quality standards. These in turn could be used as the basis for establishing State and EPA permit discharge limits pursuant to section 301(b)(1)(C) which requires NPDES permits to contain

> * * * any more stringent limitation, including those necessary to meet water quality standards * * *, or required to implement any applicable water quality standard established pursuant to this Act.

Thus, the adoption by States of appropriate toxics criteria applicable to their surface waters, such as those recommended by EPA in its criteria documents, would be translated by regulatory agencies into point source permit limits. Through the use of water quality standards, all discharges of toxics are subject to permit limits and not just those discharged by particular industrial categories. In order to facilitate this process, the Agency amended the water quality standards regulation to explicitly address toxic criteria requirements in State standards. The culmination of this effort was the promulgation of the present water quality standards regulation on November 8, 1983 (40 CFR part 131, 48 FR 51400).

The current water quality standards regulation (40 CFR part 131) is much more comprehensive than its predecessor. The regulation addresses in detail both the beneficial use component and the criteria component of a water quality standard. Section 131.11 of the regulation requires States to review available information and,

> * * * to identify specific water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use.

The regulation provided that either or both numeric and narrative criteria may be appropriately used in water quality standards.

EPA's water quality standards emphasis since the early 1980's reflected the increasing importance placed on controlling toxic pollutants. States were strongly encouraged to adopt criteria in their standards for the priority toxic pollutants, especially where EPA had published criteria guidance under section 304(a) of the Act.

Under the statutory scheme, during the 3-year triennial review period following EPA's 1980 publication of water quality criteria for the protection of human health and aquatic life, States should have reviewed those criteria and adopted standards for many priority toxic pollutants. In fact, State response to EPA's criteria publication and toxics initiative was disappointing. A few States adopted large numbers of numeric toxics criteria, although primarily for the protection of aquatic life. Most other States adopted few or no water quality criteria for priority toxic pollutants. Some relied on a narrative "free from toxicity" criterion, and so-called "action levels" for toxic pollutants or occasionally calculated site-specific criteria. Few States addressed the protection of human health by adopting numeric human health criteria.

In support of the November, 1983, water quality standards rulemaking, EPA issued program guidance entitled, Water Quality Standards Handbook (December 1983) simultaneously with the publication of the final rule. The foreword to that guidance noted EPA's two-fold water quality based approach to controlling toxics: chemical specific numeric criteria and biological testing in whole effluent or ambient waters to comply with narrative "no toxics in toxic amounts" standards. More detailed programmatic guidance on the application of biological testing was provided in the Technical Support Document for Water Quality Based Toxics Control (TSD) (EPA 440/4-85-032, September 1985). This document provided the needed information to convert chemical specific and biologically based criteria into water quality standards for ambient receiving waters and permit limits for discharges to those waters. The TSD focused on the use of bioassay testing of effluent (so-called whole effluent testing or WET methods) to develop effluent limitations within discharge permits. Such effluent limits were designed to implement the "free from toxicity" narrative standards in State water quality standards. The TSD also focused on water quality standards. Procedures and policy were presented for appropriate design flows for EPA's section 304(a) acute and chronic criteria. In 1991, EPA revised and expanded the TSD. (Technical Support Document for Water Quality-based Toxics Control, EPA 505/2-90-001, March 1991.) A Notice of Availability was published in the Federal Register on April 4, 1991 (56 FR 13827). All references in this Preamble are to the revised TSD.

The Water Quality Standards Handbook and the TSD are examples of EPA's efforts and assistance that were intended to help, encourage and support the States in adopting appropriate water quality standards for the protection of their waters against the deleterious effects of toxic pollutants. In some States, more and more numeric criteria for toxics were being adopted as well as more aggressive use of the "free from toxics" narratives in setting protective NPDES permit limits. However, by the time of Congressional consideration and action on the CWA reauthorization, most States had adopted few, if any, water quality standards for priority toxic pollutants.

State practices of developing case-by-case effluent limits using procedures that were not standardized in State regulations made it difficult to ascertain whether such procedures were consistently applied. The use of approaches to control toxicity that did not rely on the statewide adoption of numeric criteria for the priority toxic pollutants generated frustration in Congress. Senator Robert T. Stafford, first chairman and then ranking minority member of the authorizing committee, noted during the Senate debate:

> An important problem in this regard is that few States have numeric ambient criteria for toxic pollutants. The lack of ambient criteria [for toxic pollutants] make it impossible to calculate additional discharge limitations for toxics * * *. It is vitally important that the water quality standards program operate in such a way that it supports the objectives of the Clean Water Act to restore and maintain the integrity of the Nation's Waters. (bracketed material added). A Legislative History of the Water Quality Act of 1987 (Pub. L. 100-4), Senate Print 100-144, USGPO, November 1988 at page 1324.

Other comments in the legislative history similarly note the Congressional perception that the States were failing to aggressively address toxics and that EPA was not using its oversight role to push the States to move more quickly and comprehensively. Thus Congress developed the water quality standards amendments to the Clean Water Act for reasons similar to those strongly stated during the Senate debate by a chief sponsor, Senator John H. Chafee,

> A cornerstone of the bill's new toxic pollution control requirements is the so called beyond-BAT program * * *. Adopting the beyond BAT provisions will assure that EPA continues to move forward rapidly on the program * * *. If we are going to repair the damage to those water bodies that have become highly degraded as a result of toxic substances, we are going to have to move forward expeditiously on this beyond-BAT program. The Nation cannot tolerate endless delays and negotiations between EPA and States on this program. Both entities must move aggressively in taking the necessary steps to make this program work within the time frame established by this Bill * * *. Ibid, at page 1309.

This Congressional impatience with the pace of State and EPA progress and an appreciation that the lack of State standards for toxics undermined the effectiveness of the entire CWA-based scheme, resulted in the 1987 adoption of stringent new water quality standard provisions in the Water Quality Act amendments.

2. The Water Quality Act Amendments of 1987 (Pub. L. 100-4)

a. Description of the New Requirements

The 1987 Amendments to the Clean Water Act added Section 303(c)(2)(B) which provides:

> Whenever a State reviews water quality standards pursuant to paragraph (1) of this subsection, or revises or adopts new standards pursuant to this paragraph, such State shall adopt criteria for all toxic pollutants listed pursuant to section 307(a)(1) of this Act for which criteria have been published under section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses. Such criteria shall be specific numerical criteria for such toxic pollutants. Where such numerical criteria are not available, whenever a State reviews water quality standards pursuant to paragraph (1), or revises or adopts new standards pursuant to this paragraph, such State shall adopt criteria based on biological monitoring or assessment methods consistent with information published pursuant to section 304(a)(8). Nothing in this section shall be construed to limit or delay the use of effluent limitations or other permit conditions based on or involving biological monitoring or assessment methods or previously adopted numerical criteria.

b. EPA's Initial Implementing Actions for Sections 303(c) and 304(l)

The addition of this new requirement to the existing water quality standards review and revision process of section 303(c) did not change the existing procedural or timing provisions. For example, section 303(c)(1) still requires that States review their water quality standards at least once each 3 year period and transmit the results to EPA for review. EPA's oversight and promulgation authorities and statutory schedules in section 303(c)(4) were likewise unchanged. Rather, the provision required the States to place heavy emphasis on adopting numeric chemical-specific criteria for toxic pollutants (i.e., rather than just narrative approaches) during the next triennial review cycle. As discussed in the previous section, Congress was frustrated that States were not using the numerous section 304(a) criteria that EPA had developed, and was continuing to develop, to assist States in controlling the discharge of priority toxic pollutants. Therefore, for the first time in the history of the Clean Water Act, Congress took the unusual action of explicitly mandating that States adopt numeric criteria for specific toxic pollutants.

In response to this new Congressional mandate, EPA redoubled its efforts to promote and assist State adoption of water quality standards for priority toxic pollutants. EPA's efforts included the development and issuance of guidance to the States on acceptable implementation procedures for several new sections of the Act, including sections 303(c)(2)(B) and 304(l).

The 1987 CWA Amendments added to, or amended, other CWA Sections related to toxics control. Section 304(l) (33 U.S.C. 1314(l)) was an important corollary amendment because it required States to take actions to identify waters adversely affected by toxic pollutants, particularly those waters entirely or substantially impaired by point sources. Section 304(l) entitled "Individual Control Strategies for Toxic Pollutants," requires in part, that States identify and list waterbodies where the designated uses specified in the applicable water quality standards cannot reasonably be expected to be achieved because of point source discharge of toxic pollutants. For each segment so identified, the State is required to develop individual control strategies to reduce the discharge of toxics from point sources so that in conjunction with existing controls on point and nonpoint sources, water quality standards will be attained. To assist the States in identifying waters under section 304(l), EPA's guidance listed a number of potential sources of available data for States to review. States generally assembled data for a broad spectrum of pollutants, including the priority toxic pollutants, which could be useful in complying with sections 304(l) and 303(c)(2)(B). In fact, between February 1988 and October 1988, EPA assembled pollutant candidate lists for section 304(l) which were then transmitted to each jurisdiction. Thus, each State had a preliminary list of pollutants that had been identified as present in, or discharged to, surface waters. Such lists were limited by the quantity and distribution of available effluent and ambient monitoring data for priority toxic pollutants. This listing exercise further emphasized the need for water quality standards for toxic pollutants. Lack of standards increased the difficulty of identifying impaired waters. On the positive side, the data gathered in support of the 304(l) activity proved helpful in identifying those pollutants most obviously in need of water quality standards.

EPA, in devising guidance for section 303(c)(2)(B), attempted to provide States the maximum flexibility that complied with the express statutory language but also with the overriding congressional objective: Prompt adoption and implementation of numeric toxics criteria. EPA believed that flexibility was important so that each State could comply with section 303(c)(2)(B) and to the extent possible, accommodate its existing water quality standards regulatory approach. The options EPA identified are described in the next Section of this Preamble. EPA's program guidance was issued in final form on December 12, 1988 but was not substantially different from earlier drafts available for review by the States. The availability of the guidance was published in a Federal Register Notice on January 5, 1989 (54 FR 346).

3. EPA's Program Guidance for Section 303(c)(2)(B)

EPA's section 303(c)(2)(B) program guidance identified three options that could be used by a State to meet the requirement that the State adopt toxic pollutant criteria "* * * the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses."

Option 1. Adopt statewide numeric criteria in State Water Quality Standards for all section 307(a) toxic pollutants for which EPA has developed criteria guidance, regardless of whether the pollutants are known to be present.

This option is the most comprehensive approach to satisfy the statutory requirements because it would include all of the priority toxic pollutants for which EPA has prepared section 304(a) criteria guidance for either or both aquatic life protection and human health protection. In addition to a simple adoption of EPA's section 304(a) guidance as standards, a State must select a risk level for those toxic pollutants which are carcinogens (i.e., that cause, or may cause cancer in humans).

Many States found this Option attractive because it ensured comprehensive coverage of the priority toxic pollutants with scientifically defensible criteria without the need to conduct a resource-intensive evaluation of the particular segments and pollutants requiring criteria. This option would also not be more costly to dischargers than other options because permit limits would only be based on the regulation of the particular toxic pollutants in their discharges and not on the total listing in the water quality standards. Thus, actual permit limits should be the same under any of the options.

Option 2. Adopt chemical-specific numeric criteria for priority toxic pollutants that are the subject of EPA section 304(a) criteria guidance, where the State determines based on available information that the pollutants are present or discharged and can reasonably be expected to interfere with designated uses.

This option results in the adoption of numeric water quality standards for some subset of those pollutants for which EPA has issued section 304(a) criteria guidance based on a review of current information. To satisfy this Option, the guidance recommended that States use the data gathered during the section 304(l) water quality assessments as a starting point to identify those water segments that need water quality standards for priority toxic pollutants. That data would be supplemented by a State and public review of other data sources to ensure sufficient breadth of coverage to meet the statutory objective. Among the data available to be reviewed were: (1) Ambient water monitoring information, including those for the water column, sediment, and aquatic life (e.g., fish tissue data); (2) NPDES permit applications and permittee self-monitoring reports; (3) effluent guideline development documents, many of which contain priority toxic pollutant scans; (4) pesticide and herbicide application information and other records of pesticide or herbicide inventories; (5) public water supply source monitoring data noting pollutants with maximum contaminant levels (MCLs); and (6) any other relevant information on toxic pollutants collected by Federal, State, industry, agencies, academic groups, or scientific organizations. EPA also recommended that States selecting this option adopt a translator provision similar to that described in Option 3 but applicable to all chemicals causing toxicity, and not just priority toxic pollutants.

This Option 2 review resulted in a State proposing new or revised water quality standards and providing an opportunity for public review and comment on the pollutants, criteria, and water bodies included. Throughout this process, EPA's Regional Offices were available to assist States by providing additional guidance and technical assistance on applying EPA's recommended criteria to particular situations in the States.

Option 3. Adopt a procedure to be applied to a narrative water quality standard provision prohibiting toxicity in receiving waters. Such procedures would be used by the State in calculating derived numeric criteria which must be used for all purposes under section 303(c) of the CWA. At a minimum, such criteria need to be developed for section 307(a) toxic pollutants, as necessary to support designated uses, where these pollutants are discharged or present in the affected waters and could reasonably be expected to interfere with designated uses.

The combination of a narrative standard (e.g., "free from toxics in toxic amounts") and an approved translator mechanism as part of a State's water quality standards satisfies the requirements of section 303(c)(2)(B). As noted above, such a procedure is also a valuable supplement to either option 1 or 2. There are several regulatory and scientific requirements EPA's guidance specifies are essential to ensure acceptable scientific quality and full involvement of the public and EPA in this approach. Briefly stated these are:

- The procedure (i.e., narrative criterion and translator) must be used to calculate numeric water quality criteria;
- The State must demonstrate to EPA that the procedure results in numeric criteria that are sufficiently protective to meet the goals of the Act;
- The State must provide for full opportunity for public participation during the adoption of the procedure;
- The procedure must be formally adopted as a State rule and be mandatory in application; and
- The procedure must be submitted for review and approval by EPA as part of the State's water quality standards regulation.

The scientific elements of a translator are similar to EPA's 304(a) criteria methodologies when applied on a site-specific basis. For example, aquatic criteria are developed using a sufficient number and diversity of aquatic species representative of the biological assemblage of a particular water body. Human health criteria focus on determining appropriate exposure conditions (e.g. amount of aquatic life consumed per person per day) rather than underlying pollutant toxicity. The results of the procedures are scientifically defensible criteria that are protective for the site's particular conditions. EPA's review of translator procedures includes an evaluation of the scientific merit of the procedure using the section 304(a) methodology as a guide.

Ideally, States adopting option 3 translator procedures should prepare a preliminary list of criteria and specify the waters the criteria apply to at the time of adoption. Although under option 3 the State retains flexibility to derive new criteria without revising the adopted standards, establishing this preliminary list of derived criteria at the time of the triennial review will assist the public in determining the scope of the adopted standards, and help ensure that the State ultimately complies with the requirement to establish criteria for all pollutants that can "reasonably be expected" to interfere with uses. EPA believes that States selecting solely option 3 should prepare an analysis (similar to that required of option 2 States) at the time of the triennial review identifying pollutants needing criteria.

EPA's December 1988 guidance also addressed the timing issue for State compliance with section 303(c)(2)(B). The statutory directive was clear: All State standards triennial reviews initiated after passage of the Act must include a consideration of numeric toxic criteria.

The structure of section 303(c) is to require States to review their water quality standards at least once each three year period. Section 303(c)(2)(B) instructs States to include reviews for toxics criteria whenever they initiate a triennial review. EPA initially looked at February 4, 1990, the 3-year anniversary of the 1987 CWA amendments, as a convenient point to index State compliance. The April 1990 **Federal Register** Notice used this index point for the preliminary assessment. However, some States were very nearly completing their State administrative processes for ongoing reviews when the 1987 amendments were enacted and could not legally amend those proceedings to address additional toxics criteria. Therefore, in the interest of fairness, and to provide such States a full 3-year review period, EPA's FY 1990 Agency Operating Guidance provided that "By the end of the FY 88–90 triennium, States should have completed adoption of numeric criteria to meet the section 303(c)(2)(B) requirements." (p.48.) The FY 88–90 triennium ended on September 30, 1990.

Clean Water Act section 303(c) does not provide penalties for States that do not complete timely water quality standards reviews. In no previous case has the EPA Administrator found that State failure to complete a review within three years jeopardized the public health or welfare to such an extent that promulgation of Federal standards pursuant to section 303(c)(4)(B) was justified. The pre-1987 CWA never mandated State adoption of priority toxic pollutants or other specific criteria. EPA generally relied on its water quality standards regulation (40 CFR 131.11) and its criteria and program guidance to the States on appropriate parametric coverage in State water quality standards to encourage State adoption of water quality standards. However, since the 1987 statutory amendments, the programmatic environment has changed. Beyond the increased Congressional and public concern, about the relative importance of toxic pollutant controls, there is increased evidence of toxic pollution problems in our Nation's waters. In response, the Agency in this rulemaking is proceeding pursuant to section 303(c)(4)(B) and 40 CFR 131.22(b) to rectify a longstanding program deficiency.

The current regulation at 40 CFR Part 131 in conjunction with the statutory language provides a clear and unambiguous basis and process for today's Federal promulgation.

C. State Actions Pursuant to Section 303(c)(2)(B)

In recent years, there has been substantial progress by many States in the adoption, and EPA approval, of water quality standards for toxic pollutants. Virtually all States have at least proposed new toxics criteria for priority toxic pollutants since section 303(c)(2)(B) was added to the CWA in February of 1987. Unfortunately, not all such State proposals address, in a comprehensive manner, the requirements of section 303(c)(2)(B). For example, some States have proposed to adopt criteria to protect aquatic life, but not human health; other States have proposed human health criteria which do not address major human exposure pathways. In addition, in some cases final adoption of proposed State toxics criteria which would be approvable by EPA has been substantially delayed due to controversial and difficult issues associated with the toxics criteria adoption process. For purposes of today's rulemaking, it is EPA's judgment that 43 States completed actions which fully satisfy the requirements of section 303(c)(2)(B).

In sum, States have devoted substantial resources, and have made substantial progress, in adopting new or revised numeric criteria for priority pollutants. In so doing, they have addressed a number of significant and difficult issues. These efforts have generated extensive examination by dischargers, States, environmental groups and the public on all aspects of the CWA water quality criteria and related issues. It amounts to a multi-year consideration of the issues that are central to this proposed and final rulemaking.

D. Determining State Compliance With Section 303(c)(2)(B)

1. EPA's Review of State Water Quality Standards for Toxics

The EPA Administrator has delegated the responsibility and authority for review and approval or disapproval of all State water quality standards actions to the 10 EPA Regional Administrators (see 40 CFR 131.21). State section 303(c)(2)(B) actions are thus submitted to the appropriate EPA Regional Administrator for review and approval. This de-centralized EPA system for State water quality standards review and approval is guided by EPA Headquarters Office of Water, which issues national policies and guidance to the States and Regions such as the annual Office of Water Operating Guidance and various technical manuals.

For purposes of evaluating State compliance with CWA section 303(c)(2)(B), EPA relied on the statutory language, the existing water quality standards regulation, and section 303(c)(2)(B) national guidance to provide the basis for EPA review. In some cases, individual Regions also used Regional policies and procedures in reviewing State section 303(c)(2)(B) actions. The flexibility provided by the national guidance, coupled with subtle differences in Regional policies and procedures, contributed to some differences in the approaches taken by States to satisfy section 303(c)(2)(B) requirements.

As discussed previously, EPA's final guidance on compliance with section 303(c)(2)(B) was developed to provide States with the necessary flexibility to allow State standards revisions that would complement the State's existing water quality standards program and still comply with section 303(c)(2)(B). As guidance, it described the range of acceptable approaches and EPA's recommendations. Some innovative State approaches were expected as well as differences in terms of criteria coverage, stringency and application procedures.

Although the guidance provided for State flexibility, it was also consistent with existing water quality standards regulation requirements of 40 CFR 131.11 that explicitly require State criteria to be sufficient to protect designated uses. Such water quality criteria also must be based on sound scientific rationale and support the most sensitive use designated for a water body.

The most complicated EPA compliance determinations involve States that selected EPA Options 2 or 3. Since most States use EPA's section 304(a) criteria guidance, where States select Option 1, EPA normally is able to focus Agency efforts on verifying that all available EPA criteria are included, appropriate cancer risk levels are selected, and that sufficient application procedures are in place (e.g. laboratory analytical methods, mixing zones, flow condition, etc.).

However, for States using EPA's Option 2 or 3, substantially more EPA evaluation and judgment was required because the Agency must evaluate which priority pollutants and, in some cases, segments or designated uses, require numeric criteria. Under these options, the State must adopt or derive numeric criteria for priority toxic pollutants for which EPA has section 304(a) criteria, "* * * the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State * * *." The necessary justification and the ultimate coverage and acceptability of a State's actions vary State-to-State because of differences in the adequacy of available monitoring information, local waterbody use designations, the effluent and nonpoint source controls in place, and different approaches to the scientific basis for criteria.

In submitting criteria for the protection of human health, States were not limited to a 1 in 1 million risk level (10^{-6}). EPA generally regulates pollutants treated as carcinogens in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations. If a State selects a criterion that represents an upper bound risk level less protective than 1 in 100,000 (i.e., 10^{-5}), however, the State needed to have substantial support in the record for this level. This support focused on two distinct issues. First, the record must include documentation that the decision maker considered the public interest of the State in selecting the risk level, including documentation of public participation in the decision making process as required by the water quality standards regulation at 40 CFR 131.20(b). Second, the record must include an analysis showing that the risk level selected, when combined with other risk assessment variables, is a balanced and reasonable estimate of actual risk posed, based on the best and most representative information available. The importance of the estimated actual risk increases as the degree of conservatism in the selected risk level diminishes. EPA carefully evaluated all assumptions used by a State if the State chose to alter any one of the standard EPA assumption values.

Where States selected Option 3, EPA reviews must also include an evaluation of the scientific defensibility of the translator procedure. EPA must also verify that a requirement to apply the translator whenever toxics may reasonably be expected to interfere with designated uses (e.g., where such toxics exist or are discharged) is included in the State's water quality standards. Satisfactory application procedures must also be developed by States selecting Option 3.

In general, each EPA Region made compliance decisions based on whatever information was available at the time of the triennial review. For some States, information on the presence and discharge of priority toxic pollutants is extremely limited. Nevertheless, during the period of February 1988 to October 1990, to supplement State efforts, EPA assembled the available information and provided each State with various pollutant candidate lists in support of the section 304(l) and section 303(c)(2)(B) activities. These were based in part on computerized searches of existing Agency data bases.

Beginning in 1988, EPA provided States with candidate lists of priority toxic pollutants and water bodies in support of CWA Section 304(l) implementation. These lists were developed because States were required to evaluate existing and readily available water-related data in order to comply with Section 304(l). 40 CFR 130.10(d). A similar "strawman" analysis of priority pollutants potentially requiring adoption of numeric criteria under Section 303(c)(2)(B) was furnished to most States in September or October of 1990 for their use in on-going and subsequent triennial reviews. The primary differences between the "strawman" analysis and the section 304(l) candidate lists were that the "strawman" analysis: (1) Organized the results by chemical rather than by water body, (2) included data for certain STORET monitoring stations that were not used in constructing the candidate lists, (3) included data from the Toxics Release Inventory database, and (4) did not include a number of data sources used in preparing the candidate lists (e.g. those, such as fish kill information, that did not provide chemical specific information).

In its 1988 section 303(c)(2)(B) guidance, EPA urged States, at a minimum, to use the information gathered in support of section 304(l) requirements as a starting point for identifying which priority toxic pollutants require adoption of numeric criteria. EPA also encouraged States to consider the presence or potential construction of facilities that manufacture or use priority toxic pollutants as a strong indication of the need for toxics criteria. Similarly, EPA indicated to States that the presence of priority pollutants in ambient waters (including those in sediments or in aquatic life tissue) or in discharges from point or nonpoint sources also be considered as an indication that toxics criteria should be adopted. A limited amount of data on the effluent characteristics of NPDES discharges was readily available to States. States were also expected to take into account newer information as it became available, such as information in annual reports from the Toxic Chemical Release Inventory requirements of the Emergency Planning and Community Right-To-Know Act of 1986. (Title III, Pub. L. 99–499.)

In summary, EPA and the States had access to a variety of information gathered in support of section 304(l), section 303(c)(2)(B), and section 305(b) activities. For some States, as noted above, such information for priority toxic pollutants is extremely limited. In the final analysis, the Regional Administrator made a judgment on a duly submitted State standards triennial review based on the State's record and the Region's independent knowledge of the facts and circumstances surrounding the State's actions. These actions, taken in consultation with the Office of Water, determined which State actions were sufficiently consistent with the coverage contemplated in the statute to justify approval. These approval actions include allowable variations among State water quality standards. EPA approval indicates that, based on the record, the State water quality standards met the requirements of the Act.

2. Determining Current Compliance Status

The following summarizes the process generally followed by the Agency in assessing compliance with section 303(c)(2)(B).

A State was determined to be in full compliance with the requirements of section 303(c)(2)(B) if,

a. The State had submitted a water quality standards package for EPA review since enactment of the 1987 Clean Water Act amendments or was determined to be already in compliance, and,

b. The State adopted water quality standards are effective under State law and consistent with the CWA and EPA's implementing regulations (EPA's December 1988 guidance described three Options, any one, or a combination of which EPA suggested States could adopt for compliance with the CWA and EPA regulations), and

c. EPA has issued a formal approval determination to the State.

States meeting these criteria are not included in this final rulemaking.

States which adopted standards following Option 1 generally have been found to satisfy section 303(c)(2)(B). An exception exists for selected States which attempted to follow Option 1 by adopting all EPA section 304(a) criteria by reference. EPA has withheld approval for one State which has adopted such a reference into their standards because the adopted standards did not specify application factors necessary to implement the criteria (e.g., a risk level for carcinogens). Other States have achieved full compliance following options 1, 2, 3, or some combination of these options.

As of the date of signature of today's rule, the Agency has determined that 43 States and Territories are in full compliance with the requirements of section 303(c)(2)(B). Compliance status for all States and Territories is set forth in Table 1.

TABLE 1.—ASSESSMENT OF STATE COMPLIANCE WITH CWA SECTION 303(c)(2)(B)

State	Is State in compliance with section 303(c)(2)(B)?
Alabama	Yes.
Alaska	No.
Arizona	Yes.
Arkansas	No.
California	No.
Colorado	Yes.
Connecticut	Yes.
Delaware	Yes.
Florida	No.
Georgia	Yes.
Hawaii	Yes.
Idaho	No.
Illinois	Yes.
Indiana	Yes.
Iowa	Yes.
Kansas	No.
Kentucky	Yes (1).
Louisiana	Yes.
Maine	Yes.
Maryland	Yes.
Massachusetts	Yes.
Michigan	No.
Minnesota	Yes.
Mississippi	Yes.
Missouri	Yes.
Montana	Yes.
Nebraska	Yes.
Nevada	No.
New Hampshire	Yes.
New Jersey	No.
New Mexico	Yes (2).
New York	Yes.
North Carolina	Yes.
North Dakota	Yes.
Ohio	Yes.
Oklahoma	Yes.
Oregon	Yes.
Pennsylvania	Yes.
Rhode Island	No.
South Carolina	Yes.
South Dakota	Yes.
Tennessee	Yes.
Texas	Yes.
Utah	Yes.
Vermont	No.
Virginia	Yes.
Washington	No.
West Virginia	Yes.
Wisconsin	Yes.
Wyoming	Yes.
American Samoa	Yes.
Commonwealth of the Northern Mariana Islands.	Yes.
District of Columbia	No.
Guam	Yes.
Puerto Rico	No.
Tr. Territories	Yes.
Virgin Islands	Yes.

Notes to Table 1

(1) At the initiation of this rulemaking, Kentucky was determined to be in compliance with the Act. On January 27, 1992, the Commonwealth of Kentucky deleted the water quality criteria for dioxin from the Kentucky water quality standards. Although EPA has not formally acted to disapprove Kentucky's action to delete the criteria, information is available which documents the need for dioxin criteria for the Commonwealth of Kentucky. Any potential EPA promulgation arising from a future EPA action to disapprove the deletion of the dioxin criteria for Kentucky will be through a rulemaking independent of today's rule.

(2) At the initiation of this rulemaking, New Mexico was determined to be in compliance with the Act. On October 8, 1991, New Mexico adopted revisions to its standards which affected compliance with acute toxicity criteria. On January 13, 1992, EPA disapproved the State's action, thus initiating the possibility of Federal promulgation should the State fail to adopt acceptable standards within 90 days from the EPA notice. Any potential EPA promulgation arising from this disapproval will be through a rulemaking independent of today's rule. EPA policy has been and continues to be that we prefer States and Territories to adopt their own standards consistent with the requirements of the Clean Water Act.

(3) EPA has become aware that several of the State water quality standards approved as complying with section 303(c)(2)(B) have been challenged in State courts for various reasons. Additional such challenges may occur in the future. In cases where such State rules are remanded or otherwise set aside, or intentionally withdrawn by the State for any reason, and the State does not pursue in good faith correcting such defects in a timely manner, it is EPA's intention to initiate appropriate rulemaking to put in place appropriate criteria for priority toxic pollutants to bring State water quality standards into compliance with the Clean Water Act.

E. Rationale and Approach for Developing the Final Rule

The addition of section 303(c)(2)(B) to the Clean Water Act was an unequivocal signal to the States that Congress wanted toxics criteria in the State's water quality standards. The legislative history notes that the "beyond BAT" program (i.e., controls necessary to comply with water quality standards that are more stringent than technology-based controls) was the cornerstone to the Act's toxic pollution control requirements.

The major innovation of the 1972 Clean Water Act Amendments was the concept of effluent limitation guidelines which were to be incorporated into NPDES permits. In many cases, this strategy has succeeded in halting the decline in the quality of the Nation's waters and, often, has provided improvements. However, the effluent limitation guidelines for industrial discharges and the similar technology-based secondary treatment requirements for municipal discharges are not capable, by themselves, of ensuring that the fishable-swimmable goals of the Clean Water Act will be met for all waters.

The basic mechanism to accomplish this in the Act is water quality standards. States are required to periodically review and revise these standards to achieve the goals of the Act. In the 1987 CWA amendments, Congress focused on addressing toxics in several sections of the Act, but special attention was placed on the section 303 water quality standards program requirements. Congress intended that the adoption of numeric criteria for toxics would result in direct improvements in water quality by forcing, where necessary, effluent limits more stringent than those resulting from technology-based effluent limitations guidelines.

As the legislative history demonstrates, Congress was dissatisfied with the piecemeal, slow progress being made by States in setting standards for toxics. Congress reacted by legislating new requirements and deadlines directing the States to establish toxics criteria for pollutants addressed in EPA section 304(a) criteria guidance, especially for those priority toxic pollutants that could reasonably be expected to interfere with designated uses. In today's action, EPA is exercising its authority under section 303(c)(4) to promulgate criteria where States have failed to act in a timely manner.

The previous section of this preamble explains EPA's approach to evaluating the adequacy of State actions in response to section 303(c)(2)(B). This section explains EPA's legal basis for issuing today's rule, and discusses EPA's general approach for developing the State-specific requirements in Section 131.36(d).

In addition to the Congressional directive and the legal basis for this action, there are a number of environmental and programmatic reasons why further delay in *establishing water quality standards for* toxic pollutants is no longer acceptable.

Prompt control of toxic pollutants in surface waters is critical to the success of a number of Clean Water Act programs and objectives, including permitting, enforcement, fish tissue quality protection, coastal water quality improvement, sediment contamination control, certain nonpoint source controls, pollution prevention planning, and ecological protection. The decade long delay in State adoption of water quality standards for toxic pollutants has had a ripple effect throughout EPA's water programs. Without clearly established water quality goals, the effectiveness of many water programs is jeopardized. For too long, the absence of water quality standards has had a chilling effect on toxic control progress in many State and Federal programs.

Failure to take prompt action at this juncture would also undermine the continued viability of the current statutory scheme to establish standards. Excessive delay subverts the entire concept of the triennial review cycle which is intended to combine current scientific information with the results of previous environmental control programs to direct continuing progress in enhancing water quality.

Finally, another reason to proceed expeditiously is to bring closure to this long-term effort and allow State attention and resources to be directed towards important, new national program initiatives. Until standards for toxic pollutants are in place, neither EPA nor the States can fully focus on the emerging, ecologically-based water quality activities such as wetlands criteria, biological criteria and sediment criteria.

1. Legal Basis

Clean Water Act Section 303(c) specifies that adoption of water quality standards is primarily the responsibility of the States. However, Section 303(c) also describes a role for EPA of overseeing State actions to ensure compliance with CWA requirements. If the Agency's review of the State's standards finds flaws or omissions, then the Act authorizes EPA to initiate promulgation to correct the deficiencies (see section 303(c)(4)). The water quality standards promulgation authority has been used by EPA to issue final rules on nine separate occasions. These actions have addressed both insufficiently protective State criteria and/or designated uses and failure to adopt needed criteria. Thus, today's action is not unique, although it would affect more States and pollutants than previous actions taken by the Agency.

The Clean Water Act in section 303(c)(4) provides two bases for promulgation of Federal water quality standards. The first basis, in paragraph (A), applies when a State submits new or revised standards that EPA determines are not consistent with the applicable requirements of the Act. If, after EPA's disapproval, the State does not promptly amend its rules so as to be consistent with the Act, EPA must promulgate appropriate Federal water quality standards for that State. The second basis for EPA's action is paragraph (B), which provides that EPA shall promptly initiate promulgation "* * * in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of this Act." EPA is relying on both section 303(c)(4)(A) and section 303(c)(4)(B) as the legal basis for this rule.

Section 303(c)(4)(A) supports today's action for several States. These States have submitted criteria for some number of priority toxic pollutants and EPA has disapproved the State's adopted standards. The basis for EPA's disapproval generally has been the lack of sufficient criteria or particular criteria that were insufficiently stringent. In these cases, EPA has, by letter to the State, noted the deficiencies and specified the need for corrective action. Not having received an appropriate correction within the statutory time frame, EPA is today promulgating the needed criteria. The action in today's rule pursuant to section 303(c)(4)(A) may differ from those taken pursuant to section 303(c)(4)(B) by being limited to criteria for specific priority toxic pollutants, particular geographic areas, or particular designated uses.

Section 303(c)(4)(B) is the basis for EPA's requirements for most States. For these States, the Administrator has determined that promulgating criteria is necessary to bring the States into compliance with the requirements of the CWA. In these cases, EPA is promulgating, at a minimum, criteria for all priority toxic pollutants not addressed by approved State criteria. EPA is also promulgating criteria for priority toxic pollutants where any previously-approved State criteria do not reflect current science contained in revised criteria documents and other guidance sufficient to fully protect all designated uses or human exposure pathways, or where such previously-approved State criteria are not applicable to all appropriate designated uses. EPA's action pursuant to section 304(c)(4)(B) may include several situations.

In some cases, the State has failed to adopt and submit for approval any criteria for those priority toxic pollutants for which EPA has published criteria. This includes those States that have not submitted triennial reviews. In other cases, the State has adopted and EPA has approved criteria for either aquatic life or human health, but not both. In yet a third situation, States have submitted some criteria but not all necessary criteria. Lastly, one State has submitted criteria that do not apply to all appropriate geographic sections of the waters of the State.

The use of section 303(c)(4)(B) requires a determination by the Administrator "* * * that a revised or new standard is necessary to meet the requirements of * * *" the Act. The Administrator's determination could be supported in different ways.

One approach would be for EPA to undertake a time-consuming effort to research and marshall data to demonstrate the need for promulgation for each criteria for each stream segment or waterbody in each State. This would include evidence for each Section 307(a) priority toxic pollutant for which EPA has Section 304(a) criteria and that there is a "discharge or presence" which could reasonably "be expected to interfere with" the designated use. This approach would not only impose an enormous administrative burden, but would be contrary to the statutory scheme and the compelling Congressional directive for swift action reflected in the 1987 addition of section 303(c)(2)(B) to the Act.

An approach that is more reasonable and consistent with Congressional intent focuses on the State's failure to complete the timely review and adoption of the necessary standards required by section 303(c)(2)(B) despite information that priority toxic pollutants may interfere with designated uses of the State's waters. This approach is consistent with the fact that in enacting section 303(c)(2)(B) Congress expressed its determination of the necessity for prompt adoption and implementation of water quality standards for toxic pollutants. Therefore, a State's failure to meet this fundamental 303(c)(2)(B) requirement of adopting appropriate standards constitutes a failure "to meet the requirements of the Act." That failure to act can be a basis for the Administrator's determination under section 303(c)(4)(B) that new or revised criteria are necessary to ensure designated uses are adequately protected. Here, this determination is buttressed by the existence of evidence of the discharge or presence of priority toxic pollutants in a State's waters for which the State has not adopted numeric water quality criteria. The Agency has compiled an impressive volume of information in the record for this rulemaking on the discharge or presence of toxic pollutants in State waters. This data supports the Administrator's determination pursuant to section 303(c)(4)(B). The record was available to the public for review during this rulemaking period and continues to be on file.

The Agency's choice to base the determination on the second approach is supported by both the explicit language of the statutory provision and by the legislative history. Congress added subsection 303(c)(2)(B) to section 303 with full knowledge of the existing requirements in section 303(c)(1) for triennial water quality standards review and submission to EPA and in section 303(c)(4)(B) for EPA promulgation. There was a clear expectation that these provisions be used in concert to overcome the programmatic delay that many legislators criticized and achieve the Congressional objective of the rapid availability of enforceable water quality standards for toxic pollutants. As quoted earlier, chief Senate sponsors, including Senators Stafford, Chaffee and others, wanted the provision to eliminate State and EPA delays and force aggressive action.

In normal circumstances, it might be argued that to exercise section 303(c)(4)(B) the Administrator might have the burden of marshalling conclusive evidence of "necessity" for Federally promulgated water quality standards. However, in adopting section 303(c)(2)(B), Congress made clear that the "normal" procedure had become inadequate. The specificity and deadline in section 303(c)(2)(B) were layered on top of a statutory scheme already designed to achieve the adoption of toxic water quality standards. Congressional action to adopt a partially redundant provision was driven by their impatience with the lack of State progress. The new provision was essentially a Congressional "determination" of the necessity for new or revised comprehensive toxic water quality standards by States. In deference to the principle of State primacy, Congress, by linking section 303(c)(2)(B) to the section 303(c)(1) three-year review period, gave States a last chance to correct this deficiency on their own. However, this Congressional indulgence does not alter the fact that section 303(c)(2)(B) changed the nature of the CWA State/EPA water quality standard relationship. The new provision and its legislative background indicate that the Administrator's determination to invoke his section 303(c)(4)(B) authority in this circumstance can be met by a generic finding of inaction on the part of a State and without the need to develop data for individual stream segments. Otherwise, the Agency could face a heavy data gathering burden of justifying the need for each Federal criterion and the process could stretch for years and never be realized. To interpret the combination of subsections (c)(2)(B) and (c)(4) as an effective bar to prompt achievement of statutory objectives would be a perverse conclusion and render section 303(c)(2)(B) essentially meaningless.

A second strong argument against requiring EPA to shoulder a heavy burden to exercise section 303(c)(4)(B) authority is that it would invert the traditional statutory scheme of EPA as national overseer and States as the entity with the greatest local expertise. The CWA provides States the flexibility to tailor water quality standards to local conditions and needs based upon their wealth of first-hand experience, knowledge and data. However, this allowance for flexibility is based on an assumption of reasoned and timely State action, not an abdication of State responsibility by failure to act. EPA does not possess the local expertise or resources necessary to successfully tailor State water quality standards. Therefore, the fact that the CWA allows States flexibility in standards development does not impose an inappropriate burden on EPA in the exercise of its oversight promulgation responsibilities. A broad Federal promulgation based on a showing of State inaction coupled with basic information on the discharge and presence of toxic pollutants meets the statutory objective of having criteria in places that are protective of public health and the environment. Without local expertise to help accurately narrow this list of pollutants and segments requiring criteria, there is no assurance of comparable protection. Nothing in the overall statutory water quality standards scheme anticipates EPA would develop this expertise in lieu of the States. EPA's lack of familiarity with local conditions argues strongly for a simple "determination" test to trigger section 303(c)(4)(B) promulgations. It also supports the concept of an across-the-board rulemaking for all priority toxic pollutants with section 304(a) criteria.

A final major reason supporting a simple determination to trigger 303(c)(4)(B) action is that comprehensive Federal promulgation imposes no undue or inappropriate burden on States or dischargers. It merely puts in place standards for toxic pollutants that are utilized in implementing Clean Water Act programs. Under this rulemaking, a State still retains the ability to adopt alternative water quality standards simply by completing its standards adoption process. Upon EPA approval of those standards, EPA will take actions to withdraw the Federally-promulgated criteria.

Federal promulgation of State water quality standards should be a course of last resort. It is symptomatic of something awry with the basic statutory scheme. Yet, when it is necessary to exercise this authority, as the compelling evidence suggests in this case, there should be no undue impediments to its use. Section 303(c)(4) is replete with deadlines and Congressional directives for the Administrator to act "promptly" in these cases. The statute indicates that the Administrator of EPA, is to "* * * promptly prepare and publish proposed regulations setting forth a revised or new water quality standard * * *" and "* * * shall promulgate any revised or new standard * * * not later than 90 days after he published such proposed standards, unless prior to such promulgation, such State has adopted a revised or new standard which the Administrator determines to be in accordance with the Act." The adoption of section 303(c)(2)(B) reinforced this emphasis on expeditious actions. EPA has demonstrated extensive deference to State primacy and a willingness to provide broad flexibility in their adoption of State standards for toxics. However, to fulfill its statutory obligation requires that EPA's deference and flexibility cannot be unlimited.

For the reasons just discussed, EPA does not believe it is necessary to support the criteria promulgated today on a pollutant specific, State-by-State, waterbody-by-waterbody basis. Nonetheless, over the course of the past several years in working with and assisting the States, the Agency has reviewed the readily-available data on the discharge and presence of priority toxic pollutants. While this data is not necessarily complete, it constitutes a substantial record to support a strong *prima facie* case for the need for numeric criteria for most priority toxic pollutants with section 304(a) criteria guidance in most States. In the absence of final State actions to adopt criteria pursuant to either Option 2 or 3 which meet the requirements for EPA approval, this evidence strongly supports EPA's decision to promulgate, pursuant to section 303(c)(4)(B), criteria for all priority toxic pollutants not fully addressed by State criteria. The EPA data supporting this assertion is discussed more fully in the next section.

2. Approach for Developing the Final Rule

The State-specific requirements in § 131.36(d) were developed using one of two approaches. In the formal review of the adopted standards for certain States, EPA determined that specific numeric toxics criteria are lacking. For some, criteria were omitted from the State standards, even though in EPA's judgment, the pollutants can reasonably be expected to interfere with designated uses. In these cases where EPA specifically identified deficiencies in a State submission, this rule establishes Federal criteria for that limited number of priority toxic pollutants necessary to correct the deficiency.

For the balance of the States, EPA applies, to all appropriate State waters, the section 304(a) criteria for all priority toxic pollutants which are not the subject of approved State criteria. EPA also is promulgating Federal criteria for priority toxic pollutants where any previously-approved State criteria do not reflect current science contained in revised criteria documents and other guidance sufficient to fully protect all designated uses or human health exposure pathways, where such previously-approved State criteria do not protect against both acute and chronic aquatic life effects, or where such previously-approved State criteria are not applicable to all appropriate State designated uses.

Absent a State-by-State pollutant specific analysis to narrow the list, existing data sources strongly support a comprehensive rulemaking approach. Information in the rulemaking record from a number of sources indicates the discharge, potential discharge or presence of virtually all priority toxic pollutants in all States. The data available to EPA was assembled into a "strawman" analysis designed to identify priority toxic pollutants that potentially require the adoption of numeric criteria. Information on pollutants discharged or present was identified by accessing various national data sources:

—Final section 304(l) short lists identifying toxic pollutants likely to impair designated uses;
—Water column, fish tissue and sediment observations in the Storage Retrieval (STORET) data base (i.e., where the pollutant was *detected*);
—The National Pollutant Discharge Elimination System's (NPDES) Permit Compliance System data base to identify those pollutants limited in direct dischargers' permits;
—Pollutants included on Form 2(c) permit applications which have been submitted by wastewater dischargers;
—Information on discharges to surface waters or POTWs from the Toxics Release Inventory required by the Emergency Planning and Community Right-To-Know Act of 1986 (Title III, P.L. 99–499);
—Pollutants predicted to be in the effluent of NPDES dischargers based on industry-specific analyses conducted for the Clean Water Act effluent guideline program.

The extent of this data supports a conclusion that promulgation of Federal criteria for all priority toxic pollutants with section 304(a) criteria guidance documents is appropriate for those States that have not completed their standards adoption process. This conclusion is supported by several other factors.

First, many of the available data sources have limitations which argue against relying on them solely to identify all needed water quality criteria. For example, the section 304(l) short lists only identified water bodies where uses were impaired by point source discharges; State 304(l) long lists did not generally identify pollutants causing use impairment by nonpoint sources. Other available data sources (i.e., NPDES permit limits) have a similar narrow scope because of their particular purposes. Even the value of those data bases designed to identify ambient water problems is restricted by the availability of monitoring data. In many States, the quantity, spatial and temporal distribution, and pollutant coverage of monitoring data is severely limited. For example, the most recent Water Quality Inventory Report to Congress included an evaluation of use attainment for only one-third of all river miles and less than one-half of lake acres. Even for those waters where use attainment status was reported, many assessments were based on data which did not include the chemical-specific information necessary to identify the priority toxic pollutants which pose a threat to designated uses. After evaluating this data, EPA concluded that it most likely understates the adverse presence or discharge of priority toxic pollutants.

Further evidence justifying a broad promulgation rulemaking can be found in the State actions to date in their standards adoption process. While many have not come to completion, the initial steps have led many States to develop or propose rulemaking packages with extensive pollutant coverage. The nature of these preliminary State determinations argues for a Federal promulgation of all section 304(a) criteria pollutants to ensure adequate public health and environmental protection against priority toxic pollutant insults.

The detailed assumptions and approach followed by EPA in writing the § 131.36(d) requirements for all jurisdictions are described below. In the following discussions, EPA refers to these assumptions and approach as "rules."

(1) No criteria are promulgated for States which have been fully approved by EPA as complying with the section 303(c)(2)(B) requirements.

(2) For States which have not been fully approved, if EPA has not previously determined which specific pollutants criteria/waterbodies are lacking from a State's standards (i.e., as part of an approval/disapproval action only), all of the criteria in Columns B, C, and D of the § 131.36(b) matrix are promulgated for statewide application to all appropriate designated uses, except as provided for elsewhere in these rules. That is, EPA brought the State into compliance with section 303(c)(2)(B) via an approach which is comparable to option 1 of the December 1988 national guidance for section 303(c)(2)(B).

(3) If EPA has previously determined which specific pollutants/criteria/waterbodies are needed to comply with CWA section 303(c)(2)(B) (i.e., as part of an approval/disapproval action only), the criteria in § 131.36(b) are promulgated for only those specific pollutants/criteria/waterbodies (i.e., EPA brought the State into compliance via an approach which is comparable to option 2 of the December 1988 national guidance for section 303(c)(2)(B)).

(4) For aquatic life, except as provided for elsewhere in these rules, all waters with designated aquatic life uses providing even minimal support to aquatic life are included in the rule (i.e., fish survival, marginal aquatic life, etc.).

(5a) For human health, except as provided for elsewhere in these rules, all waters with designated uses providing for public water supply protection (and therefore a potential water consumption exposure route) or minimal aquatic life protection (and therefore a potential fish consumption exposure route) are included in the rule.

(5b) Where a State has determined the specific aquatic life segments which provide a fish consumption exposure route (i.e., fish or other aquatic life are being caught and consumed) and EPA approved this determination as part of a standards approval/disapproval action, the rule includes the fish consumption (Column D2) criteria for only those aquatic life segments, except as provided for elsewhere in these rules. In making a determination that certain segments do not support a fish consumption exposure route, a State must have completed, and EPA approved, a use attainability analysis consistent with the provisions of 40 CFR 131.10(j). In the absence of such an approved State determination, EPA promulgated fish consumption criteria for all aquatic life segments.

(6) Uses/Classes other than those which support aquatic life or human health are not included in the rule (e.g., livestock watering, industrial water supply), unless they are defined in the State standards as also providing protection to aquatic life or human health (i.e., unless they are described as protecting multiple uses including aquatic life or human health). For example, if the State standards include a use such as industrial water supply, and in the narrative description of the use the State standards indicate that the use includes protection for resident aquatic life, then this use is included in this rule.

(7) For human health, the "water + fish" criteria in Column D1 of § 131.36(b) are promulgated for all waterbodies where public water supply and aquatic life uses are designated, except as provided for elsewhere in these rules (e.g., rule 9).

(8) If the State has public water supplies where aquatic life uses have not been designated, or public water supplies that have been determined not to provide a potential fish consumption exposure pathway, the "water + organisms only" criteria in Column D1 of § 131.36(b) are promulgated for such waterbodies, except as provided for elsewhere in these rules (e.g., rule 9).

(9) EPA is generally not promulgating criteria for priority toxic pollutants for which a State has adopted criteria and received EPA approval. The exceptions to this general rule are described in rules 10 and 11.

(10) For priority toxic pollutants where the State has adopted human health criteria and received EPA approval, but such criteria do not fully satisfy section 303(c)(2)(B) requirements, the rule includes human health criteria for such pollutants. For example, consider a case where a State has a water supply segment that poses an exposure risk to human health from both water and fish consumption. If the State has adopted, and received approval for, human health criteria based on water consumption only (e.g., Safe Drinking Water Act Maximum Contaminant Levels (MCLs)) which are less stringent than the "water + fish" criteria in Column D1 of § 131.36(b), the Column D1 criteria are promulgated for those water supply segments. The rationale for this is to ensure that both water and fish consumption exposure pathways are adequately addressed and human health is fully protected. If the State has adopted water consumption only criteria which are more stringent or equal to the Column D1 criteria, the "water + fish" criteria in Column D1 criteria are not promulgated.

(11) For priority toxic pollutants where the State has adopted aquatic life criteria and previous to the 1987 CWA Amendments received EPA approval, but such criteria do not fully satisfy section 303(c)(2)(B) requirements, the rule includes aquatic life criteria for such pollutants. For example, if the State has adopted not-to-be-exceeded aquatic life criteria which are less stringent than the 4-day average chronic aquatic life criteria in § 131.36(b) (i.e., in Columns B2 and C2), the acute and chronic aquatic life criteria in § 131.36(b) are promulgated for those pollutants. The rationale for this is that the State-adopted criteria do not protect resident aquatic life from both acute and chronic effects, and that Federal criteria are necessary to fully protect aquatic life designated uses. If the State has adopted not-to-be-exceeded aquatic life criteria which are more stringent or equal to the chronic aquatic life criteria in § 131.36(b), the acute and chronic aquatic life criteria in § 131.36(b) are not promulgated for those pollutants.

(12) Under certain conditions discussed in rules, 9, 10, and 11, criteria listed in § 131.36(b) are not promulgated for specific pollutants; however, EPA made such exceptions only for pollutants for which criteria have been adopted by the State and approved by EPA, where such criteria are currently effective under State law the appropriate EPA Region concluded that the State's criteria fully satisfy section 303(c)(2)(B) requirements.

3. Approach for States that Fully Comply Subsequent to Issuance of this Final Rule

As discussed in prior Sections of this Preamble, the water quality standards program has been established with an emphasis on State primacy. Although this rule was developed to Federally promulgate toxics criteria for States, EPA prefers that States maintain primacy, revise their own standards, and achieve full compliance. EPA is hopeful this rule will provide additional impetus for non-complying States to adopt the criteria for priority toxic pollutants necessary to comply with section 303(c)(2)(B).

Removal of a State from the rule will require another rulemaking by EPA according to the requirements of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). EPA will withdraw the Federal rule without a notice and comment rulemaking when the State adopts standards no less stringent than the Federal rule (i.e., standards which provide, at least, equivalent environmental and human health protection). For example, see 51 FR 11580, April 4, 1986, which finalized EPA's removal of a Federal rule for the State of Mississippi.

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

EPA cautions States and the public that promulgation of this Federal rule removes most of the flexibility available to States for modifying their standards on a discharger-specific or stream-specific basis. For example, variances and site-specific criteria development are actions sometimes adopted by the States. These are optional policies under terms of the Federal water quality standards regulation. Except for the water-effect ratio for certain metals, EPA has not incorporated either optional policy, in general, in this rulemaking; that is, EPA has not generally authorized State modification of Federal water quality standards. Each of these types of modifications will, in general, require Federal rulemaking on a case-by-case basis to change the Federal rule. Because of the time consuming nature of reviewing such requests, limited Federal resources, and the need for the Agency to move into other priority programs areas in establishing environmental controls, EPA alerts the States and the public that a prompt Agency response to requests for variances and site-specific modifications to the Federal criteria is unlikely. The best course of action, if such provisions are desired in a State, is for a State to adopt its own standards and take advantage, if it so chooses, of the flexibility offered by these optional provisions.

The Federal criteria published today are effective in 45 days. However, this action does not change existing applicable State and EPA provisions related to permit issuance or reissuance as they affect schedules of compliance. EPA and the States may continue issuing permits containing enforceable compliance schedules for these Federally established water quality standards if it is consistent with State policy.

F. Derivation of Criteria

1. Section 304(a) Criteria Process

Under the authority of CWA section 304(a), EPA has developed methodologies and specific criteria to protect aquatic life and human health. These methodologies are intended to provide protection for all surface water on a national basis. As described below, there are site-specific procedures for more precisely addressing site-specific conditions for an individual water body. However, the water quality criteria are scientifically sound and will achieve the statutory objective of protecting designated uses even in the absence of these modification procedures. Although the site-specific procedures may allow for more precise criteria for certain waterbodies, these procedures are infrequently used because the Section 304(a) criteria recommendations are designed to protect all waterbodies and have proven themselves to be appropriate. The methodologies have been subject to public review, as have the individual criteria documents. Additionally, the methodologies have been reviewed and approved by EPA's Science Advisory Board of external experts. Additional comments on the methodologies were taken as part of this action and have been considered and responded to in developing this final rule. In addition, these comments will be considered in the Agency's ongoing effort to propose revised methodologies for public review and comment in fiscal year 1993.

EPA incorporated by reference into the record of this rule the aquatic life methodology as described in "Appendix B—Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses" (45 FR 79341, November 28, 1980) as amended by "Summary of Revisions to Guildlines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (50 FR 30792, July 29, 1985).

Note: Throughout the remainder of this rule, this reference is described as the 1985 Guidelines. Any page number references are to the actual guidance document, not the notice of availability in the **Federal Register**. The actual guidelines document was available through the National Technical Information Service (PB85-227049), is in the record of this rulemaking, and is abstracted in Appendix A of Quality Criteria for Water, 1986.

EPA also incorporated by reference into the record of this rule the human health methodology as described in "Appendix C—Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Criteria Documents" (45 FR 79347, November 28, 1980).

Note: Throughout the remainder of this Preamble, this reference is described as the Human Health Guidelines or the 1980 Guidelines.

EPA also recommends that the following be reviewed: "Appendix D—Response to Comments on Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses," (45 FR 79357, November 28, 1980); "Appendix E—Responses to Public Comments on the Human Health Effects Methodology for Deriving Ambient Water Quality Criteria" (45 FR 79368, November 28, 1980); and "Appendix B—Response to Comments on Guidelines for Deriving Numerical National Water quality Criteria for the Protection of Aquatic Organisms and Their Uses" (50 FR 30793, July 29, 1985). EPA also placed into the record the most current individual criteria documents for the priority toxic pollutants included in today's rule.

The primary focus of this rule is the inclusions of the water quality criteria for pollutant(s) in State standards as necessary to support water quality-based control programs. The Agency accepted comment on the criteria proposed for inclusion in this rule. However, Congress established a very ambitious schedule for the promulgation of the final criteria. The statutory deadline in section 303(c)(4) clearly indicates that Congress intended the Agency to move very expeditiously when Federal action is warranted.

The methodology used to develop the criteria and the criteria themselves (to the extent not updated through IRIS) have previously undergone scientific peer review and public review and comment, and have been revised as appropriate. For the most part, this review occurred before Congress amended the Act in 1987, to require the inclusion of numeric criteria for certain toxic pollutants in State standards. Congress acted with full knowledge of the EPA process for developing criteria and the Agency's recommendations under section 304(a). EPA believes it is consistent with Congressional intent to rely in large part on existing criteria rather than engage in a time-consuming reevaluation of the underlying basis for water quality criteria. Accordingly, the Agency stands by its prior decisions regarding its published methodology and criteria even after review of the comments received. It is the Agency's belief that this approach will best achieve the purpose of moving forward in promulgating criteria for States not in compliance with section 303(c)(2)(B) so that environmental controls intended by Congress can be put into place to protect public health and welfare and enhance water quality.

It should be noted that the Agency is initiating a review of the basic guidelines for developing criteria and that comments received during this rulemaking will be considered in that effort. Future revisions to the criteria guidelines will be reviewed by the Agency's Science Advisory Board and submitted to the public for review and comment following the same process that was used in issuing the existing methodological guidelines. Subsequent revisions of criteria documents and the issuance of any new criteria documents will also be subject to the public review.

2. Aquatic Life Criteria

Aquatic life criteria may be expressed in numeric or narrative forms. EPA's 1985 Guidelines describe an objective, internally consistent and appropriate way of deriving chemical-specific, numeric water quality criteria for the protection of the presence of, as well as the uses of, both fresh and marine water aquatic organisms.

An aquatic life criterion derived using EPA's section 304(a) method "might be thought of as an estimate of the highest concentration of a substance in water which does not present a significant risk to the aquatic organisms in the water and their uses." (45 FR 79341.) The term "their uses" refers to consumption by humans and wildlife (1985 Guidelines, page 48). EPA's guidelines are designed to derive criteria that protect aquatic communities by protecting most of the species and their uses most of the time, but not necessarily all of the species all of the time (1985 Guidelines, page 1). Aquatic communities can tolerate some stress and occasional adverse effects on a few species so that total protection of all species all of the time is not necessary. EPA's 1985 Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of substantial overprotection or underprotection. As discussed in detail below, there are several individual factors which may make the criteria somewhat overprotective or underprotective. The approach EPA is using is believed to be as well balanced as possible, given the state of the science.

Numerical aquatic life criteria derived using EPA's 1985 Guidelines are expressed as short-term and long-term numbers, rather than one number, in order that the criteria more accurately reflect toxicological and practical realities. The combination of a criteria maximum concentration (CMC), a one-hour average acute limit, and a criteria continuous concentration (CCC), a four-day average concentration chronic limit, provide protection of aquatic life and its uses from acute and chronic toxicity to animals and plants, and from bioconcentration by aquatic organisms, without being as restrictive as a one-number criterion would have to be. (1985 Guidelines, pages 4–5.)

The two-number criteria are intended to identify average pollutant concentrations which will produce water quality generally suited to maintenance of aquatic life and their uses while restricting the duration of excursions over the average so that total exposures will not cause unacceptable adverse effects. Merely specifying an average value over a time period is insufficient unless the time period is short, because excursions higher than the average can kill or cause substantial damage in short periods.

A minimum data set of eight specified families is required for criteria development (details are given in the 1985 Guidelines, page 22). The eight specific families are intended to be representative of a wide spectrum of aquatic life. For this reason it is not necessary that the specific organisms tested be actually present in the water body. States may develop site-specific criteria using native species, provided that the broad spectrum represented by the eight families is maintained. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available.

EPA's application of guidelines to develop the criteria matrix in the final rule is judged by the Agency to be applicable to all waters of the United States, and to all ecosystems (1985 Guidelines, page 4). There are waters and ecosystems where site-specific criteria could be developed, as discussed below, but it is up to States to identify those waters and develop the appropriate site-specific criteria.

Fresh water and salt water (including both estuarine and marine waters) have different chemical compositions, and freshwater and saltwater species rarely inhabit the same water simultaneously. To provide additional accuracy, criteria developed recently are developed for fresh water and for salt water.

Assumptions which may make the criteria underprotective include the fact that not all species are protected, the use of criteria on an individual basis, with no consideration of additive or synergistic effects, and the general lack of consideration of impacts on wildlife, due principally to a lack of data. Chemical toxicity is often related to certain receiving water characteristics, (pH, hardness, etc.) of a waterbody. Adoption of some criteria without consideration of these parameters could result in the criteria being overprotective.

3. Criteria for Human Health

EPA's section 304(a) human health guidelines attempt to provide criteria which minimize or specify the potential risk of adverse human effects due to substances in ambient water (45 FR 79347). EPA's section 304(a) criteria for human health are based on two types of biological endpoints: (1) Carcinogenicity and (2) systemic toxicity (i.e., all other adverse effects other than cancer). Thus, there are two procedures for assessing these health effects: one for carcinogens and one for non-carcinogens.

EPA's human health guidelines assume that carcinogenicity is a "non-threshold phenomenon," that is, there are no "safe" or "no-effect levels" because even extremely small doses are assumed to cause a finite increase in the incidence of the response (i.e., cancer). Therefore, EPA's water quality criteria for carcinogens are presented as pollutant concentrations corresponding to increases in the risk of developing cancer.

For pollutants that do not manifest any apparent carcinogenic effects in animal studies (i.e., systemic toxicants), EPA assumes that the pollutant has a threshold below which no effects will be observed. This assumption is based on the premise that a physiological mechanism exists within living organisms to avoid or overcome the adverse effects of the pollutant below the threshold concentration.

The human health risks of a substance cannot be determined with any degree of confidence unless dose-response relationships are quantified. Therefore, a dose-response assessment is required before a criterion can be calculated. The dose-response assessment determines the quantitative relationships between the amount of exposure to a substance and the onset of toxic injury or disease. Data for determining dose-response relationships are typically derived from animal studies, or less frequently, from epidemiological studies in exposed populations.

The dose-response information needed for carcinogens is an estimate of the carcinogenic potency of the compound. Carcinogenic potency is defined here as a general term for a chemical's human cancer-causing potential. This term is often used loosely to refer to the more specific carcinogenic or cancer slope factor which is defined as an estimate of carcinogenic potency derived from animal studies or epidemiological data of human exposure. It is based on extrapolation from test exposures of high dose levels over relatively short periods of time to more realistic low dose levels over a lifetime exposure period by use of linear extrapolation models. The cancer slope factor, $q1^*$, is EPA's estimate of carcinogenic potency and is intended to be a conservative upper bound estimate (e.g. 95% upper bound confidence limit).

For non-carcinogens, EPA uses the reference dose (RfD) as the dose response parameter in calculating the criteria. The RfD was formerly referred to as an "Acceptable Daily Intake" or ADI. The RfD is useful as a reference point for gauging the potential effects of other doses. Doses that are less than the RfD are not likely to be associated with any health risks, and are therefore less likely to be of regulatory concern. As the frequency of exposures exceeding the RfD increases and as the size of the excess increases, the probability increases that adverse effects may be observed in a human population. Nonetheless, a clear conclusion cannot be categorically drawn that all doses below the RfD are "acceptable" and that all doses in excess of the RfD are "unacceptable." In extrapolating non-carcinogen animal test data to humans to derive an RfD, EPA divides a no-observed-effect dose observed in animal studies by an "uncertainty factor" which is based on profession judgment of toxicologists and typically ranges from 10 to 10,000.

For section 304(a) criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. This is the exposure default assumption although the human health guidelines provide for considering other sources where data are available (see 45 FR 79354). Thus the criteria are based on an assessment of risks related to the surface water exposure route only.

The assumed exposure pathways in calculating the criteria are the consumption of 2 liters per day at the criteria concentration and the consumption of 6.5 grams per day of fish/shellfish contaminated at a level equal to the criteria concentration but multiplied by a "bioconcentration factor." The use of fish consumption as an exposure factor requires the quantification of pollutant residues in the edible portions of the ingested species. Bioconcentration factors (BCFs) are used to related pollutant residues in aquatic organisms to the pollutant concentration in ambient waters. BCFs are quantified by various procedures depending on the lipid solubility of the pollutant. For lipid soluble pollutants, the average BCF is calculated from the weighted average percent lipids in the edible portions of fish/shellfish, which is about 3%; or it is calculated from theoretical considerations using the octanol/water partition coefficient. For non-lipid soluble compounds, the BCF is determined empirically. The assumed water consumption is taken from the National Academy of Sciences publication "Drinking Water and Health" (1977). (Referenced in Human Health Guidelines, 45 FR 79356). The 6.5 grams per day contaminated fish consumption value is equivalent to the average per-capita consumption rate of all (contaminated and non-contaminated) freshwater and estuarine fish for the U.S. population. (See Human Health Guidelines, 45 FR 79348.)

EPA also assumes in calculating water quality criteria that the exposed individual is an average adult with body weight of 70 kilograms. The issue of concern is dose per kilogram of body weight. EPA assumes 6.5 grams per day of contaminated fish consumption and 2 liters per day of contaminated drinking water consumption for a 70 kilogram person in calculating the criteria. Persons of smaller body weight are expected to ingest less contaminated fish and water, so the dose per kilogram of body weight is generally expected to be roughly comparable. There may be subpopulations within a State, such as subsistence fishermen, who as a result of greater exposure to a contaminant, are at greater risk than the hypothetical 70 kilogram person eating 6.5 grams per day of maximally contaminated fish and shellfish and drinking 2 liters per day of maximally contaminated drinking water.

For example, individuals that ingest ten times more of a pollutant than is assumed in derivation of the criteria at a 10^{-6} risk level will be protected to a 10^{-5} level, which EPA has historically considered to be adequately protective. There may, nevertheless, be circumstances where site-specific numeric criteria that are more stringent than the State-wide criteria are necessary to adequately protect highly exposed subpopulations. Although EPA intends to focus on promulgation of appropriate State-wide criteria that will reduce risks to all exposed individuals, including highly exposed subpopulations, site-specific criteria may be developed subsequently by EPA or the States where warranted to provide necessary additional protection. (See Human Health Guidelines, Issue 8, 45 FR 79369.)

For non-carcinogens, oral RfD assessments (hereinafter simply "RfDs") are developed based on pollutant concentrations that cause threshold effects. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. (See Human Health Guidelines, 45 FR 79348.)

Criteria are calculated for individual chemicals with no consideration of additive, synergistic or antagonistic effects in mixtures. If the conditions within a State differ from the assumptions EPA used within the constraints of the Federal rule, the States have the option to perform the analyses for their conditions.

EPA has a process to develop a scientific consensus on oral reference dose assessments and carcinogenicity assessments (hereinafter simply cancer slope factors or slope factors). Reference doses and slope factors are validated by two Agency work groups (i.e., one work group for each) which are composed of senior Agency scientists from all of the program offices and the Office of Research and Development. These work groups develop a consensus of Agency opinion for RfDs and slope factors which are then used throughout the Agency for consistent regulation and guidance development. EPA maintains an electronic data base which contains the official Agency consensus for oral RfD assessments and carcinogenicity assessments which is known as the Integrated Risk Information System (IRIS). It is available for use by the public on the National Institutes of Health's National Library of Medicine's *TOXNET system, and through diskettes* from the National Technical Information Service (NTIS). (NTIS access number is PB 90-591330).

For the criteria included in today's rule, EPA used the criteria recommendation from the appropriate Section 304(a) criteria document. (The availability of EPA's criteria documents has been announced in various Federal Register Notices. These documents are also placed in the record for today's rule.) However, if the Agency has changed any parameters in IRIS used in criteria derivation since issuance of the criteria guidance document, EPA recalculated the criteria recommendation with the latest information, invited comment on the updating procedure and the numbers that would be derived from it. (This information is included in the record.) Thus, there may be differences between the original criteria guidance document recommendation, and those in this rule, but this rule presents the Agency's most current section 304(a) criteria recommendation. The recalculated human health numbers are denoted by an "a" in the criteria matrix in subsection 131.36(b) of today's rule.

A difficult and controversial problem facing both the States and EPA in attempting to comply with the requirements of section 303(c)(2)(B) involved selecting a criterion for 2,3,7,8-TCDD (dioxin). EPA, the States, dischargers, environmental groups and the public at large have been involved in discussions concerning the ambient level of protection that is protective of public health. At issue during the State debates on selecting criterion for dioxin and in comments to this rulemaking are scientific questions specific to dioxin such as determining the carcinogenic potency of the pollutant and the extent to which the pollutant tends to accumulate in fish tissues. Other issues are raised that are more generic to EPA's human health criteria. Most of these issues relate, directly or indirectly, to concerns expressed by dischargers regarding the cost of complying with water quality-based effluent limits for dioxin.

In order to base its regulatory decisions on the best available science, EPA continuously updates its assessment of the risk from exposure to contaminants. On September 11, 1991, EPA's Office of Research and Development (ORD) began reassessing the scientific models and exposure scenarios used to predict the risks of biological effects from exposure to low levels of dioxin. This reassessment has the potential to alter the risk assessment for dioxin and accordingly the Agency's regulatory decisions related to dioxin. At this time, EPA is unable to say with any certainty what the degree or directions of any changes in risk estimates might be. Moreover, the results of the assessment and any potential impact on the criteria limit will not be known for quite some time.

Considerable comment was received that the Agency not include dioxin in the rule pending the results of the dioxin reassessment. However, no additional data was submitted by the commenters that adds to the information available upon which to make a decision. Based on information currently available to the Agency and in the face of known uncertainties, the limit promulgated today is within the range of scientific defensibility.

A State may adopt a different limit subsequent to this rule, following the normal procedures for adopting or revising water quality standards (40 FR 131). The adoption by a State of a new or revised criterion for dioxin, whether more or less stringent than the existing section 304(a) guidance, will be accepted by the Agency based on the results of the Agency's reassessment without any further justification. Once a State adopts a new dioxin criterion, the permitting authority, either EPA or the State (if authorized to administer a permit program), may change the effluent limitation for dioxin in a permit subject to the antibacksliding requirements of sections 402(o) and 303(d)(4) of the CWA and the antidegradation policy of the State.

This final rule includes criteria for dioxin. This action encourages and supports the ongoing efforts of fourteen States actively considering adopting criteria for dioxin. Most of these States are relying on the same data used by EPA in deriving its criterion for dioxin. In addition, dioxin limits are included as appropriate in Individual Control Strategies (ICS's) developed under section 304(l), so there should be no immediate regulatory action that will be based upon the promulgation of Federal criteria.

Moreover, as discussed in more detail in Section J, Executive Order 12291, example 5, it is unlikely that the practical impact of including dioxin at the 0.013 ppq level in this rule will affect the need for treatment and thus, is unlikely to be the basis for any incremental costs for pulp and paper mills to reduce dioxin discharges.

4. Section 304(a) Human Health Criteria Excluded

Today's rule does not contain certain of the section 304(a) criteria for priority toxic pollutants because those criteria were not based on toxicity. The basis for these particular criteria are organoleptic effects (e.g., taste and odor) which would make water and edible aquatic life unpalatable but not toxic. Because the basis for this rule is to protect the public health and aquatic life from toxicity consistent with the language and intent in section 303(c)(2)(B), EPA is promulgating criteria only for those priority toxic pollutants whose criteria recommendations are based on toxicity. The Section 304(a) human health criteria based on organoleptic effects for copper, zinc, 2,4-dimethylphenol, and 3-methyl-4-chlorophenol are excluded for this reason.

5. Cancer Risk Level

EPA's section 304(a) criteria guidance documents for priority toxic pollutants that are based on carcinogenicity present concentrations for upper bound risk levels of 1 excess cancer per 100,000 people (10^{-5}), per 1,000,000 people (10^{-6}), and per 10,000,000 people (10^{-7}). However, the criteria documents do not recommend a particular risk level as EPA policy.

In the April, 1990, Federal Register notice of preliminary assessment of State compliance, EPA announced its intention to propose this rule with an incremental cancer risk level of one in a million (10^{-6}) for all priority toxic pollutants regulated as carcinogens (55 FR 14351). This risk level was in fact proposed in the November 19, 1991 Federal Register Notice of proposed rulemaking. However, EPA's Office of Water's guidance to the States has consistently reflected the Agency's policy of accepting cancer risk policies from the States in the range of 10^{-6} to 10^{-4} (see 45 FR 79323, November 28, 1980; Guidance for State Implementation of Water Quality Standards for CWA section 303(c)(2)(B), November 12, 1988 (54 FR 346); see also document described in footnote 3 of this preamble). EPA reviews individual State policies as part of its water quality standards oversight function and determines if States have appropriately consulted their citizenry and applied good science in adopting water quality criteria.

In the proposal, EPA not only sought public comment on its decision to propose criteria based on a 10^{-6} risk level, but also specifically solicited comment on an alternate risk level of 10^{-5}. EPA received extensive comments that the proposed application of the criteria at the 10^{-6} risk level was contrary to Agency policy, contradicted other risk levels accepted by EPA in States included in the proposal, oversteps EPA authority by failing to recognize that such a decision more properly should be a State decision, given their primary authority to establish water quality standards, and that EPA should not include a risk level in the final rule.

Upon consideration of these comments, EPA agrees that establishing a single risk level for all States departs from Agency policy in the standards program. The application of the human health criteria in today's rule, on a State-by-State basis, therefore, has been changed. In today's rule, the risk level for each State is based on the best information available to the Agency as to each State's policy or practice regarding what risk level is, or should be, used in regulating carcinogens in surface waters. In most cases the risk levels were based on a State-adopted or formally proposed risk level, or in the case of Idaho, Rhode Island, and Nevada on an expression of State policy preference. EPA is therefore promulgating criteria at either the 10^{-5} or 10^{-6} risk level, either of which is consistent with EPA policy and with the requirements of the Clean Water Act.

The Agency recognizes that it made some of its decisions regarding the appropriate risk level on limited data. However, in the time available to the Agency, we relied on the best available information. The Agency believes it is important to move forward with this rule based on available information. To ensure that the Agency has selected the appropriate risk level for each State, the Agency is providing a final opportunity for the Governor of each State (or other official with authority to determine risk levels with respect to water quality criteria) to inform EPA if they believe a different risk level should be selected for their State.

Today's regulation will become effective 45 days from publication in the Federal Register. However, if within 30 days of publication of this rule in the Federal Register, the Governor or other appropriate official determines that the final rule is not based on the correct State policy or practice with regard to risk levels, the Governor (or other appropriate official) may request the Administrator in writing to adopt a different risk level for the State.

Note: The Governor is not constrained to requesting the Administrator to adopt a single risk level for all carcinogenic compounds. It is also acceptable for a State to select more than one risk level. For example, New Jersey is proposing to adopt 10^{-6} for Class A and B carcinogens, and 10^{-5} for Class C carcinogens. In this rule, EPA is promulgating the two risk level concept for New Jersey. The Governor must explain the basis for the request to change the risk level.

If EPA determines, after receipt of such a letter from the Governor or other appropriate State official, the State's preference is consistent with EPA policy, as set out in this rulemaking, and the requirements of the Clean Water Act, EPA will amend the rule accordingly.

As noted above, in this rulemaking EPA is adopting risk levels that it believes best reflects the expressed preferences of the covered States (10^{-6} or 10^{-5} for all carcinogens). If there were, however, no clear expression of preference by a State, EPA also believes it is reasonable for States to adopt a risk level of 10^{-5} for many of the covered carcinogens and a more stringent risk level of 10^{-6} for those carcinogens with substantially higher bioconcentration factors. Recognizing the current limitations of the scientific data available for this rulemaking, EPA believes it would be reasonable to conclude that carcinogens that bioaccumulate, particularly given the exposure of fishermen to such carcinogens, may justify a more protective risk level of 10^{-6} for the average fish consumer, but for other carcinogens a less conservative level (10^{-5}) may be appropriate.

6. Applying EPA's Nationally Derived Criteria to State Waters

To assist States in modifying EPA's water quality criteria, the Agency has provided guidance on developing site specific-criteria for aquatic life and human health (see Chapter 4, Water Quality Standards Handbook, Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses, and the Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents). This guidance can be used by the appropriate regulatory authority to develop alternative criteria. Where such criteria are more stringent than the criteria promulgated today, Section 510 of the Clean Water Act (33 U.S.C. 1370) allows their implementation and enforcement in lieu of today's promulgated criteria.

EPA's experience with such site-specific criteria has verified that the national criteria are generally protective and appropriate for direct use by the States. (See Response to Comments on the 1985 Aquatic Life Guidelines, Comment 57, 50 FR 30796, July 29, 1985.)

7. Application of Metals Criteria

A substantial number of comments were received requesting Agency guidance on the implementation of metals criteria for aquatic life. In response, the Agency has prepared guidance on this issue, which is described in general terms below, and which is being applied to the metals criteria being promulgated today. Responses to individual comments may be found in section I, comments 19 to 53.

In selecting an approach for implementing the metals criteria, the principal issue is the correlation between metals that are measured and metals that are biologically available and toxic, as discussed more fully in EPA's Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, U.S. EPA, 1992, Office of Science and Technology, May 1992. (Notice of availability published at 57 FR 24041, June 5, 1992.

In order to assure that the metals criteria are appropriate for the chemical conditions under which they are applied, EPA is promulgating the criteria in terms of total recoverable metal and providing for adjustment of the criteria through application of the "water-effect ratio" procedure as described and recommended in the above Guidance document. This procedure was developed in the early 1980's, and was originally set forth, along with several case study applications, as the Indicator Species procedure in Chapter 4 of the Water Quality Standards Handbook (U.S. EPA 1983 at page 4–12). EPA notes that performing the testing to use site-specific water-effect ratios is optional on the part of the States.

In natural waters metals may exist in a variety of dissolved and particulate forms. The bioavailability and toxicity of metals depend strongly on the exact physical and chemical form of the metal. Generally, dissolved metal has greater toxicity than particulate metal, and for some metals, such as copper, certain dissolved forms have greater toxicity than other dissolved forms. Because the speciation among the various forms of a particular metal may vary from place to place, the same metal concentration may cause different toxicity from place to place.

With one exception (selenium), EPA's metals criteria for aquatic life protection are developed from laboratory toxicity data. Use of laboratory toxicity testing is usually much more cost-effective for obtaining data on (1) the toxicity of substances to a variety of species, and (2) the effect of various water quality characteristics on toxicity. (See 1980 Aquatic Life guidelines, comment 21, 45 FR 79360. See also responses to comments 17, 18, 19, 20.) The dilution water used in laboratory toxicity tests is ordinarily low in particulate matter (i.e. suspended solids), and low in organic matter compared to many ambient waters. As a result, laboratory toxicity tests are ordinarily more likely to overestimate the toxicity than underestimate the toxicity of metals in some ambient waters, particularly fresh waters.

Because of the complexity of metals speciation and its effect on toxicity, the relationship between measured concentrations and toxicity is not precise. Consequently, any method that could be recommended would not guarantee precise comparability between concentrations measured in the field and concentrations employed in the toxicity tests underlying the criteria.

For metals criteria derived from laboratory toxicity tests, the best approach is to use a biological method to compare bioavailability and toxicity in receiving waters versus laboratory test waters (the water-effect ratio) and to adjust the criteria values accordingly. This involves running toxicity tests for at least two species, each preferably from a different family, measuring acute (and possibly chronic) toxicity values for the pollutant using (a) the local receiving water, and (b) standard laboratory toxicity testing water, which is also the source of toxicity test dilution water. A water-effect ratio is the acute (or chronic) value in site water divided by the acute (or chronic) value in standard laboratory water. An acute value is an LC50 from a 48–96 hour test, as appropriate for the species. A chronic value is a concentration resulting from hypothesis testing or regression analysis of measurements of survival, growth, or reproduction in life cycle, partial life cycle, or early life stage tests on aquatic species.

Chemical approaches for defining and comparing bioavailable metal are subject to greater uncertainty than the above biological approach.

Chemical approaches, such as dissolved and total recoverable metals are easier to apply than biological approaches. One approach that EPA has approved in State standards is to measure metals in ambient waters in terms of dissolved metal, and to compare such measurements to criteria appropriate for dissolved metal. Since effluent limits, for both technical and legal (see NPDES permits regulation, 40 CFR 122.45) reasons, should be expressed in terms of total recoverable metal, it is necessary to translate between the dissolved and total recoverable concentrations. EPA has not incorporated the alternative of dissolved metals criteria into this rule, because the use of the water-effect ratio accomplishes the same ends but is technically superior and subject to fewer uncertainties than implementation of the criteria as dissolved concentrations.

The simplest approach for ambient metals standards is the use of the total recoverable analytical method without a water-effect ratio adjustment. This is a reasonable, albeit environmentally conservative strategy, for applying EPA's aquatic life criteria. Where the toxicity testing necessary to develop an alternative water-effect ratio has not been performed, this rule will apply the total recoverable analytical method without a water-effect ratio adjustment. This occurs because EPA assigns the water-effect ratio a value of 1.0, subject to being rebutted by toxicity testing results.

Because of the comments received, and because of the desire to achieve the greatest possible degree of accuracy, EPA has chosen to apply the total recoverable metals criteria unadjusted for site-specific water chemistry, unless the State adjusts the criteria through the use of a water-affect ratio as provided for in this rule. Allowance for water-effect ratio adjustment also satisfies the concerns of comments requesting consideration of dissolved criteria.

The water-effect ratio approach compares bioavailability and toxicity of a specific pollutant in receiving waters and in laboratory test waters. It involves running toxicity tests for at least two species an appropriate number of times, as determined by the States, ordinarily on samples collected in at least two seasons (or more where large metal loadings are involved). As with other site-specific procedures, the basic analysis or testing may be performed by the State, a permittee, or any other interested party. Acute or chronic toxicity for the pollutant are measured using (a) the local receiving water where the criterion is being implemented, and (b) standard laboratory toxicity testing water, as the sources of toxicity test dilution water. The water-effect ratio is calculated as the acute or chronic value in site water divided by respective acute or chronic values in standard laboratory water. Ordinarily, the geometric mean water-effect ratio from the valid tests is used for calculation of the criterion, except where protection of sensitive species requires a more stringent value. Because the metal's toxicity in standard laboratory water is the basis for EPA's criterion, this comparison is used to adjust the national criterion to a site-specific value. Because the procedure is a biological measure of differences in water chemistry, the water-effect ratio, even when derived from acute tests, usually may be assumed to also apply to chronic criteria.

For criteria that do not vary with hardness, the criterion for a specific site equals the acute or chronic value tabulated in the rule (i.e., the matrix in 40 CFR 131.36(b)) multiplied by the site-specific water-effect ratio for that pollutant. The result may either reduce or increase the stringency of the criteria.

For criteria whose toxicity varies with hardness, the criterion for a specific site equals the criterion calculated at the design hardness (see 40 CFR 131.36(c)(4)), multiplied by the site-specific water-effect ratio.

The water-effect ratio is assigned a value of 1.0, unless scientifically defensible data clearly demonstrate that a value less than 1.0 is necessary or a value greater than 1.0 is sufficient to fully protect the designated uses of the water body from the toxic effects of the pollutant. Any data accepted for calculation of the water-effect ratio is to be generated through standard toxicity testing protocols (EPA recommends the methodology in Annual Book of ASTM Stds. 1991, Vol 11.04. ASTM. Philadelphia, PA.), using sampled ambient water representative of conditions in the affected water body, and using laboratory dilution water comparable to that used in toxicity tests underlying the criteria. The guidance documents cited at the beginning of this section provides more guidance on generating the information necessary to determine the correct value of the water-effect ratio. However, EPA intends within the next few months to provide additional guidance or performing the analyses necessary to develop scientifically defensible water-effect ratios for metals. As envisioned at this time, EPA will expand Chapter 4 in the Handbook to apply the appropriate procedures described there specifically to metals. EPA will look at the chemical characteristics of the laboratory water used in the toxicity tests included in the metals criteria data base, appropriate test organisms, analytical methods, safeguards against unintended metals contamination during toxicity testing, and appropriate data handling and statistics. While EPA believes the current guidance is adequate for application of the water-effect ratio, the additional guidance should help standardize procedures and make results more comparable and defensible.

The rule as promulgated is constructed as a rebuttable presumption. The water-effect ratio is assigned a value of 1.0 but provides that a State may assign a different value derived from suitable tests. As EPA has noted elsewhere, the actual decision as to the numeric value assigned to a water-effect ratio may be made during a State or EPA NPDES permit proceeding provided that adequate notice and opportunity for public participation is provided. It is the responsibility of the permit writing authority to determine whether to apply the water-effect ratio in an NPDES permit. However, EPA believes use of the ratio will lead to more appropriate permit limits. States may wish to allow permittees to fund State-administered studies necessary to develop the ratio for particular waterbodies.

EPA reviews State issued NPDES permits. To facilitate EPA consideration of a State-developed water-effect ratio, a State should specify in documentation supporting that action what decisions were made for critical parameters such as toxicity testing protocols used, frequency of testing, critical periods for sampling and testing, and analytical quality control and assurance. Each of the factors must be articulated in a record as a basis for a determination that the water-effect ratio is scientifically defensible.

The procedure applies only to aquatic life criteria derived from laboratory toxicity data. That is, it applies to the acute and chronic criteria (Columns B and C in 40 CFR 131.36(b)) for arsenic, cadmium, chromium, copper, lead, nickel, and zinc. It also applies to the acute criteria for mercury and silver, and the saltwater acute and chronic criteria for selenium. It does not apply to the chronic criteria for mercury, because they are residue based, or to the freshwater acute and chronic criteria for selenium, because they are field based.

The water-effect ratio is affected not only by speciation among the various dissolved and particulate forms, but also by additive, synergistic, and antagonistic effects of other materials in the affected site waters. As such, the water-effect ratio is a rather comprehensive measure of the effect of water chemistry on the toxicity of a pollutant. Because the procedure accounts for any reduction in bioavailability resulting from binding of the metal to particulate matter, all metals criteria have been appropriately expressed as total recoverable metal in this rule.

Where measured water-effect ratios are used in deriving NPDES permit limits, data from appropriate testing during the term of the permit should be accumulated so that the value of the water-effect ratio can be reevaluated each time the permit is reissued. Thus, were measured water-effect ratios are involved, EPA recommends that NPDES permits establish monitoring requirements that include periodic determinations of water-effect ratios.

G. Description of the Final Rule and Changes From Proposal

1. Changes From Proposal

Several changes were made in the final rule from the proposal both as a result of Agency and State action with respect to the ongoing adoption of water quality standards by the States and because of the Agency's consideration of issues raised in specific public comments.

The States of Arizona, Colorado, Connecticut, Louisiana, New Hampshire, Virginia, the Commonwealth of the Northern Mariana Islands, and Hawaii are not included in the final rule as their standards were duly adopted and approved by EPA as fully meeting the requirements of section 303(c)(2)(B). Arizona's water quality standards were approved on March 2, 1992; Colorado's standards were approved by EPA on December 10, 1991; Connecticut on May 15, 1992; Louisiana on January 24, 1992; New Hampshire on June 25, 1992; Virginia on June 30, 1992; CNMI on January 13, 1992; and Hawaii on November 4, 1992. Copies of the approval letters are included in the record to this final rulemaking.

In addition, human health criteria adopted by the State of Arkansas were approved by EPA on January 24, 1992, and such criteria were removed from today's rule as it affects Arkansas. EPA is not promulgating and aquatic life criterion in Arkansas for arsenic because a review of monitoring data from 1985 to the present reveals no reason to conclude that arsenic will interfere with designated aquatic life uses. Additional details on EPA's action with respect to Arkansas may be found in Section I—Response to Public Comments, subsection 6.

Except for dioxin, criteria for the State of Florida for both human health and protection of aquatic life were approved by EPA on February 25, 1992. Florida is included in the rule only for the purposes of establishing a criterion for dioxin. More details on Florida's action are included in the Florida section of subsection 6 of the Response to Comments section of this preamble.

The criteria applicable to California have been revised to reflect a partial approval of the State's water quality standards on November 6, 1991. Additional comments with respect to California may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to the State of Washington was revised after discussion with the State as to EPA's interpretation of the uses designated by the State. The rule is now based on use categories rather than use classes. Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Alaska was modified to delete the assignment of criteria to a seafood processing use. This use falls under the standards program. However, because it applies to food preparation only, it is not appropriate to apply to it aquatic life or human health criteria. Additional aquatic life and human health criteria were added to several use classifications after discussions with the State clarified the State's use classifications. Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Idaho was modified to add additional criteria for the protection of primary contact recreation after discussions with the State concerning that use. Additional details may be found in subsection 6 of Section I—Response to Public Comments.

The rule as it applies to Kansas was changed by removing the promulgation of silver for sections (2) (A), (B), (C), and (6)(C) as the State has an EPA approved aquatic life criterion more stringent than the EPA criterion. The human health criterion for silver was removed because EPA has withdrawn its silver human health criterion.

The rule as it applies to New Jersey was revised to reflect comments received from the New Jersey Department of Environmental Protection and Energy to add waters classified as Pinelands and to extend coverage of the criteria to the mainstem Delaware River and Delaware Bay (zones 1C–6). Additional details on this change may be found in subsection 6 of Section I—Response to Public Comments.

Clarifications on several aspects of the rule with respect to implementation procedures are addressed in the response to public comments section of this preamble (section I).

Language was added in § 131.36(c)(4) dealing with the application of metals criteria as discussed in section F–7 of this preamble. We also added requirements to clarify how hardness should be handled in doing water-effect ratio determinations (see 131.36(c)(4)(iii), footnotes "e" and "m" to 131.36(b)).

The criteria for carcinogenic compounds included in this rule are applied at a risk level based on State preference as reflected by adopted or proposed standards, or in the case of Idaho, Nevada, and Rhode Island, on expression of State policy preference, rather than at an across-the-board 10^{-6} risk level as was proposed by the Agency. The rationale for this change is discussed in detail in section F–5 and there is additional discussion in the Response to Public Comment Section. The basis for EPA's selection of a risk level for an individual State is described in the following paragraphs:

Alaska: Risk Level: 10^{-5}

In July 1992, the State proposed human health water quality based on achieving a 10^{-5} risk level for two carcinogens: Dioxin and chloroform. Also, on November 16, 1992, the Commissioner of the Alaska Department of Environmental Conservation wrote the Director, Water Division, in EPA Region X, and indicated that ". . . I also had this matter reviewed by our Attorney General's Office, and hereby confirm the appropriateness of utilizing a 10^{-5} risk level for Alaska in the National Toxics Rule."

California: Risk Level: 10^{-6}

Standards adopted by the State contained in the Enclosed Bays and Estuaries Plan, and the Inland Surface Waters Plan, approved by EPA on November 6, 1991, and the Ocean Plan approved by EPA on June 28, 1990, contain a risk level of 10^{-6} for carcinogens. The total number of toxic pollutants differs in each plan but approximately 60–65 pollutants are covered.

District of Columbia: Risk Level: 10^{-6}

In 1985 the District adopted water quality criteria for human health, based solely on exposure through water consumption. The criteria were based on a 10^{-6} risk level. See D.C.M.R. title 21, chapter 1102.8(I).

Florida: Risk Level: 10^{-6}

The State adopted human health criteria for all toxic pollutants, except dioxin, and received EPA approval on February 25, 1992, at a risk level of 10^{-6}.

Idaho: Risk Level: 10^{-6}

On November 12, 1992, the Administrator of the Division of Environmental Quality, Idaho Department of Health and Welfare, indicated in a letter to the EPA Assistant Administrator for Water that while Idaho would be publishing proposed standards for public review and comment in the next several months. . . . "Until we know what standard the public in Idaho prefers, we believe it is prudent to adopt the more protected standards of ten to the minus six."

EPA Region X is the permit issuing authority for the State and applies 10^{-6} for water quality based human health requirements. These permits have been certified by the State under section 401 as meeting water quality standards.

Kansas: Risk Level: 10^{-6}

The State completed a series of public hearings in August 1992 on proposed water quality standards revisions and is now processing public comments leading to the final, formal adoption hearing scheduled for January 1993. Formal adoption is scheduled for February 1993. The risk level in the current proposed standards is 10^{-6}. See proposed K.A.R. 28-16-28e(c)(4)(B).

Michigan: Risk Level: 10^{-5}

For several years Michigan has been controlling toxics through application of the Guidelines for Rule 57. These guidelines are applied at a 10^{-5} risk level. See R 323, 1057(2)(d).

Nevada: Risk Level: 10^{-5}

On November 3, 1992, EPA received a letter from the Administrator of the Division of Environmental Protection, Department of Conservation and Natural Resources, ". . . that the public health risk level that DEP would prefer to see in federal regulations is 10^{-5} (one in one hundred thousand), unless a state can provide substantial support in the record that a risk level of 10^{-4} (one in ten thousand) is appropriate and protective. This gives states the flexibility to use a more conservative 10^{-6} risk level if they see fit, but without requiring it when it is not necessary."

New Jersey: Risk Level: 10^{-6} For Class A and B Carcinogens, 10^{-5} For Class C Carcinogens

New Jersey, on October 20, 1992, solicited public comment on proposed surface water quality standards. The comment period is to close on December 18, 1992. The proposed human health criteria for carcinogens are established on a two-tiered system for risk levels. See proposed N.J.A.C. 7:9B-1,5(a)4. The State previously had indicated their intention to do this in a letter to EPA on December 19, 1991.

Puerto Rico: Risk Level: 10^{-5}

In 1990, the State proposed and held public hearings on criteria for human health using a 10^{-5} risk level. Subsequently, the proposed standards were revised. Just recently the State completed public hearings on the most recent revision to standards. The standards are under review by the Environmental Quality Board. The risk level remains at 10^{-5}.

Rhode Island: Risk Level: 10^{-5}

On November 2, 1992, the EPA Regional Administrator received a letter from the Director, Department of Environmental Management, that, along with the Department of Health, the State's "* * * policy choice on the promulgation of the human health criteria is for the adoption of a cancer risk level of 10^{-5}." The Director also indicated that "* * * future modifications of this risk level, whether it be to 10^{-4} or 10^{-6}, could be considered on a pollutant and subpopulation basis to produce a site specific risk assessment and protection of human health."

Vermont: Risk Level: 10^{-6}

On May 27, 1991, State submitted to EPA final water quality standards which reference the EPA section 304(a) criteria to be applied at a 10^{-6} risk level. However, the effective date of these standards is not until January 1, 1995. This delayed effective date was the reason Region I advised the State that the State did not comply with section 303(c)(2)(B).

Washington: Risk Level: 10^{-6}

During the summer of 1992, the State formally proposed and held public hearings on revisions to its water quality standards. The standards, scheduled for adoption in late November 1992, include a risk level of 10^{-6}.

On December 18, 1991, in its official comments on the proposed rule, the Department of Ecology urged EPA to promulgate human health criteria at 10^{-6}. Specifically, "The State of Washington supports adoption of a risk level of one in one million for carcinogens. If EPA decides to promulgate a risk level below one in one million, the rule should specifically address the issue of multiple contaminants so as to better control overall site risks."

The final phrase in § 131.36(c)(2) relating to the applicability of the rule was amended by deleting the text beginning "but only * * *" EPA received numerous comments that the Federal criteria should be implemented consistently with current State practices. EPA amended the language because the Agency had not intended to be inconsistent with the provisions of the water quality standards regulation (40 CFR 131.21(c)), which provides that a State water quality standard remains in effect even though disapproved by EPA, until the State revises it or EPA promulgates a rule that supersedes the State water quality standards.

Although not directly resulting in a change to the rule, this preamble clarifies, at the public's request, whether schedules of compliance were applicable to this rule. In Section E-3 EPA clarifies that schedules of compliance for these criteria are not provided for in these rules, but that such schedules of compliance are available in NPDES permits if authorized by State regulations. See *In the Matter of Star-Kist Caribe, Inc.*, NPDES Appeal No. 88-5, Before the Environmental Appeals Board, EPA. May 26, 1992.

Several deletions were made to the proposed human health criteria as a result of the Agency's review of data submitted in public comments and to reflect the pertinent impact of other relevant Agency actions. The revisions are as follows:

(1) Criteria for three pollutants included in the matrix of the proposed rule are not included in the final rule for (A) acenaphthylene, (B) benzo(ghi)perylene, and (C) phenanthrene. The criteria for these pollutants were removed because they are not recognized by the Agency as carcinogenic compounds nor do they have a reference dose that would allow the Agency to calculate a criterion level.

(2) Silver: The human health criteria for silver were deleted from this final rule because the criteria were developed based on a cosmetic effect impact and not a toxicity endpoint.

(3) Cadmium, Chromium, Selenium and Beryllium: As described below, the Agency has determined that the proposed criteria for these contaminants are no longer scientifically defensible and accordingly has withdrawn these criteria pending evaluation of relevant data regarding their toxicity. EPA notes that the criteria promulgated for aquatic life will provide adequate protection for human health in most instances.

(4) Methyl Chloride, Lead and 1,1,1, Trichloroethane: As described below, the Agency has determined that there is currently an insufficient basis for calculating human health criteria for these three contaminants. Accordingly, EPA has withdrawn the proposed criteria for these contaminants pending further analysis.

In addition to the above changes, the Agency is today withdrawing the human health criteria recommendations previously published in the 1980 Ambient Water Quality Criteria Documents for silver, cadmium, chromium, selenium, beryllium, lead, methyl chloride, and 1,1,1, Trichloroethane. Summaries of the human health criteria were also published in Quality Criteria for Water, 1986. These summaries are also being officially withdrawn today.

EPA's final rule establishes a new § 131.36 in 40 CFR part 131 entitled, "Toxics Criteria for Those States Not Fully Complying with Clean Water Act, section 303(c)(2)(B)."

2. Scope

Subsection (a), entitled "Scope", clarifies that this Section is not a general promulgation of the section 304(a) criteria for priority toxic pollutants but is restricted to specific pollutants in specific States.

3. EPA Criteria for Priority Toxic Pollutants

As proposed, subsection (b) presents a matrix of the applicable EPA criteria for priority toxic pollutants. Section 303(c)(2)(B) of the Act addresses only pollutants listed as "toxic" pursuant to section 307(a) of the Act. As discussed earlier in this preamble, the section 307(a) list of toxics contains 65 compounds and families of compounds, which potentially include thousands of specific compounds. The Agency uses the list of 126 "priority toxic pollutants" for administrative purposes (see 40 CFR 131.36(b) herein). Reference in this rule to priority toxic pollutants, toxic pollutants, or toxics refers to the 126 priority toxic pollutants.

However, EPA has not developed both aquatic life and human health section 304(a) criteria for all of the 126 priority toxic pollutants. The matrix in paragraph (b) contains human health criteria in Column D for 91 priority toxic pollutants which are divided into criteria (Column 1) for water consumption (i.e., 2 liters per day) and aquatic life consumption (i.e., 6.5 grams per day of aquatic organisms), and Column 2 for aquatic life consumption only. The term aquatic life includes fish and shellfish such as shrimp, clams, oysters and mussels. The total number of priority toxic pollutants with criteria promulgated today differs from the total number of priority toxic pollutants with section 304(a) criteria because EPA has developed and is promulgating chromium criteria for two valence states with respect to aquatic life criteria. Thus, although chromium is a single priority toxic pollutant, there are two criteria for chromium for aquatic life. However, the human criterion is based on total chromium consistent with Agency policy. See pollutant 5 in § 131.36(b).

The matrix contains aquatic life criteria for 30 priority pollutants. These are divided into freshwater criteria (column B) and saltwater criteria (Column C). These columns are further divided into acute and chronic criteria. The aquatic life criteria are considered by EPA to be protective when applied under the conditions described in the section 304(a) criteria documents and in the "Technical Support Document for Water Quality-based Toxics Control." For example, waterbody uses should be protected if the criteria are not exceeded, on average, once every three year period. It should be noted that the criteria maximum concentrations (the acute criteria) are one-hour average concentrations and that the criteria continuous concentrations (the chronic criteria) are four-day averages. It should also be noted that for certain of the metals, the actual criteria are equations which are included as footnotes to the matrix. The toxicity of these metals are water hardness dependent and may be adjusted by determining appropriate water-effect ratios. The values shown in the table are based on a hardness expressed as calcium carbonate of 100 mg/l and a water-effect ratio of 1.0. Finally, the criterion for pentachlorophenol is pH dependent. The equation is the actual criterion and is included as a footnote. The value shown in the matrix is for a pH of 7.8 units.

Several of the freshwater aquatic life criteria are incorporated into the matrix in the format used in the 1980 criteria methodology which uses a final acute value instead of a continuous maximum concentration. This distinction is noted in footnote (g) to the table.

4. Applicability

Section 131.36(c) establishes the applicability of the criteria for each included State. It provides that the criteria promulgated for each State supersede and/or complement any State criteria for that toxic pollutant. EPA believes it has not superseded any State criteria for priority toxic pollutants unless the State-adopted criteria are disapproved or otherwise insufficient. The approach followed by the Agency in preparing § 131.36(d) is described in section E.2, and further rationale is provided in section E.3 of this preamble.

EPA's principal purpose today is to promulgate the toxics criteria necessary to comply with section 303(c)(2)(B). However, in order for such criteria to achieve their intended purpose the implementation scheme must be such that the final results protect the public health and welfare. In section F of this preamble a discussion focused on the factors in EPA's assessment of criteria for carcinogens. For example, fish consumption rates, bioaccumulation factors, and cancer potency slopes were discussed. When any one of these factors is changed, the others must also be evaluated so that, on balance, resulting criteria are adequately protective.

Once an appropriate criterion is selected for either aquatic life or human health protection, then appropriate conditions for calculating water quality-based effluent limits for that chemical must be established in order to maintain the intended stringency and achieve the necessary toxics control. EPA has included in this rule appropriate implementation factors necessary to maintain the level of protection intended. These factors are included in subsection (c).

For example, in order to do steady state waste load allocation analyses, most States have low flow values for streams and rivers which establish flow rates below which numeric criteria may be exceeded. These low flow values became design flows for sizing treatment plants and developing water quality-based effluent limits. Historically, these so-called "design" flows were selected for the purposes of waste load allocation analyses which focused on instream dissolved oxygen concentrations and protection of aquatic life. With the publication of the 1985 Technical Support Document for Water Quality Based Toxics Control (TSD), EPA introduced hydrologically and biologically based analyses for the protection of aquatic life and human health.[1] EPA recommended either of two methods for calculating acceptable low flows, the traditional hydrologic method developed by the U.S. Geological Survey and a biological based method developed by EPA. The results of either of these two methods may be used.

Some States have adopted specific low flow requirements for streams and rivers to protect designated uses against the effects of toxics. Generally these have followed the guidance in the TSD. However, EPA believes it is essential to include design flows for steady state analyses in today's rule so that, where

[1] These concepts have been expanded subsequently in guidance entitled "Technical Guidance Manual for Performing Wasteload Allocations, Book 6, Design Conditions," USEPA, Office of Water Regulations and Standards, Washington, DC. (1986). These new developments are included in Appendix D of the revised TSD. The discussion here is greatly simplified and is provided to support EPA's decision to promulgate baseline application values for instream flows and thereby maintain the intended stringency of the criteria for priority toxic pollutants.

States have not yet adopted such design flows, the criteria promulgated today would be implemented appropriately. The TSD also recommends the use of three dynamic models to perform wasteload allocations. Dynamic wasteload models do not generally use specific steady state design flows but accomplish the same effect by factoring in the probability of occurrence of stream flows based on the historical flow record. For simplicity, only steady state conditions will be discussed here. Clearly, if the criteria were implemented using inadequate design flows, the resulting toxics controls would not be fully effective, because the resulting ambient concentrations would exceed EPA's criteria.

In the case of aquatic life, more frequent violations than the once in 3 years assumed exceedences would result in diminished vitality of stream ecosystems characteristics by the loss of desired species such as sport fish. Numeric water quality criteria should apply at all flows that are equal to or greater than flows specified below. The low flow values are:

Aquatic Life
  acute criteria (CMC) 1 Q 10 or 1 B 3
  chronic criteria (CCC) 7 Q 10 or 4 B 3
Human Health
  non-carcinogens 30 Q 5
  carcinogens harmonic mean flow

Where:

1 Q 10 is the lowest one day flow with an average recurrence frequency of once in 10 years determined hydrologically;

1 B 3 is biologically based and indicates an allowable exceedence of once every 3 years. It is determined by EPA's computerized method (DFLOW model);

7 Q 10 is the lowest average 7 consecutive day low flow with an average recurrence frequency of once in 10 years determined hydrologically;

4 B 3 is biologically based and indicates an allowable exceedence for 4 consecutive days once every 3 years. It is determined by EPA's computerized method (DFLOW model);

30 Q 5 is the lowest average 30 consecutive day low flow with an average recurrence frequency of once in 5 years determined hydrologically; and

the harmonic mean flow is a long term mean flow value calculated by dividing the number of daily flows analyzed by the sum of the reciprocals of those daily flows.

EPA is promulgating the harmonic mean flow to be applied with human health criteria for carcinogens. The concept of a harmonic mean is a standard statistical data analysis technique. EPA's model for human health effects assumes that such effects occur because of a long-term exposure to low concentration of a toxic pollutant. For example, two liters of water per day for seventy years. To estimate the concentrations of the toxic pollutant in those two liters per day by withdrawal from streams with a high daily variation in flow, EPA believes the harmonic mean flow is the correct statistic to use in computing such design flows rather than other averaging techniques.[2]

All waters, whether or not suitable for such hydrologic calculations but included in this rule (including lakes, estuaries, and marine waters), must attain the criteria promulgated today. Such attainment must occur at the end of the discharge pipe, unless the State has a mixing zone regulation. If the State has a mixing zone regulation, then the criteria would apply at the locations stated in that regulation. For example, the chronic criteria (CCC) must apply at the geographically defined boundary of the mixing zone. Discussion of and guidance on these factors are included in the revised TSD in chapter 4.

EPA is aware that the criteria promulgated today for some of the priority toxic pollutants are at concentrations less than EPA's current analytical detection limits. Analytical detection limits have never been an acceptable basis for setting standards since they are not related to actual environmental impacts. The environmental impact of a pollutant is based on a scientific determination, not a measuring technique which is subject to change. Setting the criteria at levels that reflect adequate protection tends to be a forcing mechanism to improve analytical detection methods. (See 1985 Guidelines, page 21.) As the methods improve, limits closer to the actual criteria necessary to protect aquatic life and human health become measurable. The Agency does not believe it is appropriate to promulgate criteria that are not sufficiently protective.

EPA does believe, however, that the use of analytical detection limits are appropriate for determining compliance with NPDES permit limits. This view of the role of detection limits was recently articulated in guidance for translating dioxin criteria into NPDES permit limits which is the principal method used for water quality standards enforcement.[3] This guidance presents a model for addressing toxic pollutants which have criteria recommendations less than current detection limits. This guidance is equally applicable to other priority toxic pollutants with criteria recommendations less than current detection limits. The guidance explains that standard analytical methods may be used for purposes of determining compliance with permit limits, but not for purposes of establishing water quality criteria or permit limits. Under the Clean Water Act analytical methods are appropriately used in connection with NPDES permit limit compliance determinations. Because of the function of water quality criteria, EPA has not considered the sensitivity of analytical methods in deriving the criteria promulgated today.

EPA has added provisions in paragraph (c)(3) to determine when fresh water or saltwater aquatic life criteria apply. In response to comments, this provision was expanded to incorporate a time parameter to better define the critical condition. The structure of the paragraph is to establish presumptively applicable rules and to allow for site-specific exceptions where the rules are not consistent with actual field conditions. Because a distinct separation generally does not exist between fresh water and marine water aquatic communities, EPA is establishing the following: (1) The fresh water criteria apply at salinities of 1 part per thousand and below at locations where this occurs 95% or more of the time; (2) marine water criteria apply at salinities of 10 parts per thousand and above at locations where this occurs 95% more of the time; and (3) at salinities between 1 and 10 parts per thousand the more stringent of the two apply unless EPA approves the application of the freshwater or saltwater criteria based on a biological assessment. The percentiles included here were selected to minimize the chance of overlap, that is, one site meeting both criteria. Determination of these percentiles can be done by any reasonable means such as interpolation between points with measured data or by the application of calibrated and verified mathematical models (or hydraulic models). It is not EPA's intent

[2] For a description of harmonic means see "Design Stream Flows Based on Harmonic Means," Lewis A. Rossman, J. of Hydraulics Engineering, Vol. 116, No. 7, July, 1990. This article is contained in the record for this proposal.

[3] Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the United States, memorandum from the Assistant Administrator for Water to the Regional Water Management Division Directors and NPDES State Directors, May 21, 1990.

to require actual data collection at particular locations.

In the brackish water transition zones of estuaries with varying salinities, there generally will be a mix of freshwater and saltwater species. Generally, therefore, it is reasonable for the more stringent of the freshwater or saltwater criteria to apply. In evaluating appropriate data supporting the alternative set of criteria, EPA will focus on the species composition as its preferred method.

This assignment of criteria for fresh, brackish and marine waters was developed in consultation with EPA's research laboratories at Duluth, Minnesota and Narragansett, Rhode Island. The Agency believes such an approach is consistent with field experience.

In paragraph (c)(4)(i) EPA included a limitation on the amount of hardness that EPA can allow to antagonize the toxicity of certain metals (see footnote (e) in the criteria matrix in paragraph (b) of the rule). The data base used for the Section 304(a) criteria documents for metals do not include data supporting the extrapolation of the hardness effects on metal toxicity beyond a range of hardness of 25 mg/l to 400 mg/l (expressed as calcium carbonate). Thus, the aquatic life values for the CMC (acute) and CCC (chronic) criteria for these metals in waters with a hardness less than 25 mg/l, must nevertheless use 25 mg/l when calculating the criteria; and in waters with a hardness greater than 400 mg/l, must nevertheless use 400 mg/l when calculating the criteria.

In paragraph (c)(4), subparagraphs (i) and (ii) are the same as proposed. Subparagraph (iii) was added to incorporate the water-effect ratio guidance described in Section F-7 of this preamble.

Subsection (d) lists the States for which rules are being promulgated. For each identified State, the designated water uses impacted (and in some cases the specific waters covered) and the criteria are identified. In all cases, the criteria are applied to use designations adopted by the States; EPA has not promulgated any new use classifications in this rule although the Agency has the authority to do so.

H. (Reserved)

I. Response to Public Comments

The Response to Public Comment Section is organized into several sub-sections, as follows:

1. Legal Authority
2. Science
3. Economics
4. Implementation
5. Timing and Process
6. State Issues

1. Legal Authority

1. *Comment:* Several comments were received that in various ways suggested that EPA exceeded its authority in proposing to establish Federal water quality standards for States because it was alleged standards are to be developed by the States. These comments tended to emphasize the primary role attributed to States under the Clean Water Act in establishing standards with some going so far as to indicate that States should have full and unrestrained authority to act. In this mode, a comment was offered that all the Clean Water Act requires is a good faith effort on the part of a State to meet the statutory requirement. A related comment suggested that EPA can promulgate standards only after specifically disapproving a State's standard. There were opposing views offered suggesting that EPA not only has the authority to act, it is obliged to act.

Response: The Clean Water Act assigns States the primary role in establishing water quality standards and EPA has continually supported that role before Congress in reauthorization hearings on the Clean Water Act. The Act, however, also defines a role for EPA in terms of reviewing and either approving or disapproving State-adopted standards and of promulgating Federal standards. Sections 303(c) (3) and (4) of the Act clearly indicate that Congress did not intend States to have full and unrestrained authority to set standards. EPA's action in developing this rulemaking is not to be taken as a change in EPA policy in dealing with the States. Our policy continues to be that we prefer States to adopt their own standards but we will use our promulgation authority when warranted. EPA believes that the need to control the discharge of toxic pollutants to protect human health and the environment, the establishment of the statutory requirement for addressing toxic pollutants, and the responsibility for EPA review of State water quality standards for consistency with the Clean Water Act coupled with the inclusion of a process for Federal promulgation in the Act strongly supports EPA's promulgation authority. Moreover, this elaborate process also makes clear that Congress intended that States do more than just evidence a good faith effort.

As described in detail in section E of this Preamble, the Clean Water Act authorizes and establishes a timetable for Federal promulgation action. Under the Clean Water Act, States must adopt water quality standards to protect public health and welfare and enhance the quality of water. Section 303(c)(4) of the Clean Water Act authorizes the Administrator of EPA to promulgate Federal standards applicable to a State when: (1) The State submits standards for EPA approval and EPA determines that the State standards fail to meet the requirements of the Act, or (2) in any case where the Administrator determines a new or revised standard is necessary to meet the requirements of the Act. EPA's implementing regulations also make clear that the Administrator may take action to promulgate either when a State fails to adopt changes specified in a disapproval or in any case where the Administrator determines a new or revised standard is necessary (40 CFR 131.22). Both these provisions are used to support this action. Although in fact EPA did notify the States in a Federal Register notice of April 19, 1990, and in a letter to the Administrator of the responsible State agency of each potentially affected State on April 9, 1990, the Administrator is not required in exercising the authority of section 303(c)(4) to specifically disapprove a State's standard when exercising the authority to promulgate Federal standards. Historically, in eight of the nine Federal promulgation actions completed, the Agency based its action on disapproval of State standards but in the ninth instance, a criterion for chloride in the Commonwealth of Kentucky, there was no disapproval involved (see 52 FR 9102, March 20, 1987).

2. *Comment:* Closely related to the above comments were others that asserted that EPA is empowered to promulgate Federal standards only on a State-by-State, waterbody-by-waterbody, pollutant-by-pollutant approach, and that Congress did not intend that national standards be developed. In the same vein, it was suggested that it would be easier for the public to respond if each State were proposed in a separate rule.

Response: Neither EPA nor the States are directed by either the statute or the implementing water quality standards regulation to establish standards in the manner suggested by the first comment. EPA's implementing regulation and policies certainly allow EPA to act in this way but it is not required to do so. Section 131.22(b) of the water quality standards regulation specifically indicates that the Administrator "* * * may propose and promulgate a regulation applicable to one or more states * * *."

We do not see this action as establishing national standards as it expressly limits the application of the criteria in the final rule to the States named in the rule. (40 CFR 131.36(a))

As explained more fully in the preamble, water quality standards consist of designated beneficial uses of a State's waters and the criteria necessary to protect those uses. The comment urges a waterbody-by-waterbody approach. For purposes of this rulemaking, EPA is presuming that the States have adequately made such designated use determinations for its waters. EPA is merely adding criteria for priority toxic pollutants on a State-by-State basis sufficient to protect the State's designated uses. EPA believes its approach accomplishes the commenters objectives but in a more comprehensive manner. Moreover, EPA doesn't believe this approach is more burdensome on dischargers in affected States. Because permit limits are incorporated into NPDES permits only for constituents having a reasonable potential to exceed State water quality standards, a discharger does not receive a limit in its permit unless its discharge contains the pollutant. Thus, comprehensive criteria coverage in water quality standards does not translate into unnecessary permit limits.

EPA is unpersuaded that somehow it would have been easier or more efficient for the public to comment on twenty-two separate rules covering the same issues than to deal with the issues in a single rulemaking. It would most likely result in EPA receiving the same type comments on each separate rule which would do nothing other than increase the administrative burden to EPA and further delay getting water quality standards in place.

3. *Comment:* A comment was made that several proposals for reauthorizing the Clean Water Act considered by Congress in 1991 contemplated giving EPA authority to promulgate Federal standards thus indicating that EPA does not have such authority now.

Response: A response to a comment above describes EPA's current authority to act under terms of the Clean Water Act. The principal CWA reauthorization bills considered by Congress in 1991 would neither question nor limit this existing authority. Rather they would alter the water quality standards program as it now exists by providing specific deadlines for States to act in adopting standards based on recommendations published by EPA and then mandating Federal promulgation by a date certain. Rather than suggesting that EPA does not now have such authority, these proposals support EPA's view that Congress is becoming increasingly impatient with the slow pace at which States adopt new criteria recommendations issued by EPA under section 304(a) and is willing to consider supplementing EPA's current discretionary promulgation authority.

4. *Comment:* Several comments suggested that EPA's promulgation action should be limited to the waterbodies and pollutants reported on the section 304(l) lists or information contained in section 305(b) Water Quality Inventory Reports. The basic thrust of these comments were that such lists, prepared by the States, contain sufficient information necessary to identify all potential toxic problem areas within the State. Some of these commenters also suggested these limited sources were more accurate than the broader approach relied on in EPA's proposal.

Response: A detailed description of the approach the Agency followed in developing this final rule is included in section E-2 of this preamble. As indicated in that section, EPA used information from a variety of sources in determining which criteria to include in the rule for each State. The Agency did not rely on a single source, such as 304(l), 305(b), or any other set of information.

Each of the data sources suggested by the commenters are valuable tools which serve specific purposes under the Clean Water Act. However, as described in section E-2, each source has limitations either as to coverage of waterbodies or sources of pollution, extent of information included, or a narrow focus because of their particular purpose. Even when information from a variety of sources is used as described as the Agency's "strawman", there remain inherent weaknesses in the underlying data.

EPA believes there is a greater possibility of achieving the statutory purpose of protecting water uses by relying on a range of available data sources rather than selecting one or two narrow databases. EPA believes that by not directing the Agency to use the results of the other statutory sections the commenters identified, and by use of the "could reasonably be expected to interfere" language, Congress directed the Agency to be more inclusive rather than less inclusive in the applicable criteria coverage. Thus, EPA urged a low threshold for inclusion of priority toxic pollutants in the guidance transmitted to the States.

5. *Comment:* One commenter argued that EPA's strawman systematically overestimates the presence of priority toxic pollutants because of its use of industry wide default assumptions for particular SIC codes. The commenter further argues that comparisons between the number of toxics adopted in States who evaluated available data for toxics and established criteria based on that data to the results of the strawman predictions show that a substantially smaller number of pollutants resulted. The commenter urged that only section 304(l) short list pollutants should be used for this rule.

Response: EPA's strawman analysis was designed to use all of the Agency's data bases to develop candidate lists of toxics on a State specific basis. States were urged to use this information as a starting point in evaluating the need for particular priority toxic pollutants.

EPA intentionally designed the analysis to yield a list of suspected priority toxic pollutants that would not understate the potential presence of such pollutants. As noted in the preamble, State monitoring information, for example, as used in the section 305(b) water quality reports, is not comprehensive in either geographic or parametric coverage. That is the reason EPA used the industry profile data—to maximize the data base.

Thus, EPA was providing the States with a listing that identified potential toxics and where those were potentially located. The State was encouraged to verify the lists. EPA has not used the list to identify pollutants for States included in this rulemaking. Rather EPA has viewed the analysis as supporting its contention that priority toxics exist in State waters and therefore, a broad promulgation for priority toxic pollutants is justified.

In arguing for limiting the promulgation to the section 304(l) short list pollutants, the commenter failed to compare the criteria the example State adopted in its water quality standards versus the pollutants identified in its section 304(l) short list. The State used as an example placed substantially more criteria in their standards than in their section 304(l) short list. The reason for this disparity is because the threshold for inclusion in water quality standards is much lower than for inclusion in the section 304(l) short list.

6. *Comment:* EPA solicited comment concerning the acceptability of the review process used by EPA to determine compliance with the Act—this process is described in section D of this preamble. EPA received few public comments in response to this request, beyond the general comment that EPA exceeded its authority to promulgate Federal standards, an issue addressed earlier in this section. One view offered was that the review process used by the Agency makes it difficult to evaluate whether adequate consistency was

applied by the Regions in evaluating acceptability of State standards.

Response: Each State's water quality standards submission is different. They require case specific review for adequacy and consistency with environmental and human health requirements and statutory and regulatory provisions. The statute allows for State flexibility. Given these factors, EPA established broad guidance parameters and Regional Offices reviewed each submission for consistency. EPA Headquarters staff exercised oversight on this process to assure appropriate inter-Regional consistency. This process did not produce identical standards in each State but that is not required. All State standards that were approved were judged by EPA to meet the twin tests of protection of water body uses and scientific defensibility.

Both the criteria development and the standards programs are iterative programs and EPA expects to request States to continue to focus on adopting criteria for additional toxic pollutants and revising existing criteria in future triennial reviews which new information indicates is appropriate. In no sense should States or the regulated community assume that the task of addressing pollution from toxics is completed by what the States have adopted or EPA is promulgating in the way of criteria for toxic pollutants.

7. *Comment:* EPA did not propose criteria for inclusion in State standards when the criteria were based on organoleptic effects. The Agency specifically solicited comment on this issue. Most of the comments received indicated that EPA was correct in not including such criteria in the rule. There were several comments to the contrary indicating that such criteria should be included because the pollutants are on the section 307(a) list and EPA did issue a criteria recommendation for the pollutant under section 304(a). Therefore, they argue that the requirements of section 303(c)(2)(B) apply.

Response: In the final rule, EPA has not included criteria for pollutants where the section 304(a) criteria recommendation was based on organoleptic effects. Such effects cause taste and odor problems which may increase treatment costs in drinking water or the selection by the public of alternative but less protective sources of drinking water and may cause tainting of or off flavors in fish flesh and other edible aquatic life reducing their marketability and resource value. EPA is also aware that some States have adopted such criteria in their standards. Nonetheless, because section 303(c)(2)(B) focuses on toxicity of the priority toxic pollutants, EPA believes its rule should likewise focus on toxicity. The 304(a) criteria documents for these pollutants do not recommend a criteria based on toxicity and therefore such criteria are outside the intent of a rulemaking for section 303(c)(2)(B).

This decision notwithstanding, it should be noted that the criteria based on organoleptic effects still represent the Agency's best scientific recommendations at this time and are within the range of scientific acceptability for a State's use.

8. *Comment:* One commenter asserted that EPA's Option 3 (i.e. adoption of a narrative standard coupled with a translator mechanism to compute a derived numeric limit) of its December 1988 guidance on complying with the Act does not meet the legal requirements of section 303(c)(2)(B). It is argued that EPA should therefore disapprove all State water quality standards which rely solely on a narrative "free from" toxics water quality standard and a translator mechanism. A related comment is that this translator procedure may be appropriate as a supplement to adopting specific numeric criteria.

Response: The legality of Option 3 is not an issue in this rulemaking. We are not promulgating any water quality standards based on Option 3. Option 3 is only a potential issue in the subsequent approval of standards for those States which are not included in this rule.

Nevertheless, as noted in the December 1988 guidance, EPA believes the combination of a narrative standard along with a translator mechanism as a part of a State's water quality standards can satisfy the substantive requirements of the Clean Water Act. Such translators would need to be subject to all the State's legal and administrative requirements for adoption of standards plus review and either approval or disapproval by EPA, and result in the development of derived numeric criteria for specific section 307(a) toxic pollutants.

EPA's guidance presented several factors that EPA expected to be incorporated into a translator process in order to comply with the Act. In essence, EPA expected that the technical mechanism used would need to be equivalent to a criteria development protocol. That is, it would need to include an appropriate number of sensitive species using suitable testing and analytical methodologies. If established and applied correctly, EPA has indicated that it could meet the legal requirements of section 303(c)(2)(B). *The central objective of* section 303(c)(2)(B)—establishing chemical specific numeric limits—is achieved by this approach. There is no statutory bar to it and the Agency sees no reason not to continue to support this approach by States.

Ultimately, EPA believes all State toxic control programs will be strengthened by adoption of both chemical specific standards and a translator mechanism for those pollutants where water quality criteria have yet to be developed.

9. *Comment:* EPA invited comment on whether to promulgate a translator mechanism for the States in this final rule. A translator mechanism would enable the States to derive numeric limits for pollutants beyond those in this promulgation based on a State's general narrative criterion. The Agency received comments both supporting and opposing this approach.

Response: While a translator mechanism could be a valuable supplement to State standards to deal with toxics for which no section 304(a) criteria recommendation is available, it is not necessary for EPA to promulgate a translator at this time to meet the objectives of section 303(c)(2)(B). Today's promulgation of chemical specific criteria fulfills that obligation. For that reason a translator mechanism is not included in today's final action. However, EPA believes that such a mechanism should be available in all States. Therefore, in revisions to the basic water quality standards regulation, EPA may propose a requirement for a translator mechanism which would be applicable to all jurisdictions included in the standards program.

10. *Comment:* Comments were received that EPA is attempting to establish use classifications in this rule and that such action is a right belonging to a State.

Response: The use classifications to which Federal criteria are applied in this rule are the classifications established and defined by each State affected by the rule. EPA is not creating State use classifications nor assigning use classifications to any water bodies in this rule. In the few instances described in Section G of this preamble, appropriate adjustments to uses and criteria were made as necessary to accurately reflect State use classifications. Further, EPA believes the regulated community is fully aware of the uses adopted by a State and to which water bodies the uses apply. Specific revisions in the rule pertaining to State use classifications are discussed in subsection 6 of the Response to Public Comments Section.

11. *Comment:* During the pendency of this rulemaking, several States asked if adopting an emergency rule would be sufficient to allow removal of the State from the final promulgation. Several States also indicated they should be removed from the rule because they had plans to adopt standards.

Response: Emergency rulemaking actions by States are not judged by EPA as sufficient basis for removal from this rulemaking. In most cases, State emergency rules have a limited duration and expire at a date certain. There is no assurance that enforceable permanent water quality standards would be in-place at that time. If EPA were to allow emergency rulemakings to be the basis for removal from this package, given the long delays to date by these States, there is the strong possibility promulgation action would have to be commenced again by EPA in the near future. The delays and related program disruptions experienced by EPA have already been too great. There has to be closure on the standards adoption portion of our toxic control efforts. Reliance on temporary emergency State actions would not produce that closure.

There is also the question of legal vulnerability to the adoption of emergency rules and whether the State emergency rule procedures allow for sufficient public review. Moreover, the emergency rules adopted would have to fully comply with the Act. States which contend they should be dropped from this rule because they now plan to adopt standards remain in this rule because EPA has no reasonable means of being assured standards will be adopted as planned. Since passage of the amendments in 1987, many State plans for standards adoption have not been completed as anticipated. When States complete approvable adoptions, EPA will take timely action to remove the promulgation as applicable to that State.

12. *Comment.* One commenter asserted that States do not have the necessary legal authority under State law to use national water quality standards in State permits.

Response. Without more information, we cannot determine the precise concerns of this commenter. However, section 402(b) of the Clean Water Act requires that States approved to administer the National Pollutant Discharge Elimination System (NPDES) program must have adequate authority to issue permits which comply with any applicable requirements of section 301 of the Act. Among those requirements are limitations to meet water quality standards, and the criteria promulgated today are "* * * applicable water quality standard(s) established pursuant to this Act." Section 301(b)(1)(C).

Once promulgated, Federal standards will be the basis of all environmental control programs designed to meet water quality standards. States which had inadequate criteria for toxics will have a much more complete basis for determining if there are toxic contamination problems in their waters. If problems are identified, the State and EPA will need to work together to see if the sources of these problems can be identified and controlled. The most direct impact will be on NPDES permits for individual point source discharges. The permitting agency, whether it be the State or EPA will have to determine on a case-by-case basis whether to re-open an individual permit or wait until a permit expires before introducing new limits.

13. *Comment.* One commenter described ongoing judicial and administrative proceedings to establish the authority of the state to set permit limits for dioxin by interpreting the state's narrative criterion using EPA's section 304(a) dioxin guidance. The commenter indicated that the state has consistently implemented its narrative water quality criterion to control dioxin discharges by interpreting that criterion using EPA's guidance. It is the commenter's view that if the state prevails in the ongoing litigation, it will effectively have a numeric criterion for dioxin.

Response The critical flaw in the commenter's argument is that the State does not have in-place an EPA-approved numeric criterion for dioxin, or an approved translator to generate a numeric criteria for dioxin. Moreover, conclusion of the litigation would not establish an approved numeric criterion, even if the State were to prevail. EPA understands that States often implement their narrative criteria by interpreting those criteria using EPA guidance. EPA supports this process by the States. However, section 303(c)(2)(B) is clear that States are to adopt numeric water quality criteria for toxic pollutants. The purpose of this rulemaking is to finally establish the necessary numeric toxic criteria in all States, and only those states with the necessary approved numeric criteria are excluded from the rule.

2. Science

The response to comments in this subsection are included under the following headings: (A) General Comment, (B) Aquatic Life Criteria, and (C) Human Health Criteria.

A. General Comments

14. *Comment:* Numerous comments were received that EPA's water quality criteria were published as scientific guidance and were never intended to be used as regulatory provisions without modification to reflect local environmental conditions. Related comments indicated that because the criteria were published as guidance, the public comment received on the draft water quality criteria documents were restricted since reviewers did not anticipate their use as enforceable limits.

Response: Water quality criteria are published as scientific information or guidance under section 304(a) of the Act because that is what the Clean Water Act specifies. EPA's implementing water quality standards regulation recognizes that the section 304(a) criteria may be used as a basis for States to establish enforceable standards. See 40 CFR 131.11(b). To imply that the section 304(a) criteria are merely informational and not directly related to establishing water quality standards under section 303(c) is not only reading the Act in an crabbed manner, it also ignores 26 years of program history which demonstrates that States generally rely on the criteria recommended by EPA in establishing standards. Moreover, this rulemaking is the process which transforms these recommendations into enforceable regulatory requirements for specific States. Any specific issues related to establishing these criteria as applicable to State standards could have been raised during this rulemaking even if the issues were raised or considered in the earlier publication of criteria documents.

Furthermore, although the EPA water quality standards regulation allows State modification of water quality criteria to reflect local, site-specific conditions, it is not a requirement to do so. EPA is also not obligated to modify criteria to reflect local environmental conditions although ideally EPA would consider any data submitted in support of establishing a site-specific criterion in determining whether site-specific criteria would be appropriate. In addition, EPA believes the methodology and the extensive data base used by the Agency results in deriving national criteria that will be protective for most species in virtually all waterbodies throughout the country. (See 1985 Guidelines, page 4.)

Congress has given substantial credibility to the section 304(a) criteria as well. For example, in section 301(h)(9) applicants must meet the section 304(a) criteria as if they were regulatory.

Finally, it should be noted that when announcing the availability of draft and final criteria documents, it is stated in the EPA announcement that such criteria may form the basis for enforceable standards. EPA believes that adequate notice of the uses of the section 304(a) criteria has been provided to the public.

15. *Comment:* Commenters suggested in general that the EPA criteria are outdated and need to be revised extensively to reflect the latest scientific information available before they can be appropriately used in rulemaking. For a few pollutants data were submitted to substantiate this claim. (See response to comments on specific pollutants below.)

Response: EPA does not agree with these comments for several scientific, programmatic, and statutory reasons. Scientific information is constantly evolving. Additional research is always being done, test methods and theories improve, and more precise analytical methods become available. There can be a long lag time between conducting the research, analyzing the data, issuing the criteria documents for review, revising the documents, and working through the State or Federal administrative processes to adopt standards. There comes a point in this process, where the administering agencies, both EPA and the States, have to act using the existing criteria recommendations based on the methodology by which they are derived, and put standards into place so that control programs can be implemented to protect the health of the public and the environment. One basic reason why criteria and standards is an iterative process is to continuously evaluate and incorporate new information. Through this process, many of EPA's criteria have been updated since issuance of the formal criteria documents.

Moreover, once standards are in place, applications can be made through the mathematical models used to derive total maximum daily loads and wasteload allocations. These determinations are associated with the NPDES permits process and result in permit limits being established that have sufficient latitude to adequately account for other than major adjustments to individual criteria recommendations.

Finally, it must be recognized that Federal promulgation is the end of the process to establish water quality standards, not the beginning. In this case, the beginning was in 1980 when most of the criteria and the first generation criteria development methodologies were issued. By 1983, due to lack of response by the States, EPA revised its basic water quality standards regulation to put primary emphasis on the adoption of water quality criteria and control of toxic pollutants. This too failed to engender adequate State response which in turn led to the directive from Congress contained in section 303(c)(2)(B). Now, five years later, and two years after the States should have taken action, this final rule completes the process of establishing the first set of comprehensive standards for toxic pollutants. This final Federal promulgation ends this current effort but the revision of criteria based on new research, the revision of applicable standards, alterations in analytical methods, and the evolution of control technologies will continue.

EPA asserts, as we have elsewhere in this preamble, that the promulgation process established under the Clean Water Act is a process designed to bring to closure the act of putting enforceable standards into place as basis for environmental control programs designed to protect public health and the environment. The promulgation process is not designed or intended to be the vehicle for a reevaluation of the scientific underpinnings of water quality criteria. It is also not the process for protracting the debates about the scientific merits of various pollutants. That debate is essential, necessary, and is constantly ongoing but as a separate activity. The promulgation process envisioned must go forward and the Agency must make decisions based on the available data. It is clearly a means to end such debates and to get environmental controls started based on available information.

EPA believes the criteria promulgated today are scientifically sound as they are based upon a technically and scientifically acceptable methodology. Detailed descriptions of the formulation of aquatic life criteria and human health criteria are included in section F (1,2, and 3). As discussed below, we have made some revisions to the criteria based on public comments. Our criteria for both human health and aquatic life provide a reasonable amount of protection with only a small possibility of substantial overprotection or underprotection.

To completely review all the criteria as some suggested would take a minimum of several years during which time the human health and environmental problems associated with the continued discharge of toxic pollutants would worsen. There is no predetermined result from an extended review—some criteria might become more stringent, some less, some might remain the same. In the meantime, the States that failed to comply with the Act are rewarded for their failure. These States have delayed while 43 of the jurisdictions included in the program have adopted water quality standards for the most part relying on EPA's section 304(a) criteria guidance.

As indicated in this preamble, we are currently re-examining our basic criteria development methodology, which is a normal course of action for the Agency. We anticipate some changes will be made and we assume some changes in the criteria will be made over the years. This, however, is no reason to suspend action now.

16. *Comment:* The use of information contained in the Agency's Integrated Risk Information System (IRIS) to update human health criteria was questioned by several commenters. The central concerns were that the information contained in the system was not subject to external peer and public review, the background information contained in IRIS is not readily available for review, and the public had little chance to review the results of the recalculations.

Response. A detailed discussion of the IRIS may be found in Section F–3 of this preamble. To summarize the salient points: (1) Reference doses and cancer classifications are validated by two Agency work groups composed of senior Agency scientists from all other program offices (i.e., internal peer review), (2) the consensus opinion for reference doses and slope factors are then used throughout EPA for consistent regulation and guidance development, (3) the data are available through the TOXNET System maintained by NIH and through diskettes available from the National Technical Information Service (NTIS), (4) the information used to recalculate the section 304(a) criteria in today's rule was included in the record of this rulemaking, and (5) through the proposal of this rule, the public had an opportunity to review and comment on the revised criteria. In addition, some of the RfD values and the cancer potency slope factors undergo public review during rulemaking for other Agency programs such as drinking water, pesticides, and Superfund. Thus, EPA believes that adequate notice about IRIS and its use in Agency programs has been provided to the public, at least as it concerns its use in this rulemaking.

17. *Comment:* Several commenters indicated that the criteria should be subjected to a peer and public review process similar to that followed by the Agency in issuing proposed criteria

under section 405 of the Act concerning the disposal of wastewater solids.

Response: The proposed regulations for the disposal of wastewater solids represented the first time EPA proposed such standards, and was the first time a methodology and specific criteria were proposed by EPA for wastewater solids. Therefore, the extensive review for that proposed regulation was appropriate. The situation is not the same for the criteria promulgated in today's rule. EPA and the States have been regulating the discharge of pollutants into surface waters for many years. The methodologies for deriving criteria for the protection of both human health and aquatic life were peer and publicly reviewed in 1980. The aquatic life guidelines were revised with peer and public review in 1985. Both methodologies are currently being reviewed for possible revisions. As discussed elsewhere in this section, this rulemaking makes use of the existing criteria and therefore is not the most effective vehicle for revising either the methodologies or the actual criteria.

18. *Comment:* Several commenters objected that applying criteria as standards when the criteria are below analytical detection limits is unreasonable because this may force the imposition of unreasonable permit limits and "false positive" indications of non-compliance. Others suggested that it was not clear how detection limits affect permit limits and compliance. There were also comments supporting EPA's position as described in the proposal.

Response: In consideration of statutory requirements that water quality standards are to be protective of designated stream uses, EPA has determined that consideration of analytical detectability would not be an appropriate factor to consider when calculating the water quality criteria component of water quality standards. This has been the Agency's position since the inception of the water quality standards program in 1965.

Although the sensitivity of analytical methods are not appropriate for setting water quality criteria, they may be appropriate in determining compliance with permit limits based water quality standards. It should also be noted that by the time standards are converted into permit limitations after calculating total maximum daily load and wasteload allocations, the actual permit limit may be in the range of standard analytical methods cited by EPA in 40 CFR part 136.

EPA's criteria development methods for aquatic life are generally based on laboratory bioassays with sensitive aquatic life. The results from these tests are analyzed by mathematical procedures outlined in EPA's criteria methodology guidelines. EPA human health criteria are developed from protocols generally using toxicity studies on laboratory animals such as mice and rats. Thus, EPA's criteria are effect-based without regard to chemical analytical methods or techniques.

Because water quality standards developed pursuant to section 303(c) of the Clean Water Act are not self-enforcing, the measurement of these chemicals in a regulatory sense is generally in the context of an NPDES permit limitation. The permit issuing authority, either a State or EPA, in conjunction with the permittee establishes the analytical methodology to be used in determining compliance with the permit limit.

As noted in footnote 3 of this preamble, EPA has issued guidance on how constituents with water quality criteria specified at less than the sensitivity of official analytical methods (i.e., those listed in 40 CFR part 136) are established in permits.

EPA's water quality standards regulation at 40 CFR 131.11 requires that criteria be adopted by States at concentrations necessary to protect designated uses. The criteria promulgated today meet that requirement while EPA's policy with respect to regulatory compliance takes analytical sensitivity and precision into consideration.

B. Aquatic Life

19. *Comment:* A few comments questioned the role of biological criteria in the standards program with one commenter suggesting that establishing numeric limits is contrary to achieving the biological goals of the Clean Water Act.

Response: Together, chemical and physical characteristics and biological integrity define the overall ecological integrity of an aquatic ecosystem. State regulatory agencies should strive to fully integrate all three approaches since each has its respective capabilities and limitations. EPA's position is that each approach as represented by whole effluent toxicity testing, chemical specific criteria, and bioassessment approaches is independently applicable (see Policy on Use of Biological Assessments and Criteria in the Water Quality Program, U.S. EPA, May 1991). A description of the integration of these approaches along with a detailed analysis of the capabilities and limitations of each approach may be found in the Technical Support Document for Water Quality-based Toxics Control, March 1991. See TSD Section 1.5 beginning on page 20, and references cited therein.

20. *Comment:* A commenter argued that EPA's proposed national aquatic life criteria will be overprotective for many surface waters because they do not account for site-specific conditions. At a minimum, any federal water quality criteria must take into account broad aquatic life categories.

Response: The development of EPA's criteria is based on a broad aquatic life data set. The 1985 guidelines recommend that eight species from eight separate families be used in the development of the freshwater and saltwater criteria. While it is always beneficial to have more data, EPA's peer reviewed guidelines establish that criteria developed from this minimum data set adequately protect aquatic communities (1985 Guidelines, see section III, p. 22). The apparent level of protection is different for each kind of effect (acute or chronic toxicity to animals, toxicity to plants, etc.) because of the quality and quantity of information. An attempt was made to take into account such things as the importance of the effect, the quality of the available data, and the probable ecological relevance of the test methods. The present approach to aquatic toxicity allows conclusions to be made about the ability of a substance to adversely affect aquatic organisms and their uses whenever the minimum data set are satisfied. See also the discussion on metals speciation in Section F–7 and the response to comment below.

21. *Comment:* One commenter asserted that EPA has incorrectly concluded that the Section 304(a) criteria are appropriate for most waters because there have been few occasions where site-specific water quality criteria have been applied.

Response: EPA's determination that Section 304(a) criteria are generally applicable is not based on a lack of site-specific criteria modification studies as asserted by the commenter. EPA has conducted a series of field applicability studies to determine the correlation between chemical specific criteria and receiving water impacts. (Technical Support Document for Water Quality-based Toxics Control, March, 1991 at p. 2). These test results indicate a good correlation between the laboratory concentrations and expected field results. The water quality criteria are not threshold values. One should not expect that once these values are exceeded, the result is a measurable impact on aquatic life. The aquatic life criteria embody conservative assumptions so that small excursions *above the criteria will not result in* adverse impacts. The data indicate that if ambient water quality criteria are met, organisms in the receiving water are protected from adverse impacts.

22. *Comment:* Comment was received that EPA should clarify that the aquatic life water quality criteria for arsenic are based on the trivalent form of arsenic.

Response: The arsenic criteria promulgated today are applied on total recoverable inorganic arsenic. The 1985 arsenic criteria document is derived from data on Arsenic (III). However, because there is no readily available or practical analytical method to quantify the various forms of arsenic in monitoring applications for aquatic life, EPA has concluded that it is reasonable to quantify environmental arsenic concentrations as total recoverable inorganic arsenic. (EPA Methods 206.2, 206.3, 206.4, 206.5.)

In addition, EPA reevaluated the acute and chronic toxicity data on the two most prevalent forms of arsenic in aquatic systems (trivalent and pentavalent arsenic) in the Arsenic criteria document. These data show that arsenic (III) and arsenic (V) toxicity is similar for both sensitive freshwater and saltwater species. For five of the six freshwater species and all of the saltwater species used in the arsenic calculation where there was comparable information on acute and chronic toxicity, values were within a factor of two or three. Certain plants, for example *Selenastrum capricornutum* (alga), are 45 times more sensitive to arsenic (V) than to arsenic (III). Therefore, it is reasonable to combine forms of arsenic to specify the criteria. The measurement of total recoverable arsenic has both toxicological and practical advantages and appropriately represents the aquatic life toxicities of arsenic compounds.

23. *Comment:* Several commenters asserted that criteria based on laboratory tests are overprotective when applied in the field. Another commenter quoted laboratory study reports stating that the results are applicable only to the particular water tested.

Response: EPA agrees that waters used for laboratory toxicity testing are generally cleaner than many natural systems. In cases where ambient waters contain constituents which alter the toxicity of chemicals, an increase in accuracy may be provided by rerunning the toxicity tests in site water. (For example, the water-effect ratio approach for metals promulgated today.) In most instances, this correction will be small. (TSD, March 1991, p.2). Therefore, applying the criteria values developed from laboratory testing provides an acceptable level of accuracy, and this approach is used by most States. In the context of this rule it represents a technically acceptable approach to cover a variety of waters, and the only feasible one. (See also the response to comments for the 1980 Guidelines, Nos. 17 and 19, 45 FR 79359, November 28, 1980.)

In response to the second comment, the scientist running the specific toxicity test referenced by the comment noted that its accuracy is only guaranteed for the specific water tested. However, applying these tests to other waters is an acceptable approximation. (See response to public comments for the 1980 Guidelines, 45 FR 79359–79360, comment #20 and #21.) Additionally, laboratory toxicity testing is the most reasonable and practical way to develop a database which is large enough to develop criteria, and diverse enough in species, which generally represent a larger source of variability.

While most States have not chosen to perform site-specific toxicity tests, any State may develop site specific-criteria. These criteria will be more appropriate and tailored to the site for setting NPDES permit limits than EPA's national criteria. Because they are amended water quality standards, site specific criteria are subject to EPA review. Other than the water-effect ratio for metals which is promulgated today, State-developed site specific-criteria do not replace the criteria promulgated in today's rule unless the site specific-criteria are approved by EPA as meeting the requirements of the Act and EPA amends the rule adopted today.

24. *Comment:* Comment was received that the proposed rule includes some aquatic life criteria computed using the 1980 guidelines methodology and others were computed using the 1985 guidelines methodology. It was asserted that the simplistic approach of the 1980 methodology ignores the scientific improvements of the 1985 guidelines. The commenter urged that these criteria should be updated to provide consistent methodology and adherence to the statutory requirement of section 304(a).

Response: As the commenter noted, some of the aquatic life criteria in this rule are based on 1980 guidelines. EPA reviewed the data base for these criteria and determined that in general they could not be recalculated by the 1985 guidelines because of differences in data base requirements between the two guidelines used species specific requirements whereas the 1985 guidelines expanded this to broader taxonomic categories.) EPA believes that the data used in the 1980 criteria document are sound. As a practical matter, a reasonable approximation to a criteria maximum concentration can be obtained by simply dividing the final acute values in the matrix by 2. The criteria in the matrix in today's rule were not changed from the results of the respective 1980 and 1985 methodologies. Therefore, EPA has reconsidered these aquatic life criteria at the commenter's request and considers them to be within the acceptable range based on uncertainties associated with computing water quality criteria. These criteria are protective of aquatic life and are scientifically sound.

The development of aquatic life criteria is a dynamic process which responds to the influence of improved science. It is expected that this science will be constantly evolving as new analytical techniques become available and new studies are evaluated. To this end, EPA is also reviewing the current methodology for developing aquatic life criteria. The current methodology will be reviewed, and if needed, revised to incorporate the latest concepts of aquatic toxicology.

25. *Comment:* A commenter asserted that the proposed aquatic life criteria may be underprotective since they fail to account for synergism and additivity and fail to consider wildlife impacts.

Response: EPA agrees that the aquatic life criteria do not deal with simultaneous exposure to more than one pollutant. This is largely because few data are available, the data which are available do not allow for development of useful principles and there are so many possible combinations of pollutants present to prevent development of appropriate guidance. EPA has considered the effects of multiple toxics discharged into receiving waters. (Technical Support Document for Water Quality-based Toxics Control; March 1991.) The studies cited in the TSD indicate that the median combined effect of a mixture of acutely toxic pollutants in receiving water is additive. EPA recommends, that in the absence of site-specific data, regulatory authorities consider combined acute toxicity to be additive. Thus, the combined acutely lethal toxicity to fish and other aquatic organisms is approximately the simple addition of the proportional contribution from each toxicant.

However, available data do not indicate additivity for chronic toxicity. EPA further recommends that chronic toxicity not be considered additive, and that each toxic be considered individually.

Synergism has not been demonstrated to be an important factor in the toxicity of effluents. Field studies or effluent toxicity and laboratory tests with specific chemicals support an inference that synergism is a rare phenomenon. (See TSD, page 24.) (See also response to comments in the 1980 Guidelines, Comment #9, 45 FR 79358, November 28, 1980.) Theoretically, antagonism is just as likely to occur, which might suggest that the criteria are overly protective in an environment exposed to contaminant mixtures.

EPA considers the criteria, when applied with the appropriate frequency and duration of exposure, to adequately protect wildlife. Three of the aquatic life criteria in this rulemaking are based on wildlife toxicity and exposure, (Selenium, DDT and Polychlorinated Biphenyls). EPA is in the process of developing a wildlife criteria development methodology to provide further guidance for wildlife concerns. Once this tool is developed, EPA will have a method of focusing criteria on wildlife issues.

26. *Comment:* Several commenters argue that the criteria do not apply to semi-arid ecosystems. None of the guidance issued to date expressly address the means to apply those criteria to semi-arid ecosystems found in Arizona. Ephemeral streams and effluent-dominated waters are distinct classes of waters that should be regulated to protect the aquatic species that typically inhabit them.

Response: Water quality criteria are toxicity based values, usually chemical specific. The criteria are based on toxic effects to a broad taxonomic group and do not consider the types of water bodies, such as semi-arid ecosystems, they may be applied to. Aquatic life criteria, when implemented as part of water quality standards, are meant to be protective of aquatic life. These standards are applied to specific waterbodies through designated uses. For this rulemaking, EPA assumes that States correctly define designated uses and the specific waterbodies to which those uses apply. EPA agrees that ephemeral streams and effluent-dominated waters are distinct classes of waters. If a State feels an aquatic life use designation is appropriate for these waterbodies, then the aquatic life criteria will apply to protect that use. If not, then they will not apply. EPA is not promulgating designated uses for State waters. EPA is only applying appropriate aquatic life criteria to waters that States designated for aquatic life protection.

27. *Comment:* Comment was made that EPA should allow an alternate methodology for calculating the Final Acute Value when dealing with small data sets.

Response: EPA has considered alternate methods for calculating the Final Acute Value (FAV). The present methodology was developed by the Agency's guidelines committee, subjected to outside peer and public review, and is a reasonable technique. EPA develops a Final Acute Value on as large a data set as available. The guidelines generally require eight separate families for derivation of acute values (1985 Guidelines, p. 23). EPA considers this to be an adequate data set for calculation of the FAV. As the data set grows it only provides additional confidence of the scientific basis for calculating the Final Acute Value. The present methodology has been reviewed both within and outside the EPA for scientific merit. EPA considers the present methodology to be sound. The guidelines are presently under review. The method suggested by the commenter is relatively new, and it and other statistical bases for criteria development are being reviewed in the Agency's current effort in reviewing the criteria development guidelines. It is intended that the guidelines reflect the best science and to that end EPA will consider all aspects to continue to provide a sound and scientifically based methodology.

28. *Comment:* Comment was received that the aquatic life criteria and guideline methodology, contrary to EPA's assertions, have not undergone sufficient scientific peer review.

Response: EPA does not agree. The criteria and underlying methodology guidelines were widely distributed to interested parties. These drafts were made available to and thoroughly discussed with experts within EPA, industry, and academia. These interactions have provided many useful comments and information which greatly improved the scientific basis of the criteria and methodologies. The methodologies were further reviewed by an independent Science Advisory Board which EPA considers to constitute external peer review. (SAB Water Quality Criteria, A Report of the Water Quality Criteria Subcommittee, April 1985). The SAB noted that since EPA's initial efforts in developing water quality criteria, the process has undergone considerable evolution. The SAB felt that each revision represented a more sophisticated and realistic approach. EPA encourages and makes every reasonable attempt to include as much of the scientific community as practical in carrying out its responsibility under the Clean Water Act.

29. *Comment:* Comment was received that EPA states in the proposal that the methodology for developing aquatic life criteria have been approved by the Science Advisory Board (SAB); however this approval was not unqualified.

Response: In its comments on EPA's 1985 guidelines, the SAB committee noted that EPA had developed a more scientifically sophisticated and realistic set of guidelines. (SAB Water Quality Criteria, A Report of the Water Quality Criteria Subcommittee, April 1985.) It noted approvingly that EPA considers such issues as mode of exposure, level of protectiveness and ecosystem protection. It further noted that the guidelines took advantage of advances in recent scientific research. The report, being a critique, did note areas where the guidelines could be improved and areas where additional research might be helpful. Overall the SAB report was supportive of the Agency's aquatic life criteria development guidelines.

30. *Comment:* Numerous comments were received with regard to the metals criteria. It was noted that the draft rule did not make clear what analytical method was to be used for implementation and that metals criteria should not be interpreted in terms of total recoverable or acid soluble metal. It was asserted that dissolved criteria would be more appropriate, and in many cases effluent limits based on dissolved metals only would be more appropriate. Many commenters urged that the rule should implement the metals criteria using the site-specific water-effect ratio, in order to target the bioavailable fraction of pollutant.

Moreover, it was asserted that the copper criteria document states that organic carbon has a strong effect in reducing copper toxicity, and that the copper criterion should be recalculated for waters having TOC greater than 2–3 mg/L. Furthermore, it was argued, the toxicity of several metals are related to pH, total organic carbon (TOC), speciation, as well as the hardness.

The commenters asserted that the criteria are overly protective when applied to the field, and are overly protective because they are not site-specific.

Another commenter argued that the criteria are underprotective because they do not account for synergism or additive effects.

Response: These diverse and recurring comments have been aggregated above because they deal in large measure with the phenomenon that the same metal concentration may cause different toxicity from place to place due to chemical differences from place to place. In natural waters metals may exist in a variety of dissolved and particulate forms. As discussed elsewhere in the preamble, the bioavailability and toxicity of a metal depends strongly on its exact physical and chemical form. See Section F.7. It also depends on the site-specific chemistry of the water, and on the other materials contained in the water.

Because of (a) the complexity of metals speciation, (b) the varying degrees of bioavailability and toxicity of the many forms and complexes, and (c) the additive, synergistic, and antagonistic influences of other materials in the water, there is no one chemical method that can assure that a unit of concentration measured in the field would always be toxicologically equivalent to a unit of concentration occurring in the laboratory toxicity tests underlying the criteria. Consequently, simply choosing a particular chemical method (such as total recoverable metal or dissolved metal) to measure attainment of the metals criteria would not assure the appropriateness of the criterion for the water chemistry of the various sites at which the criteria apply.

In response to comments, EPA is implementing the criteria in terms of total recoverable metal while calculating the criteria value using the water chemistry adjustment provided by the "water-effect ratio" procedure for certain metals as described and reocmmended in its current Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, May 1992. This approach takes into account, directly, water characteristics such as total organic carbon, pH, metals speciation and hardness, as suggested by the commenter.

The water-effect ratio approach compares bioavailability and toxicity of a specific pollutant in receiving waters and in laboratory test waters. It involves running toxicity tests for at least two species, measuring LC50s for the pollutant using (a) the local receiving water collected from the site where the criterion is being implemented, and (b) laboratory toxicity testing water made comparable to the site water in terms of chemical hardness. Because the water-effect ratio procedure, described in the above referenced guidance, provides a biological measure of differences in water chemistry, the ratio between site water and lab water LC50s is used to adjust the national acute and chronic criteria to site-specific values.

Because the water-effect ratio is a comprehensive measure of differences in bioavailability and toxicity, including the differences between dissolved and particulate bioavailability, it will produce a more appropriate criterion than simply expressing the criteria as dissolved metal. Some metals, such as copper and silver, can exist in a variety of dissolved forms that differ greatly in toxicity. The water-effect ratio is the best procedure EPA currently has for measuring such differences.

The water-effect ratio is also a reasonable method now available for accounting for synergistic and additive effects of pollutants. Regardless of whether a value less than or greater than one is measured for the water-effect ratio, synergistic and additive effects of other pollutants in the site water are working against the antagonistic effects of any metal binding agents present.

EPA recognizes that the comprehensive qualities of the water-effect ratio do come at a cost. The procedure will yield results that are locally the most appropriate, but it is more difficult and expensive than a purely chemical approach. Consequently, performing such an analysis is not mandatory. In the absence of acceptable data, the rule assigns the ratio a value of 1.0, which yields no change in the national criteria. The rule also stipulates that the water-effect ratio cannot be set at a value different than 1.0 unless such value protects the water body from the toxic effects of the pollutant, and is derived from suitable tests on samples appropriately representative of the water body. Consequently, inadequacies, uncertainties, or ambiguities in the data will also result in the water-effect ratio being set at 1.0.

The type of specific data needed to implement the method is described in guidance: The 1992 Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, and the 1983 Water Quality Standards Handbook. As discussed in Section 7 of the preamble, EPA is currently developing more specific procedures and methods to assist States in implementing the water-effect ratio approach.

31. *Comment:* A commenter asserted that laboratory tests using artificial testing conditions have little or no direct applicability to actual discharges and receiving water situations, therefore the criteria are overprotective.

Response: Laboratory tests are not conducted in pure water and pollutants are not solely in a free ionic form (complexed by nothing but water). (For example, laboratory waters are described in some detail in various standard protocols for doing toxicity testing, e.g., American Society for Testing Materials (ASTM), Standard E729, "Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.") Laboratory waters have low, but still significant, levels of organic carbon and suspended particles that are in the range of a significant number of receiving waters. In the case of heavy metals, for example, certain particulate forms may be partially bioavailable and particulate forms in effluents may become dissolved after discharge into receiving waters. It is not appropriate to attribute toxicity solely to a particular form of metal: This has never been clearly demonstrated for any metal, being only questionably inferred under very restrictive conditions. (See response to public comment for the 1980 Guidelines, comment nos. 17, 19 & 20; 45 FR 79359.)

Because water quality criteria are derived to be protective in almost all situations, they may be overprotective in some situations. Moreover, site water effects may be most prevalent for heavy metals, this rule thus provides for site-specific determination of criteria values for metals based on local water-effect ratios.

32. *Comment:* EPA's aquatic life criteria for metals do not take into account the effect that water chemistry and metals speciation has on toxicity. EPA should withdraw criteria (such as zinc and copper), and provide criteria that vary with pH, total organic carbon (TOC), and other factors that affect speciation and toxicity.

Response: While it is true that speciation and site water chemistry can modulate toxicity and that the national criteria do not account for most of these factors, we do not agree with the comment that we should withdraw the criteria. There is inadequate data on enough species and conditions to adjust for all important factors in the national criteria, although current work is trying to address this situation. However, this uncertainty is insufficient reason to not issue and apply criteria; criteria are sufficiently applicable without modification to most receiving waters and can be appropriately adjusted for other waters by the water-effect ratio approach. The purpose of water effect calculation is to provide a means for setting the value appropriate for the site-specific water chemistry, where sufficient data are available. By providing for such a calculation in the rule, the criteria thereby appropriately incorporate such factors.

33. *Comment:* EPA's aquatic life criteria do not take into account acclimation. As a result, the criteria are overly protective.

Response: Acclimation is the ability of organisms to tolerate higher concentrations or pollutants or other conditions, developed through an exposure to such chemical or condition without apparent adverse effects. Studies with fish have not documented large changes in sensitivity because of acclimation effects, the typical factor being about two. Furthermore, significant changes have usually been reported under very restrictive and unusual exposure conditions—a prolonged exposure in a narrow concentration range near chronic toxicity values followed by a sharp rise to acutely toxic concentrations. Acclimation of individuals under most exposure conditions would be less and does not persist for long once exposures drop significantly below toxic levels. To try to account for such conditions in nationally applicable criteria is not feasible. Adaptation of populations can occur due to natural selection, but is not well described; in any event, it cannot be accounted for in any generally applied presumptive standard but only documented on a site specific basis.

34. *Comment:* Several commenters asserted that the metals criteria are below natural background levels, as shown by EPA's own studies. Thus, such criteria are overprotective and invalid.

Response: EPA studies which examine USGS data, appear to indicate that the natural background concentrations in undisturbed watersheds at times exceed the criteria for copper, lead, zinc, iron, and aluminum. However, recent work by USGS and by others (for example, Windom et al. in Environ. Sci. Technol. Vol. 25, 1137) indicates that much of this data, that is the copper, lead, and zinc data, are not valid. The measured concentrations of these metals are largely artifacts of external contamination of the sample during collection and processing. At this time USGS has suspended collecting data on these metals nationwide, until improved methods can be implemented in their central laboratories.

EPA notes that USGS generates a large portion of the data available for the nation's ambient waters, and that the federally approved protocols are used by a variety of other agencies that collect ambient data. Consequently, it appears likely that many waters may be improperly determined not to be attaining the metals criteria.

Based on USGS results, the data for the metals on the priority toxic pollutant list most likely to be affected by external contamination are arsenic, beryllium, cadmium, copper, mercury, lead, and zinc. The nickel data is unlikely to be affected. USGS suspects that filtering artifacts, rather than contamination, may produce anomalies in dissolved data for other metals not in today's rule. USGS has not yet ascertained quality of its selenium and silver data. Moreover, EPA has reviewed the data used in establishing the EPA metals criteria and does not believe these criteria are affected by the analytical problems noted by USGS. (Erickson, 1992, personal communication, in EPA's record).

To assure the reliability of the data in the lower microgram per liter range, priority toxic pollutant metals should be sampled and analyzed using protocols that involve ultra-clean reagents, ultra-clean Teflon or polyethylene labware, and ultra-clean laboratory environments.

EPA is not aware of reliable analytical data showing excursion of aquatic life criteria by natural background concentrations of the metals covered by this rule.

35. *Comment:* Commenters asserted that the acute and chronic averaging periods are unnecessarily restrictive, and were set in an arbitrary manner. As the acute criteria are derived from 48–96 hour tests, the EPA's one-hour averaging period for acute criteria cannot be correct. As the chronic criteria are derived from 30–360 day tests, the EPA's four-day period for chronic criteria cannot be correct. Pollutant specific averaging periods should be used, based on the latest scientific information, including the 1983 work of Mancini (Water Res. 17: 1355), which dealt with the effects of time varying concentrations.

Response: The quality of ambient water typically varies in response to variations in effluent quality, stream flow, and other factors. Organisms in the receiving water are not experiencing essentially constant exposure as in laboratory bioassays, but fluctuating exposures which may include short periods of high concentrations potentially causing adverse effects. EPA's criteria formulations therefore include an exposure period for concentration averaging which must be sufficiently short to limit elevated concentrations that might cause harm to aquatic life.

The 1-hour average exposure for the criteria maximum concentration (CMC) was derived to protect against the effects of fast acting toxicants like ammonia and cyanide. Thus, short-term spike increases in certain of these toxicants have been observed to cause toxic effects. (See 1991 Technical Support Document, appendix D.)

The 4-day averaging period for the criteria continuous concentration (CCC) is based on the shortest duration in which chronic effects are sometimes observed for certain species and toxicants. The most important consideration in establishing duration criteria is how long the exposure concentrations can exceed the criterion without affecting the endpoint of the test (e.g., survival, growth or reproduction). EPA believes 4 days should be fully protective even for the fastest acting toxicants.

The approach of Mancini (or similar modeling cited in Chapter 2 of EPA's Technical Support Document) is certainly a promising one for establishing averaging periods. It and similar methods are being evaluated for incorporation as options into new water quality criteria guidelines. However, the validity and applicability of these methods are still not completely resolved. Applying Mancini's model to available toxicity data forces an analyst to immediately deal with problems of delayed mortality and limitations on observation times. The fit of the model to data is also only approximate and requires professional judgment in appropriately applying it.

Because of such considerations, EPA's current approach remains reasonably protective and is therefore appropriate.

36. *Comment:* Commenters asserted that the three-year return interval is too stringent for marginal excursions of water quality criteria. As a result the criteria are overprotective. It is argued that: EPA's Technical Support Document has cited information on recovery from severe or catastrophic acute stresses as the basis for its recommended return interval for both acute and chronic criteria; EPA's criteria, however, are intended to avoid even slight stresses; and cites on EPA draft staff analysis showing that a three-year return interval for slight excursions results in a billion-year return interval for a severe stress.

Response: EPA is promulgating its proposed general rules of applicability (40 CFR 131.36(c)(2)) for the return interval based on guidance contained in chapter 2 and appendix D of the TSD. As discussed in the TSD, EPA expects the three-year return interval to provide "a very high degree of protection" (TSD at page 36). The three-year return interval approximates the same degree of protection as a once-in-ten-year seven-day average low flow design condition (7Q10), the use of which has historical precedent and is in many State water quality standards. (*Id.*)

Given the state of the science, and the limitations of available data, EPA as a matter of policy, takes the position that it should assure adequate protection and takes a conservative approach. This policy is also consistent with and recognizes historic program practices and procedures used by both the Agency and the States in implementing the water quality standards and related implementation programs. (Guidelines for Developing or Revising Water Quality Standards, April 1973, p.7.)

The draft EPA staff analysis referred to by the commenter was prepared solely as background information for discussions by the committee reviewing the methodological guidelines. EPA neither confirms or rejects the calculations.

37. *Comment:* The Guidelines indicate that criteria may be derived using data that have not undergone formal peer review, but the Guidelines do not offer meaningful guidance to determine the acceptability of test results. Inappropriate data are used to derive criteria.

Response: Toxicity tests methods have changed over time to improve precision and accuracy. This requires use of judgment in evaluation of test acceptability and results. EPA utilizes the Guidelines and professional judgment to reject unacceptable data (see Unused Data sections of Criteria Documents). Reservations about data are considered when judging acceptability of results in the context of criteria development. EPA also receives public comments on the criteria documents.

EPA's criteria for accepting or rejecting data do not depend on whether the data were published in peer-reviewed journals. The guidance provided in the 1985 Guidelines is predicated on more explicit review considerations than may be provided by most publishers of peer-reviewed journals addressing toxicity tests with aquatic organisms. EPA has observed that the public comments have also raised specific technical issues regarding the validity of peer-reviewed results.

Occasionally values in publications are not used because they are not biologically important or statistically different. In addition, recalculation of authors raw data may occur. This is part of the judgment required by criteria document preparers.

All published and unpublished references cited in aquatic life criteria documents are on file at EPA's Duluth or Narragansett laboratories.

38. *Comment:* A commenter asserted that analysis indicates that databases that have few genus mean acute valves (GMAVs) produce significantly more restrictive final acute valves (FAVs). The commenter asserts that EPA needs to increase the size of such databases to avoid promulgation of excessively restrictive water quality criteria.

Response: This comment summarizes hypothetical calculations in which the effect of the number of tested genera on the FAV were examined. It concludes that because the FAV changes as this number changes, the database size is insufficient.

EPA disagrees with the commenter's interpretation of the analysis. The commenter studied the effect of database size by changing the insensitive species while keeping the four most sensitive species the same (Commenter number 133, Appendix A., page 26). It is therefore quite expected and proper that the FAV would change as indicated. The FAV is designed to protect the fifth percentile in the sensitivity of organisms (see 1985 Guidelines, section IV, p. 26) (also 50 FR 30784, at pg. 30794; July 29, 1985). Using available suitable tests as representative of the species that are to be protected is the most reasonable feasible approach to establishing criteria values. If the sample size is 8, the four most sensitive values must be considered representative of half of the species that are to be protected and the fifth percentile would be expected to be somewhat below the lowest value. If the sample size is 32, the four most sensitive values are representative of the lowest 12.5% of the species and the fifth percentile would be expected to be near the middle of these values. And it is not just the fifth percentile that is expected to change but the entire distribution—for a sample size of 8 the mean will be near the highest of the four most sensitive values; for a sample size of 32 the mean would be far above the four most sensitive values (near the sixteenth most sensitive value).

Therefore, the response of the FAV cited in this comment is fully expected and appropriate; it in no way indicates a deficiency in the procedure or the database requirements. Similarly, the response of the FAV cited in site-specific calculations is also reasonable. If site calculations are based on fewer species and if these species tend to be more sensitive on average than the total dataset, the FAV should be lower.

39. *Comment:* A comment was received that most of the data used to derive the criteria were not developed for that purpose.

Response: The reason a toxicity test was originally conducted is not important. If the data are considered to be pertinent, of acceptable quality, and meet our protocols and other data requirements in the 1985 Guidelines, they should be used in the derivation of water quality criteria. Moreover, as stated in the 1985 Guidlines, p. 26, "confidence in a criterion usually increases as the amount of pertinent data increases."

40. *Comment:* A commenter asserted that since EPA has acknowledged that species can exhibit a significant substance tolerance range and inter-laboratory variability, the databases for many of the criteria must be significantly improved before they can be considered suitable for use in the promulgation of water quality standards. The commenter cited. Schimmel, S.C., 1981. Results: Interlaboratory Comparison—Acute Toxicity Tests Using Estuarine Organisms (EPA–600/4–81–001).

Response: Inter- and intra-laboratory variation is expected and unavoidable. Variation that causes imprecision is undesirable, but is not nearly as undesirable as is error that causes bias (Lemke, A.E.; 1981; Inter-Laboratory Acute Testing; EPA 600/3–87–005). More data are always desirable, and EPA welcomes the submission of additional high quality pertinent data, whether or not they have been peer-reviewed. The guidelines for deriving water quality criteria for aquatic life specify minimum data requirements that are intended to ensure reasonable confidence in the appropriateness of the resulting criteria.

The Science Advisory Board review referenced earlier at comment 29 accepted the EPA aquatic life 1985 Guidelines which permit the use of a single test to fulfill the minimum data base requirement. The results cited by the commenter when referring to a study conducted by Schimmel, 1981, were used by the Agency in developing the revised aquatic life guidelines in 1985. The guidelines specifically allow the use of a single-species test to fulfill the requirement for a species mean acute value. (1985 Guidelines, p. 29.)

41. *Comment:* A commenter asserted that very few of the studies used to develop the criteria cited any assessment of precision or accuracy and there was no standardization of testing protocols. Consequently, the commenter believes that the data are inadequate for the promulgation of water quality standards; and that only data from current testing protocols should be used.

Response: There is no way to fully assess the accuracy of a toxicity test because the "real" toxicity of the test material cannot be known. Various lines of evidence including results of toxicity tests and correlations between species and between test materials can help increase confidence in an estimate of toxicity. Studies of inter- and intra-laboratory variation are conducted to allow assessments of precision. Very few, if any, studies are perfect, even if they exactly followed a "current testing protocol"; the acceptability of each study must be judged individually. Studies that follow approved methodology are more likely to be high quality, but some are not; some studies that deviate from approved methodology do provide useful information.

42. *Comment:* A commenter suggested that EPA provided no data to support its contention that acute-chronic ratios are similar in fresh and salt water.

Response: As quoted by the commenter, the 1985 Guidelines, p. 15, states that "When data are available to indicate that these ratios and factors are probably similar, they are used interchangeably." The guidelines do not contend that acute-chronic ratios are similar; the guidelines state that the ratios should be considered similar only when data are available to support the decision of similarity. Ratios are usually considered to be dissimilar if the range is greater than a factor of 10 (1985 Guidelines, p. 45).

43. *Comment:* A commenter asserted that EPA should establish a separate warm-water cadmium criterion, because the national criterion is set based on rainbow trout, a cold-water fish.

Response: The commenter misconstrues EPA's criteria development protocol. EPA's aquatic life guidelines require data for the family Salmonidae as one of the minimum eight species required to calculate a water quality criterion (1985 Guidelines, Section III, p. 23). EPA did not base its criteria for cadmium solely on rainbow trout data. (Rainbow trout is a member of the family Salmonidae.) EPA used this data to meet one of the requirements for tested species required by the guidelines (Ambient Water Quality Criteria for Cadmium-1984, Table 2, p. 6). Moreover, a review of toxicity data in EPA's criteria document does not indicate that the sensitivities of so-called coldwater for warmwater species differ significantly (Ambient Water Quality Criteria for Cadmium-1984, Table 2, pp. 46–47). EPA had no scientific basis to develop separate cadmium criteria based on the division of aquatic species into coldwater or warmwater types.

44. *Comment:* A commenter argued that because EPA did not follow its own Guidelines, EPA should withdraw the lead criteria document, update and complete the species database, and recalculate an appropriate freshwater lead criterion.

Response: EPA recognizes that the lead criterion is based on seven rather than eight freshwater acute tests as recommended in the aquatic life guidelines. EPA has determined that the criteria are valid and that an additional test would not cause a sufficiently large change in the criteria (in the computation formula [see page 97, appendix 2 of the Aquatic Life Guidelines] increasing N, the number of species tested, by one with an LC50 value that is higher than the four most sensitive values only increases the acute criterion from 34 to 37 μg/l, at a hardness of 50). (See Memorandum to the Record, Kennard Potts, March 12, 1992.) This change does not warrant withdrawing the current criteria. This decision to establish the criterion based on seven tests is consistent with Section 12—Final Review, paragraph B, page 57 of the Guidelines, which allow "On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, should be derived using appropriate modifications of these Guidelines."

45. *Comment:* A commenter asserted that there is a significant error in the lead saltwater acute database, and it has implications on the validity (or lack thereof) of the saltwater acute-chronic ratio for lead.

Response: EPA recognized the error in the ambient water quality criteria document for lead in the genus mean acute value (GMAV) for *Fundulus* and corrected that error in the criteria matrix included in the proposed rule. The result of this correction was to increase the criteria maximum concentration (CMC) to 220 μg/l and criteria continuous concentration (CCC) to 8.5 μg/l.

The use of the acute-chronic ratio (ACR) of 51.29 for lead is reasonable, given the available information (see p. 9, Ambient Water Quality Criteria for Lead). The GMAV for *Mysidopsis* included in the criteria document for lead (p. 26), is ranked 7th of the 11 genera tested for lead toxicity. Therefore, *Mysidopsis* might be considered among the less sensitive genera as suggested by the commenter. However, the GMAV for *Mysidopsis* is less than 10 times the value for *Mytilus* suggesting the acute sensitivities of two genera are not greatly different. (*Ibid.*)

Other factors are more important than species sensitivity in selecting the final acute to chronic ratio (FACR) for lead. EPA did not believe that the data from chronic tests with freshwater species clearly demonstrated that acute-chronic ratios changed with acute sensitivity for the following reason. Acute values for the copepod (*Acartia*), amphipod (*Ampelisca*) and dungeness crab (*Cancer*) are within a factor of less than 2 times the value for *Mytilus*. EPA then assumed that the ratio was not related to acute sensitivity. Even if an ACR of 2.0 could be justified for larval molluscs and lead, this value should not be applied to crustaceans when an experimentally derived value for *Mysidopsis* and *Daphnia* are available. See Table 3, Ambient Water Quality Criteria for Lead.

The commenter felt EPA was inconsistent in its use of ACR values from toxicity tests and the ACR of 2.0, when the most acutely sensitive organism is larval molluscs. EPA used acute-chronic ratios from toxicity tests for lead and silver and the value of 2.0 for copper (see ambient water quality criteria documents for lead and copper, and the draft water quality criteria document for silver, 55 FR 19988, May 14, 1990. The reason experimental ACR values were selected for lead instead of the value of 2.0 are described above.

46. *Comment:* A commenter suggested that the saltwater silver criterion is not valid and submitted test results to support this claim.

Response: Some of the data presented by the commenter (Number 80) to show problems in the silver data base actually supports its validity. Acute and chronic values for *Mysidopsis* are within the range reported by others. Silver's acute toxicity to sheepshead minnows is at silver's solubility. This probably accounts for the large range in reported silver toxicity. For these species only flow-through tests with measured silver concentrations were used. The data submitted in the public comment did not include information on the test conditions, and would not be used in criteria derivation without that information. See Ambient Water Quality Criteria Document for Silver, 1980; see also draft criteria document referenced in 55 FR 19988, May 14, 1990.

Results from silver tests from Cardin (1986) where control mortalities exceeded 10% were not used. In tests with copepods and larval silversides and flounder, control mortality of <20% is judged acceptable by those who conduct tests with fragile life stages of these species. Control survival requirements for chronic tests (ASTM protocol) are more liberal than those for acute tests.

EPA's rapid chronic toxicity protocols are not appropriate test methods for deriving chronic values for water quality criteria derivation because they are not true chronic tests. Only early life-stage tests with fish and partial and entire life-cycle tests with fishes and invertebrates are acceptable as provided for in the 1985 Guidelines, section VI, part E, pages 37–39.

47. *Comment:* Comment was received that the proposed silver numeric standards should be revised to apply to the free silver ion. The commenter asserted that available information demonstrates that only the free silver ion is highly toxic to aquatic organisms while most other common forms of silver, whether soluble or insoluble, are several orders of magnitude less toxic.

Response: It would be appropriate to interpret the criterion in terms of the free silver ion only if all the silver that was included in the measured or nominal concentrations of silver in the pertinent toxicity tests would have been measured as free silver ion. Some silver would be complexed by such things as chloride, hydroxide, or carbonate in acute toxicity tests. Moreover, the feeding of the organisms in the chronic tests would result in complexation of at least some silver. This has been postulated as the explanation as to why (a) the addition of food to an acute toxicity test raises the EC50 for daphnids and (b) silver has appeared to be more toxic to daphnids in some acute toxicity tests than in comparable chronic tests. Absent a criterion that correctly applies to the free silver ion, the water-effect ratio procedure incorporated into today's rule is an appropriate means to deal with differences in toxicity caused by silver speciation.

48. *Comment:* A comment was made that the numeric silver standards should not be proposed until EPA's May 14, 1990 proposed revisions to the current ambient silver water quality criteria are finalized to reflect comments about the current science as submitted for the record of that proposal.

Response: EPA agrees with some of the comments on the May 14, 1990 proposed silver criteria. As a result, additional testing is planned and a revised document for silver will be prepared, but this is not anticipated in the near future. With this rule, EPA is promulgating its 1980 criteria for silver, because the Agency believes the criteria is protective and within the acceptable range based on uncertainties associated with deriving water quality criteria. In addition, the water-effect ratio promulgated in this rule offers development of appropriate site-specific criteria.

49. *Comment:* A commenter asserted that in the studies of Calabrese and Nelson 1974, Calabrese et al. 1973, and Coglianese 1982, the properties of the dilution water significantly affected the metals toxicity.

Response: EPA agrees that there may be differences in metals toxicity between laboratory test waters and ambient waters. For this reason, EPA has incorporated use of water-effect ratios in this rule (see Section F–7 of this preamble and an earlier response to public comment).

50. *Comment:* A comment was made that EPA should not use the metals toxicity data from Dinnel et al. 1983, who were evaluating alternative conditions in order to refine the testing protocol.

Reponse: EPA disagrees. Valid toxicity data can come from tests used to develop test methodologies and EPA determined that the Dinnel, et al. toxicity data was valid toxicity data. For example, see draft Ambient Water Quality Criteria for Silver, September 24, 1987.

51. *Comment:* A commenter argued that the metals toxicity data from Eisler 1977 are not valid because they involve 168-hour static tests. The currently recommended maximum duration for such tests is 48 hours.

Reponse: EPA disagrees. Most values reported in criteria documents are 96-hour LC50s for adult clams. EPA considers the Eisler data to be from valid and reliable tests even though they were based on other than 96-hour tests.

52. *Comment:* Comment was received that the 20–25 degree Celsius temperatures and 12:12 hour light cycle used to obtain the metals toxicity data of Lussier 1985, do not match current mysid protocol's 26–27 degree Celsius temperature and 16 hour light:8 hour dark light cycle.

Response: The submitted comments provided no data to show the effect of temperature or lighting on the chronic value. EPA does not consider Lussier's results to be artifacts because test conditions duplicate conditions found in nature.

53. *Comment:* The zinc and chromium toxicity data of Nelson 1972 should not be used because it involves an endpoint not recognized by EPA approved protocols.

Reponse: EPA disagrees. The test endpoint (the development of a hinge after 48 hours) is the same as that of the American Society for Testing Materials (ASTM), which is a standard, recognized protocol.

C. Human Health Criteria

The guideline references in the sub-section refer to Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Quality Criteria Documents, 45 FR 79347, November 28, 1980. The short reference in this sub-section is "the 1980 Guidelines."

54. *Comment:* A comment was received that use of the harmonic mean flow is a new technique and is not consistent with the way sampling is in fact done.

Response. Harmonic mean flow determinations have been adopted because the underlying hydrology support this analytical procedure. Such flows are applied only to human health criteria where human exposure is expected over a long period of time. It is derived by analyzing the pollutant mass a consumer would received by, for example, consuming a uniform amount of water everyday from a natural waterbody receiving a uniform mass loading of a pollutant.

Theoretical development as shown in the reference cited in footnote 2 of the preamble of the proposed rule (56 FR 58438) demonstrates that actual human exposure is best ascertained by using harmonic mean flow to account for concentration variation in computing the actual exposure to a pollutant.

55. *Comment:* The exposure assumptions used by EPA in developing human health criteria do not account for the variability of the population nor the consideration of exposure to more than one chemical and more than one exposure route.

Response: The EPA assumed exposure model was based on estimates or measures of national norms (see preamble discussion on human health criteria, Section F–3 and 1980 Guidelines, 45 FR 79347, Nov. 28, 1980). EPA has suggested in these and other documents that States select more appropriate fish and other aquatic life consumption rates for local populations. Some States have done so.

EPA's risk calculations aim to protect individuals exposed at an average level (*Ibid*). Thus, EPA does the calculation for average daily consumption of 2 liters of water and 6.5 grams of aquatic life for a 70 kg size individual over a 70-year lifetime. Then the Agency selects a conservative risk level (e.g., 10^{-6} or 10^{-5}) for such an average person.

People who do not fit this norm are subjected to more or less exposure to the pollutants of concern. For example, assuming a criterion based on a 10^{-6} risk level, a person who consumes 65 grams of contaminated aquatic life per day from ambient water at the criterion level would be protected at the 10^{-5} risk level, still well within EPA's desired risk range.

The effects of multiple toxicants is a more difficult problem. The science of toxicology has not developed generic ways to combine multiple risks. For specific chemicals, analysis would focus on whether the same organ and mode of toxicity were implicated. For example, it may be more significant if two chemicals both caused liver cancer as compared with a situation where one chemical was carcinogenic and the other caused other systemic effects. Thus, a case-by-case approach is currently the only feasible approach available.

EPA has clearly delineated the human health models it uses. That is, one for systemic toxicity and one for carcinogenicity. The Agency's accepted factors are available in the Integrated Risk Information System (IRIS) and in the section 304(a) water quality criteria documents, and in the 1980 Guidelines, page 79353. Locally specific risk can be estimated using the readily available information based on monitoring data for local public water supplies or fish tissue analysis for specific chemicals.

However, in a rule affecting large areas of the country, EPA's view is that it should focus on the average exposure, as a protective basis for this rule. States may take subsequent action to provide the means to account for specific cases. This rule attains that goal.

56. *Comment:* Since EPA is undertaking a dioxin reassessment, it should not be included in this rule.

Response: We believe there are sound reasons for proceeding to promulgate dioxin criteria. First, the dioxin criteria are within the range of scientific defensibility. EPA's action will also encourage and support the fourteen States now considering adopting a dioxin criterion to complete their action. Most of those States are relying on the same data used by EPA to derive its criterion. Individual Control Strategies developed under section 304(l) of the Act contain limits on dioxin as appropriate, so there will be no immediate impact from this promulgation. It is too early in the process of scientific reassessment to support major changes in either the substance or timing of regulatory decisions related to dioxin.

It should also be pointed out that 42 states and territories have adopted criteria or translator procedures for dioxin; EPA approved 40 of those actions.

57. *Comment:* Several commenters raised questions concerning the methodology used to develop the human health criteria. Some stated that the CWA methodology did not reflect changes in risk assessment and therefore was obsolete. Some commenters noted the differences between the risk ranges under the CWA and the SDWA and argued that the acceptable range of cancer risk should be the same under both statutes. Several commenters discussed specific contaminants and argued that the regulatory levels under the CWA and SDWA should be the same. One commenter provided a list of contaminants where drinking water standards were more stringent than the proposed criteria and urged that criteria should be established equal to drinking water MCLs.

Response: EPA has developed risk assessment methodologies to protect human health from contaminants in drinking water and ambient waters. Although there are some differences in the methodologies, both are scientifically defensible. Both methodologies stem from Agency risk assessment values for noncancer effects (the Reference Dose or Rfd) and for cancer effects (the cancer potency factor, q1*). See Water Quality Criteria documents (the 1980 Guidelines), 45 FR 793180 (November 28, 1980) and 56 FR 3526 (January 30, 1991) (SDWA Phase II regulations).

Both methodologies follow the Agency's Guidelines for Carcinogen Risk Assessment (the Cancer Guidelines). 51 FR 33992 (September 24, 1986). Under both programs, the Agency takes the position that there is no threshold for carcinogenic effect unless there is convincing evidence to the contrary. Both programs therefore recommend that contaminant concentration for carcinogens should be zero based on this "no threshold" presumption. See SDWA Phase II regulations at 56 FR 3533 and the 1980 Guidelines at 45 FR 79324.

The nature of the human exposure to contaminants is somewhat different in the two programs, and the assumptions used in the methodologies reflect those differences. Under the SDWA, it is protection from exposure to contaminants in drinking water that is the concern. The maximum contaminant level goals (MCLGs) reflect the level of contamination where "no known or anticipated adverse effects on the health of persons occurs and which allows an adequate margin of safety." 42 U.S.C. 300g–1(b)(4). For those contaminants that are not suspected of posing carcinogenic risk for drinking water, the Agency bases the MCLG on noncancer effects and adjusts the RfD to reflect drinking water consumption of an average of two liters of tap water per day by a 70 kg adult. This value is further adjusted by exposure assumptions; the key assumption in the drinking water program is that significant exposure to a contaminant comes from sources other than drinking water (*e.g.*, ingestion of food, inhalation), and it is prudent to allow for the contingency that other exposure may occur. While EPA uses actual exposure data where they are available, the Agency assumes, as a default position, that drinking water contributes 20%–80% of the total exposure to a contaminant. 56 FR 3532. MCLs can also be adjusted for non-health reasons, such as treatability and detectability.

Under CWA section 304(a), EPA developed human health criteria to protect for exposure to ambient water contaminants. In this case, exposure comes from ingestion of surface water and consumption of aquatic organisms which are assumed to have bioconcentrated pollutants from the water in which they live. Accordingly, the 1980 Guidelines assumes the consumption of two liters of water and the ingestion of 6.5 grams of fish per day, and the bioconcentration potential of a contaminant in fish tissue may be a significant factor in the human health criteria value. The exposure assumption in the 1980 Guidelines differs from that in the drinking water program. If data were available on exposure to a contaminant from other media such as air or non-aquatic diet, such data could be used in setting criteria. Absent such data, EPA assumes, as a default position, that ambient water (i.e., aquatic exposure and organism ingestion) contributes 100% of the exposure to a contaminant. 1980 Guidelines, 45 FR 79323. EPA considers both methods to be protective of human health for their respective exposure scenarios.

EPA agrees with commenters that the Agency has chosen somewhat different risk levels in the two programs for determining MCLs and criteria for carcinogens, but does not agree that the different levels indicate major scientific differences. Under the SDWA, it is EPA policy to establish MCLs at a range associated with excess risks of one in ten thousand (10^{-4}) to one in one million (10^{-6}). In the CWA water quality criteria documents, the Agency presents a range of concentrations corresponding to incremental cancer risks of one in one hundred thousand (10^{-5}) to one in ten million (10^{-7}); the risk ranges are presented only as information. Under the usual process in which States develop water quality criteria, the risk management decision on an appropriate risk level is made by each State. In these circumstances, States have the flexibility to choose a risk level as long as the decision is well documented, was subject to public notice and comment, and protects water uses. In this rulemaking, EPA proposed criteria with an incremental cancer risk level of one in a million (10^{-6}) for carcinogens. Today's action promulgates a risk level for each State to reflect the State's risk management decision where such a decision is discernable. See discussion in section F-5 of the preamble. In the Agency's view, the considerable overlap between the risk ranges in the two programs indicates that they are not significantly different.

Accordingly, EPA does not agree with commenters' arguments that the Agency must have identical risk assessments under the CWA and SDWA. At the same time, the Agency is studying the extent to which both methodologies might start with the same presumptions. If any changes to the methodologies seem appropriate, the changes would be proposed for public comment. In the meantime, because both methodologies stem from the same Agency risk assessment values, RfD and q1*, they are considered appropriate for deriving human health criteria for water contaminants. Therefore, as a general matter, EPA does not intend to revise the human health criteria unless and until there are changes in the 304(a) methodology.

One commenter urged the Agency to establish human health criteria equal to MCLs when the 304(a) methodology resulted in less stringent criteria. The commenter provided a list of contaminants for which the proposed criteria are less stringent than proposed or promulgated drinking water regulations for the contaminants (MCLs), and recommended that EPA promulgate water quality criteria equal to the MCLs for antimony, cadmium, nickel, selenium, silver, thallium, cyanide, ethylbenzene, toluene, 1,1,1-trichloroethane, benzylbutylphthalate, hexachlorocyclopentadiene, and 1,2,4-trichlorobenzene. EPA notes that there are five other contaminants in this proposed rulemaking for which the SDWA regulatory levels (either final or proposed) are more stringent than the proposed human health criteria; these are chromium, lead, chlorobenzene, trans-1, 2-dichloroethylene, and o-dichlorobenzene.

The fact that the numeric standards for these contaminants are different under the two programs is not a sufficient basis for replacing the proposed human health criteria with criteria equal to the MCLs. As discussed above, the methods used to derive the human health values under both the SDWA and the CWA are generally considered protective of human health. The differences that occur in the regulatory standards under the two statutes result from the assumptions used in their respective methodologies, particularly the default values chosen to estimate exposure. These assumptions are reasonable policy choices for implementing the statutory directives of the two programs. Since the CWA section 1980 Guidelines are adequately protective of human health, EPA does not consider it necessary to undertake a large scale revision of the proposed criteria in this rule to make them correspond to the SDWA standards. Moreover, EPA does not agree that MCLs are an appropriate value for a human health criterion since MCLs are partially based on feasibility considerations, including the availability of technology to achieve the regulatory level and the cost of such treatment. It is the MCLG that reflects solely health considerations. Accordingly, the Agency will not promulgate criteria equal to MCLs in lieu of less stringent proposed human health criteria. Except as noted below, the human health criteria are promulgated as proposed.

The Agency does find it necessary to withdraw the proposed human health criteria for seven contaminants pending further consideration. In the case of three contaminants—1,1,1-trichloroethane, methyl chloride, and lead—there is currently an insufficient basis for calculating human health criteria. For cadmium, chromium, selenium, and beryllium, the proposed criteria are no longer scientifically defensible. EPA is withdrawing the criteria while it evaluates all relevant data regarding the toxicity of these contaminants. The Agency's basis for deferring action on the human health criteria for these contaminants is discussed further below. For several of these contaminants, the Agency is today promulgating aquatic life criteria that are more stringent than the proposed human health criteria. However, the Agency recognizes that in limited circumstances, there might be regulatory voids in the absence of promulgated human health criteria. To minimize this potential problem, the Agency has added a footnote, footnote n, to the table setting out the criteria in § 131.36(b) that directs permit authorities to specifically address these contaminants in NPDES permit actions using the States' existing narrative "free from toxicity" criteria.

(A). 1,1,1-Trichloroethane

No public comments were received on the proposed human health criteria for this contaminant. However, in response to other comments, EPA evaluated the proposed criteria and has decided not to promulgate human health criteria. EPA proposed the human health criteria using an RfD based on inhalation data.

However, the Agency has withdrawn that RfD from the IRIS database since it is generally not appropriate to use inhalation data to estimate oral risk. As noted above, EPA bases the proposed criteria on Agency-wide RfDs in IRIS. Since no such RfD currently exists, there is no basis to support the proposed values.

(B). Methyl Chloride

58. *Comment:* A commenter stated that the criteria should not be based on carcinogenicity but on systemic toxicity. Another commenter stated that it is inappropriate to establish criteria for methyl chloride based on the carcinogenicity for chloroform.

Response: EPA agrees there are now data available on methyl chloride itself, and it is no longer scientifically defensible to rely on surrogate data for chloroform. EPA is currently evaluating a q1* and RfD for methyl chloride for developing an RfD. In view of the availability of chemical specific data and the ongoing risk assessment process, EPA does not believe it is appropriate to promulgate human health criteria for methyl chloride at this time.

(C). Selenium

59. *Comment:* One commenter noted that in the case of selenium, EPA proposed a human health criterion of 100 ug/l even though the current MCL for selenium is 50 ug/l (the same as the MCLG). The commenter believes the numbers should be the same and urged EPA to set the human health criterion at the MCL.

Response: As discussed above, EPA does not intend to replace proposed criteria with criteria equal to the MCL solely because the latter is the more stringent level. However, in the case of selenium, the Agency has determined that further consideration should be given to recent data on selenium before setting the human health criteria. Selenium is an essential nutrient in humans and plays a vital role in cell metabolism. See Health Criteria Document for Selenium, (May 1989). In such instances, the Agency must evaluate evidence of the compound's essentiality as well as evidence of toxicological effects. The Agency's Science Advisory Board has noted that synergistic effects—the interaction between selenium and other inorganic chemicals—are an important consideration in determining regulatory standards. Moreover, there are individuals who, whether from diet or supplements, consume significantly more selenium than EPA estimates of average consumption levels.

During the development of drinking water regulations for selenium, the Agency discussed new epidemiological data that were becoming available. See 56 FR 3526 at 3538–39 (January 30, 1991). In view of these new data, the numerous complex issues concerning essentiality, the consumption of elevated levels by some members of the population, and the need to ensure a protective level, EPA is unable to determine the scientific defensibility of the human health criteria, and therefore will not promulgate human health criteria for selenium at this time.

(D). Beryllium

60. *Comment:* One commenter stated that EPA's beryllium criterion is too low (i.e., 0.0077 ug/l). The commenter alleged three serious flaws in the proposed criterion for beryllium. These are: (1) Beryllium does not pose a carcinogenic risk by ingestion; (2) EPA's use of animal inhalation and injection data to support a cancer risk by human ingestion is arbitrary and capricious and is not consistent with EPA's methodology in setting human health criteria for other metals; and (3) the proposed criteria are less than natural ambient levels as well as EPA's proposed drinking water standards and would have very significant and unwarranted economic impacts.

The commenter further argued the defects in the data upon which EPA relies are so fundamental that the classification of beryllium as a Group B2 substance is unreasonable; and the EPA should classify beryllium in Group D for purposes of its potential ingestion carcinogenicity, and should adopt a human health criterion for beryllium of 1.6 mg/l, based upon a no-observed adverse effects calculation for a non-carcinogenic substance. Information on the Agency's classification system for carcinogens is included in U.S. Environmental Protection Agency (EPA), 1986, Guidelines for Carcinogen Risk Assessment. 51 FR 33992, September 24, 1986.

Response: EPA does not agree with the commenter's argument that the Agency's weight of evidence classification of beryllium as a B2 carcinogen is incorrect. There is clear evidence of carcinogenicity through inhalation or injection in monkeys, rats and rabbits, and animal studies showing tumors at sites different from the route of exposure. On this basis, the Agency has concluded that the overall weight of evidence in beryllium studies proves sufficient evidence of carcinogenicity to support a B2 classification. Drinking Water Criteria Document for Beryllium, September 1991. However, the Agency has determined that it is necessary to give further consideration to the toxicity and carcinogenicity of beryllium through ingestion before promulgating human health criteria. In the final drinking water rulemaking regarding beryllium (see 57 FR 31776, July 17, 1992), Agency analysis of the ingestion route of exposure failed to provide definitive evidence that correlates ingestion with tumor appearance. Drinking Water Criteria Document at I–7. The Agency has determined that these ingestion analyses are relevant in this rulemaking and therefore the proposed criteria are not scientifically defensible. The Agency will give additional consideration to the question of whether beryllium in water could pose a carcinogenic risk to humans before issuing criteria and accordingly, will not promulgate criteria for beryllium.

(E). Lead

61. *Comment:* A commenter noted that EPA proposed a 50 ppb lead human health criteria for consumption of water and organisms. The commenter argued that a 50 ppb criteria is not compatible with EPA's overall lead control strategy reflected under the drinking water standards, and recommended a 5 ppb lead health criteria.

Response: As noted above, differences in the proposed human health criteria and regulatory levels under the SDWA methodology are not, in themselves sufficient basis for revising the criteria. In this case, the original basis for the 1980 Guidelines and, in turn, the proposed criteria was however the MCL. In 1991, EPA promulgated a zero MCLG and treatment technique for lead in drinking water, which will, when effective, replace the current MCL. The treatment technique includes a 15 ppb lead action level at the tap.

In view of drinking water regulatory action, EPA has determined that it is not appropriate to promulgate a human health criteria based on a drinking water MCL that no longer reflects the Agency's position. The Agency has given preliminary consideration to other numeric values but has not yet reached a consensus on an appropriate human health criteria. Accordingly, EPA is not promulgating human health criteria for lead at this time.

(F). Cadmium

62. *Comment:* A commenter noted that EPA had proposed criteria for cadmium that were less stringent than the MCLs. The commenter urged EPA to set the criteria at the MCL level.

Response: As noted above, differences in the two regulatory levels is not a sufficient basis for using the more stringent MCL. However, the Agency has determined that it is necessary to give further consideration to the toxicity of cadmium from exposure to water in terms of the bioconcentration potential of this contaminant. As discussed earlier, one of the factors used to calculate the human health criteria is consumption of aquatic organisms. It is, therefore, particularly important that the Agency ensure that the criteria adequately reflect the bioconcentration of cadmium. EPA is currently addressing this issue in other regulatory actions (*e.g.*, sewage sludge and the Great Lakes initiative) and expects that the data and analyses being developed in these efforts will be of value in further examination of the human health criteria. Accordingly, the proposed criteria are not scientifically defensible and EPA will not promulgate human health criteria for cadmium.

(G). Chromium

63. *Comment:* A commenter noted that in the case of chromium with valences of plus VI and III, EPA proposed human health criteria of 170 and 33,000 µg/l, but that the Agency had promulgated a total chromium MCL of 100 µg/l. The commenter urged the Agency to take a similar position here.

Response: As noted above, the fact that the numeric values for CWA and SDWA regulatory actions are different is not a sufficient basis for revising the CWA criteria. However, in this instance, EPA has determined that the proposed criteria are not scientifically defensible. New information concerning the conversion of chromium III to a more toxic chromium VI during the chlorination process should be considered in setting the criteria as well. (See 56 FR 3526 at 3737, January 30, 1991). Accordingly, EPA will not promulgate the proposed human health criteria for chromium.

For other reasons, proposed human health criteria were withdrawn for four pollutants.

(H). Silver

64. *Comment:* Several commenters stated that silver should no longer be classified as a toxic pollutant for human health concerns and that no further regulation for silver is appropriate. Commenters also addressed the issue that the proposed silver criteria should be revised to delete human health as a toxicity-based criterion to be consistent with the recent deletion of the MCL for silver under the Safe Drinking Water Act. (56 FR 3526, January 30, 1991.)

Response: EPA deleted the human health criteria for silver, because the *only potential* adverse effect from exposure to silver in drinking water is argyria (a discoloration of the skin). EPA considers argyria a cosmetic effect since it does not impair body function. However, free silver ion is highly toxic to fish. Therefore, to protect aquatic life, silver will be regulated with aquatic life criteria as promulgated in today's rule.

(I). Acenaphthylene, Phenanthrene, Benzo(g,h,i)Perylene

65. *Comment:* Several comments were received which stated that (1) the EPA has expanded the list of polynuclear aromatic hydrocarbon (PAH) compounds to be regulated as carcinogens. Specifically, the commenters do not agree with the Agency that acenaphthylene, phenanthrene, benzo(g,h,i)perylene, and chrysene should be treated as carcinogens, and (2) the proposed rule establishes human health criteria for a diverse class of compounds (such as polynuclear aromatic hydrocarbons) based solely on structural similarity, and the assumption that all of the compounds are of equal toxicity to the most potent compound within the "class."

Response: The Agency agrees with the several comments that the water quality criteria for acenaphthylene, phenanthrene, and benzo(g,h,i)perylene should be based on non-carcinogenic effects of these chemicals since inadequate toxicity data are available to assess carcinogenic potential of these chemicals. However, there are insufficient toxicity data available to provide risk assessment for these three compounds at this time. Therefore, they have been deleted from this rule.

The Agency does not agree with the comment regarding chrysene. Chrysene has shown carcinogenicity in several animal studies. (U.S. EPA, 1991. Drinking Water Criteria Document for Polynuclear Aromatic Hydrocarbons (PAH's) Office of Water.) Chrysene produced tumors (as did other PAHs included in this rule) in several mouse strains when applied topically in assays for complete skin carcinogenicity or in initiation/promotion protocols. Several early studies employing intramuscular or subcutaneous injection of mice and rats produced negative or equivocal results. Three studies wherein neonatal mice of two strains were exposed intraperitoneally reported increased tumor incidence in liver and other sites (*Ibid*). Chrysene produced mutations in *Salmonella* and chromosome aberrations and morphologic transformation in mammalian cells.

The Agency recognizes that carcinogenicity of various PAHs vary with each PAH, however, Benzo(a)pyrene being the most potent carcinogen of this class, was used to develop criteria for all the PAHs.

(J). Other Pollutants

66. *Comment:* A commenter requested that EPA explain the origin of the use of safety (uncertainty) factors.

Response: The safety factors (now referred to as uncertainty factors [UF]) used in calculation of the Acceptable Daily Intake (how referred to as the Reference Dose [RfD]) were developed from the National Academy of Science guidelines (1977) with modification by the EPA. These factors are similar to those used by the World Health Organization (Food Chemistry Toxicology, Vol. 27, No. 4, pp. 273–274, 1989). The EPA is presently working on new approaches to calculation (estimation) of a RfD (ADI).

The term "safety factor" (now UF) was initially used by the Food and Drug Administration (FDA). They used no-effect levels (in mg/kg of diet) from chronic animal feeding studies and divided by 100 to get an Acceptable Daily Intake (ADI) level. For less-than-lifetime (or sub-chronic) studies, they divided the no-effect level by 1000. The National Academy of Science recommended that EPA use a similar approach and outlined the use of 10-fold UFs for intra- and interspecies variation. An additional 10-fold UF is also included to calculate a lifetime number from a less-than-lifetime study. The term "RfD (Reference Dose)" is now used by the EPA instead of the ADI. The above referenced information is included in the Agency's Risk Assessment Guidelines published at 51 FR 33992, September 24, 1986.

67. *Comment:* A commenter stated that EPA should not use Structure-Activity Relationships (SAR) techniques to regulate chemicals, such as methyl chloride, when data on the specific chemical are available.

Response: The EPA uses SAR only when data on specific chemicals of a chemical group are lacking (see 1980 Guidelines, Section D, page 79355). SAR is a technique used to compare the toxicity of individual chemical in the group with the known toxicity of one member of the group based on chemical structural similarities. For example, SAR was used in criteria development for polynuclear aromatic hydrocarbons (PAHs), polychlorinated bi-phenyls (PCBs), and tri-halomethanes (THMs) because the EPA does not have adequate health data on most of the chemicals in the class under review. For a detailed discussion on methyl chloride, see previous comment.

68. *Comment:* A commenter stated *that the toxicities of inorganic arsenic* (As) and the organic arsenic derivatives present in fish may be quite different.

Response: EPA agrees with the commenter—the organic arsenic forms are known to be less acutely toxic then inorganic arsenic forms ("Threshold Carcinogenicity Using Arsenic as an Example," Advances In Modern Environmental Toxicology, 15:133–158, 1988). In addition, since the organic forms found in fish appear to be excreted as the parent molecules, they are likely to have less long-term toxicity. A footnote has been added to section 131.36(b) stating that the criteria for arsenic refers to the inorganic form only.

69. *Comment:* A commenter stated that the arsenic standard is based on an IRIS recalculation that has never been open for public inspection.

Response: The 0.018 µg/l (water and aquatic life consumption) and 0.14 µg/l (aquatic life consumption) criteria were calculated from the unit risk factor of $5x10^{-5}$ $(\mu g/l)^{-1}$. The unit risk factor of $5x10^{-5}$ $(\mu g/l)^{-1}$ is on IRIS and available for public inspection. Although EPA incorrectly indicated in the proposal that the criterion was calculated using an addendum to the prior criteria document and not IRIS, in fact the addendum included the IRIS information and this information was in the record. There is an IRIS submission desk for public comments. Moreover, this rulemaking provided an opportunity for public comment.

70. *Comment:* A commenter claims that the EPA's Science Advisory Board (SAB) is critical of EPA's criteria for arsenic.

Response: The SAB stated that "at doses below 200 to 250 µg As^{+3}/person/day there is a possible detoxication mechanism" and recommended that EPA "develop a revised risk assessment based on estimates of the delivered dose on non-detoxified arsenic." (EPA–SAB–EHC–89–038. Letter from SAB to William Reilly, September 28, 1989.)

Since it is not known exactly when and how arsenic can be considered to be detoxified, EPA cannot, at present, calculate this "delivered non-detoxified" dose. It has been postulated by Marcus and Rispin ("Threshold carcinogenicity using arsenic as an example" Adv. Modern Environ. Toxicol. 15:133–158, 1988) that methylation is a detoxification process. While methylation certainly decreases the acute lethality of arsenic, we do not have enough toxicity data to regard the mono- and dimethylated methobolites as "non-toxic".

71. *Comment:* A commenter noted that no significant health effects from

arsenic exposure has been found in the U.S., as compared to the effects seen in Taiwan.

Response: The cancer potency for arsenic is calculated using standard Agency methods. The available U.S. epidemiology studies are small and do not have the statistical power to state whether the effects and risks in the U.S. are dissimilar to those that have been reported in Taiwan.

72. Comment: A commenter questioned the effects of arsenic at low dose and states that a threshold for arsenic may exist. The Marcus and Rispin paper is cited as justification. (Threshold Carcinogenicity Using Arsenic as an Example!', "Advances in Modern Toxicology, 15:133-158, 1988.)

Response: There are no adequate data on whether arsenic exerts the same effects at low doses that it does at higher doses. To extrapolate to low dose effects, the EPA uses the linearized multistage model. At the present time, there is no substantial database which demonstrates that arsenic has a threshold for adverse effects. Marcus and Rispin theorized that there is a threshold for arsenic. However, there is no adequate proof that such a threshold exists. In addition, it should be noted that there is not an adequate epidemiology study on U.S. populations. Accordingly, at the present time, there is no way to establish the presence or absence of a threshold level for arsenic.

73. Comment: Arsenic causes skin cancer, and not all forms of skin cancer are equally lethal.

Response: The EPA knows that the form of skin cancer induced by Arsenic is treatable and agrees with the commenter that not all forms of cancer are equally lethal. However, the EPA is aware of data showing that arsenic can cause internal cancer and is reluctant to change the risk assessment based on skin cancer until the recent data can be evaluated (the Taiwan data).

74. Comment: EPA assumes that all forms of arsenic are equally carcinogenic and therefore the proposed criteria are overly conservative.

Response: The Agency does not consider all forms of arsenic to be equally carcinogenic and has clarified this issue by adding footnote "b" to the matrix in this rule.

75. Comment: Several commenters stated that the exposure assumptions or models used to generate ambient water quality criteria are extremely conservative for the following reasons: (1) 6.5 g/d reflects consumption of both contaminated and non-contaminated fish, (2) given the mobility of the population, drinking water from the same source over an average lifetime is extremely remote, (3) the supposition that a person will be drinking water from a surface stream in the first place is questionable, and (4) criteria assume that the same person would actually be consuming "contaminated" water which should have been prohibited under the Safe Drinking Water Act.

Response: The EPA exposure model was based on estimates or measures of national averages (Seafood consumption data analysis, U.S. EPA, 1980—see Guidelines, page 79356). Data indicate that fish consumption rates for recreational and subsistence anglers can exceed 6.5 g/day. EPA has suggested that States select more appropriate fish and other aquatic life consumption rates for local populations. Some States have done so. (See TSD, p.37.) The commenter is correct that the 6.5 grams data reflects consumption of both contaminated and non-contaminated fish. The 6.5 grams is the quantitative daily aquatic life consumption used by EPA. However, EPA's methodology assumes that the 6.5 grams per day of aquatic life were taken from waters meeting the criteria level (see 1980 Guidelines, Section A, page 79348).

In EPA's view, the assumption that an individual may drink from the same surface water for their lifetime is reasonable and meets the goal of the CWA. Drinking water directly from surface supplies is not always regulated under the SDWA: There are many circumstances which are not regulated by the SDWA. SDWA regulations are only applicable to public water supplies serving populations of 25 people or more or in which there are 15 or more service connections.

76. Comment: Several commenters questioned the fish and water consumption rates of humans as related to the dioxin criteria.

Response: The Agency is reviewing the scientific basis for the human fish consumption factor used in the derivation of dioxin criteria. (56 FR 50903; October 9, 1991.) When these reviews are completed and the findings critically evaluated, the Agency will initiate a process to determine whether the criteria for dioxin should be revised.

77. Comment: Bioconcentration factors (BCFs) should be based on the proportion and type of organisms that would be non-migratory and likely to be caught and consumed by recreational fishermen.

Commenters disagreed with the way the BCF's were derived for 8 chemicals:

Antimony
Arsenic
Beryllium
Cadmium
Chromium
Mercury
Selenium
Thallium

Response: BCFs for all of the criteria, including the above cited metals were supplied by EPA's Duluth laboratory and were used to calculate the promulgated criteria (i.e., from the list above, antimony, arsenic, mercury and thallium which are still in today's rule. The other four metals have been deleted. See comment number 57). (See 1980 Guidelines, pp. 79348-49.) EPA has suggested that States may select more appropriate fish species such as non-migratory and recreational species in developing BCF values which would more appropriately reflect local conditions and aquatic species (see response to comment earlier regarding BCFs and the Technical Support Document for Water Quality-based Toxics Control, EPA/505/2-90-001; March, 1991 at pp. 36-41.) Some States have chosen to do so.

78. Comment: A commenter stated that EPA utilized a high degree of overprotection in developing criteria for antimony. The commenter requested EPA to update the IRIS and Health Effects Assessment Summary Tables by using available data to provide toxicity information for various antimony compounds that more appropriately reflects such factors as differences in gastrointestinal absorption rates.

Response: In developing a criteria for antimony the Agency relied upon the available data which is very limited for antimony compounds. The greatest volume of information in terms of chronic exposures to antimony salts was for potassium antimony tartrate. This compound is also the most toxic antimony compound tested. In order to be protective of antimony in all its possible forms, organic and inorganic, the Agency relied upon data from potassium antimony tartrate. Therefore, the IRIS-listed reference dose (RfD) for antimony tartrate is used in the criteria development.

It is true that this criterion may be conservative in some cases. EPA is promulgating this antimony criterion because the criteria must protect human health and it has not been established which antimony compounds may be produced under natural conditions in ambient waters.

79. Comment: A commenter stated that EPA should establish separate criteria for the less soluble and commercially more important antimony oxides. The IRIS database indicates a much higher NOAEL for antimony trioxide than for antimony tartrate.

Response: As stated above, the Agency is setting criteria which would result in protection from all soluble forms of antimony, not just the most common forms. It is true that antimony oxide is much less toxic than potassium antimony tartrate. However, the Agency is taking a conservative approach and assuming that there is the potential for toxic organic antimony compounds, such as the tartrate compound, to form under ambient water conditions. For this reason, the Agency chose the more stringent of the two RfDs listed on IRIS for antimony compounds. (See 1980 Guidelines discussion, p. 79355.)

80. *Comment*: A commenter stated that EPA should use a less conservative application of uncertainty factors in developing the RfD for antimony.

Response: The RfD for antimony, based on the lifetime rat study by Schroeder et al. cited in IRIS (1992), includes an uncertainty factor of 1000 since the study resulted in a Lowest Observed Adverse Effect Level (LOAEL). A No Observed Adverse Effect Level (NOAEL) could not be determined from this study. It is Agency policy to assign an uncertainty factor of 1000 to a LOAEL from an animal study of lifetime duration. If there had been a higher degree of certainty that this LOAEL was indeed close to an observed NOAEL, then the uncertainty factor assigned may have been reduced. However, given the paucity of data on antimony, the Agency assigned the full 1000 uncertainty factor in developing an RfD. (See discussion in the 1980 Guidelines, pp. 79353–54.)

81. *Comment*: A commenter stated that EPA should use the revised bioconcentration factor (BCF) of 0.5 recently developed by EPA for antimony instead of the outdated BCF (1.0) used in calculating the criteria.

Response: It is not true that the BCF for antimony has been officially revised since the 1980 ambient water quality criteria (AWQC) was developed. There are draft updated BCFs under development by the Agency. However, the Agency has not provided the public an opportunity for comment on the new BCF as it has for the revised RfD values which were derived from IRIS. Information on IRIS is considered public information, easily accessed and open to public review. The Agency decided it would be unfair to include revised BCF values into this rulemaking without giving all interested parties a chance to comment on them. For this reason the Agency has presented criteria with 1980 BCF values. EPA will revise the criteria for human health once a revised methodology is developed. At that time we will also include all updated BCF values.

82. *Comment*: Several commenters stated that the polychlorinated biphenyls (PCBs) criteria needed revisions. These included: (1) Revising the cancer potency factor estimated by EPA, (2) setting criteria for each of the Aroclor mixtures separately rather than for a single Aroclor mixture, (3) translating the animal evidence of carcinogenicity into human risk values.

In support of their argument concerning the cancer potency of PCBs, the commenters cited from the report, "Reassessment of Liver Findings in PCB Studies in Rats by Pathology Working Group" prepared by the Institute for Evaluating Health Risk (IEHR). The report reviewed five chronic studies in rats using Aroclor 1260, Aroclor 1254, Clophen A–60 and Clophen A–30. PCBs with chlorine content of less than 60% i.e., Aroclor 1254 and Clophen A–30 had little or no evidence of carcinogenicity. With respect to Aroclor 1260 study, the commenter recommended that the EPA should use a cancer potency factor of either 5.1 or 1.8 $(mg/kg/day)^{-1}$. The EPA potency factor of Aroclor 1260 is 7.7 $(mg/kg/day)^{-1}$. The cancer potency factor of 5.1 $(mg/kg/day)^{-1}$ was calculated from the same study (Norback and Wellman) as used by the EPA. Use of geometric means of all the studies with chlorine content of 60% resulted in the cancer potency factor of 1.9 $(mg/kg/day)^{-1}$.

The commenter argues since there is no evidence that the PCBs with chlorine content of less than 60%, are carcinogenic, the Agency should set a separate criterion for each of the mixtures i.e., Aroclor 1242, Aroclor 1254, etc.

Response: EPA disagrees with the commenter concerning the cancer potency calculations using geometric means of several studies resulting in value of 1.9 $(mg/kg/day)^{-1}$. Utilization of a geometric means approach for the calculation of potency estimates from the available studies is not reasonable because different animal strains and age levels were used in these studies. In addition, the study of Norback and Wellman, cited in IRIS (1992), from which EPA calculated its potency factor of 7.7 $(mg/kg/day)^{-1}$, was much superior in its design and conduct than the other studies. Therefore, the Norback and Wellman study is expected to provide a more precise criterion. The re-examination of slides from the Norback and Wellman study by a group of private pathologists and the use of the revised data is alleged to a yield cancer potency factor of 5.1 $(mg/kg/day)^{-1}$. This potency factor is not very different from that calculated by the Agency.

The Agency believes that it is not reasonable to develop a criterion for each of the PCB Aroclor mixtures. PCBs are mixtures of chlorinated biphenyls. Each mixture may contain up to 209 possible individual compounds. These mixtures are prepared by treating biphenyls and chlorine under alkaline conditions and are characterized by the chlorine contents of the mixtures. For example Aroclor 1242, 1254 and 1260 contain 42, 54 and 60 percent chlorine contents respectively. These mixtures are not characterized by the occurrence of each possible compound in the mixture. Each of the mixtures would be expected to contain all combinations of chlorinated compounds even though some of them in small or trace amounts. In summation, all the Aroclors are expected to contain chlorinated carcinogenic PCB isomers. Besides expecting carcinogenic compounds in each mixture, these mixtures cannot adequately be analyzed with commonly available methods.

The Agency believes that the evidence of carcinogenicity observed in animals can be used to estimate risk values. The Agency has used this approach in this regulation based on the existing Agency 1980 Guidelines (51 FR 33992).

83. *Comment:* One commenter noted that there is a marked range of carcinogenic potencies between the various nitrosamines with some nitrosamines exhibiting no carcinogenic activity. The commenter argued that reliance on structural similarity methodology could therefore result in misclassification errors as to whether specific compounds should be treated as carcinogens.

Response: EPA agrees that there is a marked range of carcinogenic potencies between the various nitrosoamines with some nitrosoamines exhibiting no carcinogenic activity. If there are adequate data available for a specific nitrosoamine, EPA uses such data in evaluating the health risks that such a chemical may present. However, such data are often not available. As a consequence, EPA must, as a practical matter, infer the toxicity of one compound from the toxicity of a chemically similar analogue.

84. *Comment:* A commenter submitted a document entitled, "Biological Risk Assessment of N-Nitrosodimethylamine." While this document does not recommend a specific human health criteria for N-nitrosodimethylamine (NDMA), it does conclude that: 0.0044 µg NDMA/kg/day will present the public with a lifetime 10^{-5} risk level of cancer.

Response: It is not at all clear how the author(s) of "Biological Risk Assessment of N-Nitrosodimethylamine" arrived at the 0.0044 µg NDMA/kg/day with 10^{-5} risk level. Assuming the ingestion of 2 L of water/day by a 70 kg adult, 0.0044 µg NDMA/kg/day is equivalent to a level of NDMA in drinking water of 0.28 µg NDMA/L. Based on the same data, IRIS concluded that the 10^{-5} risk level for NDMA in drinking water is 0.007 µg/L (i.e., 1/40 the value of "Biological Risk Assessment of N-Nitrosodimethylamine"). Thus, EPA disagrees with the comment since inadequate data and analysis were provided.

85. *Comment:* A commenter noted that the human health criteria presented in the table (in parentheses) are for pollutants which had *no* health based criteria in the 1980 criteria documents (45 FR 79318). The commenter urged EPA to not include these criteria in the final rulemaking.

Response: The proposed rule indicated these values presented with parentheses in the matrix were *not* being proposed as regulatory criteria but were presented as notice for inclusion in future State triennial reviews. So as not to confuse these values with the criteria being promulgated today, those values were deleted from the matrix and presented below.

Compound	Water and organisms (µ/L)	Organisms only (µg/L)
Copper	1300	----
1,2-Dichloropropane	0.52	39
1,2-Trans-Dichloroethylene	700	----
2-Chlorophenol	120	400
2,4-Dimethylphenol	540	2300
Acenaphthene	1200	2700
Butyl Benzene Phthalate	3000	5200
2-Chloronaphthalene	1700	4300
n-Nitrosodi-n-Propylamide	0.005	1.4

3. Economics

86. *Comment:* Many commenters objected to the Agency's decisions not to develop detailed cost estimates and not to conduct a comprehensive Regulatory Impact Analysis. The objections were presented in terms of (a) EPA's obligation pursuant to Executive Order 12291 to conduct an analysis; (b) the need to use benefit-cost analysis to make effective public policy decisions, and (c) EPA's error in relying on the difficulty of the task as a reason for not conducting the analysis.

Response: EPA's decision not to provide detailed cost estimates was based on the unusually complex characteristics of this rule with respect to projecting the burden on dischargers. Section J of this preamble includes a discussion of EPA's effort to estimate costs for the rule. As a very brief summary, cost estimates for compliance with water quality-based permits would be based on numerous assumptions; results are sensitive to these assumptions; and consequently, the results would not provide meaningful information to the rulemaking process.

For the final rule, the Agency has undertaken a cost assessment to express a range of compliance costs for several combinations of industries and pollutants. The Agency has also estimated and/or described a range of health and ecological benefits for the rule. While this information about costs and benefits does not constitute a comprehensive Regulatory Impact Analysis, the assessment provides descriptive information about the types of costs that might be incurred as new water quality standards are translated into specific NPDES permits. Also, the ranges illustrate the uncertainties inherent in any estimate of costs.

In addition to the compliance costs to dischargers, other types of cost impacts may occur as a result of EPA-imposed numeric criteria in State water quality standards. For example, nonpoint sources of pollution may incur costs to the extent that best management practices need to be modified to meet water quality standards. In addition, States may incur increased monitoring costs, but only if there is some reasonable expectation that the pollutants are manufactured or actually used in the State.

Several commenters, representing the interests of industrial and municipal dischargers, provided cost estimates; others provided cost data for various compliance strategies. These cost estimates cannot form the basis of an economic impact analysis. Insufficient information is presented in the comments to determine whether these costs reflect the most cost-effective means of achieving the required pollutant reductions. Similarly, EPA cannot confirm whether the cost estimates reflect the incremental cost to comply with water quality-based standards beyond the cost to comply with technology-based regulations. It is the incremental costs that are relevant to this assessment. In addition, the information supplied in the comments is not sufficient to measure the impact of these costs on the financial condition of the dischargers (whether industrial or households).

Due to the uncertainties, a Regulatory Impact Analysis would not alter the Agency's decision to fulfill its statutory responsibilities and promulgate numeric criteria for toxic pollutants. The same conclusion applies to detailed compliance cost estimates.

U.S. Government Standard Form 83, Request for OMB Review, includes a section for OMB to waive the requirements to conduct a Regulatory Impact Analysis, so OMB does have such authority.

87. *Comment:* Several commenters asserted that EPA has not demonstrated that the costs and operating inefficiencies of complying with federal criteria are commensurate with environmental benefits.

Response: The provisions in the Clean Water Act covering water quality standards and specifically, establishing numeric water quality criteria for toxic pollutants, do not include consideration of costs or benefit-cost comparisons. As explained above in section J, economic factors are considered at some points in the process (such as establishing water body use classifications), but not as a component of adopting water quality criteria. The statutory requirements covering water quality criteria focus instead on protection of human health and the environment.

EPA has considered the ability and value of estimating the benefits associated with revised water quality criteria. A summary of the human health and ecological benefits is included in Section J of this preamble.

Briefly, the Agency finds that reduced pollutant discharges are feasible at reasonable costs for several examples. In addition, the national toxics rule has the potential to reduce excess cancer cases. Other ecological benefits, such as protection of wildlife and aquatic organisms, are also projected as an outcome of States adopting numeric pollutant criteria in their water quality standards.

88. *Comment:* Several commenters argued that EPA should conduct a Regulatory Flexibility Analysis because not to do so is a violation of the Regulatory Flexibility Act, and an agency cannot abrogate its statutory duty by pleading hardship.

Response: EPA finds that meaningful results from extensive cost and regulatory impact analyses for this rule are unlikely to be achieved. The same conclusion applies to a detailed analysis conducted in response to the Regulatory Flexibility Act. Briefly, the numerous assumptions and analytical difficulties that are inherent to this rulemaking yield information about the scope of costs, but not detailed cost estimates for specific groups of discharges, such as small entities. Nonetheless, as described above, EPA's evaluation does not find that there will be a significant impact on a substantial number of small entities; therefore, a final Regulatory Flexibility Analysis is not required.

89. *Comment:* Several commenters asserted that EPA should consider current economic conditions in determining whether to promulgate Federal criteria.

Response: While EPA acknowledges that prevailing economic conditions affect individual business decisions concerning investment in pollution control, Congress clearly intended the Agency to move expeditiously when Federal action is warranted. In compliance with congressional intent, EPA is promulgating these criteria at this time.

In addition, it is not clear which "current economic conditions" should be taken into account in establishing federal criteria. The limitation of toxic discharges is intended to be a continuing process, with this rule a part of the on-going control process. Since the criteria will be in effect during all phases of business cycles, current conditions cannot be the sole determinant of economic conditions when analyzing the economic impact of a regulation. Likewise, the impact of this rule will not be incurred immediately because the criteria will be written into new discharge permits as the current permits expire.

90. *Comment:* Several commenters, representing industrial and municipal dischargers, asserted that the economic impacts of complying with EPA-imposed criteria will be substantial and will be burdensome.

Response: While it is likely that some dischargers will incur compliance costs when the EPA-imposed numeric toxic pollutant criteria are translated into specific NPDES permits, it is not certain that such costs or their impacts will be unreasonable. For several industries, as described in the Agency's cost assessment, large segments of the discharging community will not be affected by this rule because, for example, costs to comply are very small, or technology-based limitations are a sufficient basis for effluent control that will also control pollutants to the level needed to comply with in-stream water quality criteria.

91. *Comment:* Commenters representing municipal interests stated that EPA is incorrect in the assumption that industrial sources are the primary source of toxics discharges by POTWs.

Response: EPA recognizes that there are several sources of toxic pollutant contributions to POTWs. Industrial indirect dischargers, while not the only source, are often the primary source, and the toxic influent from these sources can often be controlled through pretreatment programs.

92. *Comment:* Several commenters stated that promulgation of Federal criteria removes the flexibility to reduce impacts that States would have had by adopting their own standards. Further, they argue, EPA is incorrect in its assumption that impacts are no different than what would occur if States had acted to adopt their own standards.

Response: States continue to have the opportunity to adopt their own standards that include numeric criteria for toxic pollutants. As they adopt and EPA approves their water quality standards, the flexibility provided in the standards-implementation and permit-writing phases of the standards process will return to the States. For a discussion of the effect of this promulgation on various implementation questions, including flexibility, see subsection 4 of this section.

In the cost assessment, EPA has investigated the potential incremental effects of EPA setting standards instead of States. Briefly, EPA finds that for certain dischargers, incremental costs may be incurred in States where toxic pollutant criteria are adopted at EPA's levels. If a State were to adopt less stringent criteria, it is possible that the impacts would be reduced. It is important to consider that in some of the examples, EPA's criteria did not result in incremental costs.

As discussed elsewhere in this preamble, EPA encourages States to adopt their own standards and make use of site-specific criteria as appropriate.

4. Implementation

93. *Comment:* The Agency received substantial comment on 40 CFR 131.36(c) which described the proposed implementation procedures for priority toxic pollutant criteria. Comments divided on whether such factors should be included or left to the discretion of the States.

Response: For reasons stated in the preamble to the proposed rule (56 FR 58437, section 3, Applicability), EPA believes that baseline application conditions must be included in order to provide the intended environmental and human health protection of the criteria. These criteria consist of more than quantitative concentrations. EPA's section 304(a) criteria methodology clearly presents the criteria as criteria maximum concentrations (CMC) and criteria continuous concentrations (CCC) which contain averaging periods and return frequencies. The implementing hydrological conditions merely provide minimum conditions to meet these definitions. The salinity conditions delineating when and where the freshwater and saltwater criteria apply are also necessary. EPA must specify where each of these sets of criteria apply. Likewise the hardness limitations for applying the metals criteria. Each of these paragraphs will be discussed in more detail below but are mentioned here to demonstrate their necessity for implementation of the criteria. Without these generic application conditions NPDES permit writers, the principal users of the criteria, would be unable to develop conditions and limits for inclusion in NPDES permits within the requisite ranges of consistency and predictability.

94. *Comment:* The ability of States to develop site-specific criteria and to grant variances and exceptions to standards received several comments generally indicating that EPA should not constrain the ability of States to use such implementation procedures.

Response: The development of site-specific criteria and the use of variances to standards are optional procedures made available to States that adopt State criteria (40 CFR 131.11(b)(ii) and 131.13). It is neither a statutory nor a regulatory requirement to develop site-specific criteria or to issue variances.

The preamble language to this final rule clarifies EPA's statement on this subject in the proposal. Since the criteria in this rule are Federal criteria applicable to the State, a State cannot unilaterally establish site-specific criteria or grant variances to the Federal rule. That is what EPA meant in the proposal when we indicated that actions pursuant to State law for Federally promulgated criteria are precluded. Such procedures are still available to the State, but are much more cumbersome as it requires the State to meet all the regulatory requirements for developing such procedures, but then EPA would need to undertake a Federal rulemaking process in order to effectuate changes to the Federal rule in accordance with the requirements of the Administrative Procedures Act. EPA continues to emphasize that this is another strong reason for States to act to adopt their own standards even after Federal promulgation action is taken.

95. *Comment:* One EPA Region questioned whether the specification of the applicable hydrological baseline mandated the use of steady state models and eliminated the use of dynamic models for wasteload allocations.

Response: The proposed rule did *not* intend to eliminate the use of dynamic models for wasteload allocations and total maximum daily load determinations. Generally the low flows specified explicitly contain duration and frequency of occurrence which represent certain probabilities of occurrence. Likewise the criteria for the priority toxic pollutants are defined with duration and frequency components. Dynamic modeling techniques explicitly predict the effects of variability in receiving water, effluent flow, and pollutant concentration. EPA has recommended and described three dynamic modeling techniques for performing waste load allocations in section 4.5 of the 1991 Technical Support Document: Continuous simulation, Monte Carlo simulation and lognormal probability modeling. These procedures allow for calculating wasteload allocations that meet the criteria for priority toxic pollutants without using a single, worst-case concentration based on a critical condition.

Thus, EPA believes that either dynamic modeling or steady State modeling can be used to implement the criteria adopted today.

96. *Comment:* Several commenters in addressing implementation conditions argued that EPA should defer entirely to State discretion including the applicable design flows. Other commenters urged removal of design flows from the rule and rely on the guidance in the TSD and/or other EPA guidance. Another commenter agreed that flow requirements were necessary but that the harmonic mean flow requirement was flawed.

Response. As noted in the preamble to the proposed rule, implementation requirements that include limitations on flow values are required in order to achieve the intended environmental and human health protection. The applicable discussion of this issue is found in the preamble to the proposed rule on pages 58437–58438 and footnotes 1 and 2. The hydrological or biological basis for the proposed low flows were taken directly from EPA's Technical Support Document for Water-Quality-based Toxics Control. (See TSD, Appendix D for aquatic life and section 4.6 for human health.)

The argument by the commenter on the harmonic mean flow was in reality a disagreement on EPA's assumed long-term dose assumption for toxics. The commenter believes short-term effects are more relevant, and therefore requires a different flow, especially for bioaccumulative pollutants. However, EPA continues to support the human health protocol used in the proposed rulemaking and notes that it explicitly accounts for bioaccumulation in the criteria development protocols. For such long-term human assumed consumption of water and aquatic life from such waters containing a pollutant, EPA's best scientific judgment is that the harmonic mean flow is the correct flow to apply in order to correctly estimate the exposure dosage of the average exposed individual.

97. *Comment:* One commenter questioned the applicability of the specified design flows in waters downstream from impoundments which have minimum release rates specified, as for example hydroelectric dams.

Response: EPA's proposed rule in § 131.36(c)(2)(ii) specifies that the low flows are applicable to "waters suitable for the establishment of low flow return frequencies." Thus, free flowing streams and rivers were the types of receiving waters contemplated. In cases where legally specified low flows exist, as for example under FERC licenses, these become the applicable minimum flows. In future State water quality standards reviews, EPA encourages the States to take into account these specified flows and adjust the criteria appropriately to provide equivalent protection of human health and the environment to that applied in today's rule.

98. *Comment:* One commenter noted that "rules" 5(a) and (b) are inconsistent with "rule" 8 in the "Assumptions and Rules Followed by EPA in Writing the proposed § 131.36(d) Requirements for All Jurisdictions." (See the appendix at page 58451 in the proposed rulemaking package.)

Response: "Rules 5(a), 5(b) and rule 8" as stated in the appendix are correct. An incorrect statement of "rule 8" is contained in the preamble to the proposed rule at page 58432. Briefly stated, these rules provide:

—Rule 5(a) applies appropriate human health criteria to all waters in a State classified for either public water supply or for minimal aquatic life protection;

—Rule 5(b) provides that where a State has determined the specific segments where aquatic life are caught and consumed, the human health fish consumption only criteria (Column D2) are being applied to those specific segments;

—Rule 8 provides that where drinking water uses are designated, and even though the State has determined that no potential fish consumption uses exist, the human health criteria for "water + fish" in column D1 are applied. EPA applies these criteria because no "water only" column is available in the section 304(a) criteria methodology and drinking water uses must be protected.

99. *Comment:* Several commenters claimed that EPA was applying the criteria too broadly; that is, to waters where aquatic life propagation or public water supply uses were either not designated or did not constitute existing uses. In contrast, another commenter urged EPA to apply the criteria to all waters of the State where an EPA-approved use attainability analysis did not exist.

Response: Water quality standards contain both a designated use and the criteria necessary to support those designated uses. In this rulemaking EPA is not addressing the designated use component at all, but only the criteria component for the priority toxic pollutants. EPA has relied entirely on the existing State water quality standards to determine the waters to which the criteria apply. In § 131.36(d) EPA refers to all waters within particular designated use classifications.

Because EPA is not addressing the State designated uses here, EPA has not attempted to review State application of designated use classification through use attainability analyses or the other requirements of 40 CFR 131.10. Any identified deficiencies will be handled during the State triennial water quality standard review process with any necessary Federal actions being taken on a State by State basis.

100. *Comment:* One commenter objected to EPA specifying that EPA-approved State mixing zone regulations could be applied to the priority toxic pollutant criteria promulgated today. Others stated that EPA should include procedures to define appropriate mixing zones, that EPA should allow mixing zones in all States and that EPA should require mixing zones in all States.

Response: Mixing zones are one of the general discretionary policies specifically authorized for State adoption by EPA's water quality standards regulation at 40 CFR 131.13. Mixing zones have most recently been defined by EPA in the revised TSD (see page "xx") as "an area where an effluent discharge undergoes initial dilution and is extended to cover the secondary mixing in the ambient waterbody. A mixing zone is an allocated impact zone where water quality criteria can be exceeded as long as acutely toxic conditions are prevented." Although mixing zones are discretionary for the States, they are part of the State's water quality standards and therefore subject to EPA review and approval pursuant to CWA section 303(c) and 40 CFR 131.

Mixing zones recognize ambient water dilution and therefore larger mixing zones generally would reduce the stringency of discharge permit limits established to meet ambient water quality criteria. It would be inconsistent with CWA section 501 (33 U.S.C. 1370) for EPA to impose a less stringent mixing zone policy in a State than is currently authorized. Therefore, in this rulemaking EPA recognizes State mixing zones and provides for their application in implementing the criteria promulgated by this rule. However it does not impose mixing zone requirements on States which do not have such policies.

101. *Comment:* Comments were received that the Federal toxics criteria are not viable because they have never been subject to public comment and review and that the criteria should be subject to continuing peer review and study in order to ensure technical viability. Commenters stated that it is improper to require development of permit limitations on the basis of technically flawed criteria which may not be relaxed in the future due to the anti-backsliding requirements of the CWA and regulations, and that EPA must find that criteria changes which result from peer reviews constitute new information which qualify as an exemption from the anti-backsliding requirements.

Response: We disagree with the premise of this comment that provision for public review and comment on the federal toxics criteria has been inadequate. The criteria methodology and documents were the subject of public review when issued. See the discussion of this issue in the preamble to the proposed rule as well as discussion of EPA's plans to revise criteria guidelines in the future and solicit public comment, 56 FR at 58433. (See also Section F of this preamble.) To the extent we received specific information concerning the criteria in this rulemaking, we have reviewed and responded to that information. Indeed, certain of the promulgated criteria have been changed to reflect public comments. EPA rejects the assertion that the criteria are "technically flawed." EPA believes the criteria are scientifically defensible and would not promulgate criteria that were technically flawed regardless of the anti-backsliding implications. With respect to the comment that revised criteria resulting from peer reviews should constitute "new information" which is exempt from the anti-backsliding requirements, that is not an issue to be decided in this rulemaking. EPA is developing proposed amendments to the NPDES regulations that will interpret and implement the provisions of section 402(o). The commenter's concerns can be addressed in that rulemaking or possibly in a prior permit proceeding if the issue is relevant.

102. *Comment:* One commenter argued that the rule will adversely affect implementation of the NPDES program by diverting resources to deal with permitting and enforcement issues arising from the use of unscientific water quality criteria. It is argued further that no discharger will accept permit conditions that are unreasonable, have no scientific basis, and do not reflect the naturally occurring environmental conditions in the receiving water.

Response: Federally promulgated water quality criteria will be implemented in NPDES permits issued by EPA Regional Offices or authorized States. Dischargers are free to challenge requirements implementing federally promulgated criteria contained in modified, reopened, or reissued permits according to established NPDES permit appeal procedures and as permitted by law. EPA, however, disagrees that the federally promulgated criteria lack a scientific basis and has explained in the preamble to this rule and elsewhere in response to comments why promulgation of the criteria as provided in this rule is necessary to meet the requirements of section 303(c)(2)(B). We anticipate that many dischargers will accept permit requirements based upon the federally promulgated criteria. Dischargers may be permitted to backslide from water-quality based permit limitations where revised criteria are developed if they meet the requirements of CWA sections 402(o) or 303(d)(4) for allowing backsliding in attained and non-attained waters.

103. *Comment:* Comments were received that either the proposed Federal or State standards should provide for a schedule of compliance so that permittees affected by the new federal criteria could have sufficient time to come into compliance.

Response: The proposed rule did not directly provide for a schedule of compliance, however, it also did not change existing applicable State and EPA provisions related to permit issuance or reissuance. EPA agrees with the commenters that some compliance implementation time may, in certain situations, be necessary and appropriate for permittees to meet new permit limits based on the new standards. EPA has not removed this flexibility in the permitting process by this rulemaking. Under the Administrator's April 16, 1990 decision in an NPDES appeal (Star-Kist Caribe Inc., NPDES Appeal No. 88-5), the Administrator stated that the only basis in which a permittee may delay compliance after July 1, 1977 (for a post July 1977 standard), is pursuant to a schedule of compliance established in the permit which is authorized by the State in the water quality standard itself or in other State implementing regulations. (This decision did not affect compliance schedules in individual control strategies issued under section 304(e) of the CWA.)

Standards are made applicable to individual dischargers through NPDES permits which reflect the applicable Federal or State water quality standards. When a permit is issued, a schedule of compliance for water quality-based limitations may be included, as necessary, and EPA assumes this is the case for permits issued to meet these new Federal criteria where States do not have existing statutes, regulations or policy prohibiting compliance schedules. EPA notes that some permits contain a "reopener" clause which may be exercised by the permitting agency on a case-by-case basis to control toxics earlier than the normal re-issuance cycle. However, EPA does not generally contemplate nor does it intend to ask States to undertake permit reissuance related to these new criteria for toxics through anything other than the normal permit reissuance cycle, except in rare instances.

104. *Comment:* EPA's section 304(a) criteria may not be appropriate when applied to non-conventional discharge situations such as stormwater discharges and discharge to ephemeral streams.

Response: EPA's criteria for priority toxic pollutants were developed to protect beneficial designated uses. The criteria are independent of considerations about kinds of dischargers whether point or nonpoint sources. If a State finds that the criteria for the current ambient water designated uses are inappropriate, then EPA's water quality standards regulations provide for a use attainability analysis and establishment of appropriate designated uses. Thus the commenter's concerns are misplaced and focus on the wrong part of the water quality standard.

105. *Comment:* Two comments addressed the salinity and effects on determining which criteria apply at particular locations in estuaries. One commenter, a State agency, supported the concept of clarifying the salinity ranges within which the various freshwater and marine water criteria apply. The State was concerned because the salinity ranges selected by EPA were different from those the State had recently placed in sediment standards. The second commenter asserted that the proposed rule created an untenable situation where fresh and salt waters mix. This commenter suggested that rather than using the more stringent of

the fresh or saltwater criteria, EPA should interpolate between the two on the basis of salinity.

Response: The range of salinities incorporated into this rule at 40 CFR 131.36(c)(3) are appropriate, especially in light of the guidance for the applications of the metals criteria addressed elsewhere in this package.

EPA's proposed rulemaking on salinity, however, was silent on the percentage of the time that the proposed salinity limits could be exceeded but the respective fresh or saltwater criteria still apply. It could be inferred that EPA intended 100% of the time as the appropriate limit. It is EPA's position that a reasonable exceedence should be specified or otherwise the intermediate brackish water zone becomes unnecessarily large. It is EPA's judgment that a factor of 95% of the time provides reasonable cut off points. Thus, for the freshwater criteria to apply, the salinity should be less than 1 ppt 95% of the time. Likewise for the marine water criteria to apply the salinity should be greater than 10 ppt 95% of the time.

EPA recognizes that judgment is required in providing guidance on the appropriateness of freshwater and saltwater water quality criteria across a salinity gradient. This is because a fundamental understanding is lacking of metals form, bioavailability and toxicity along with the relative sensitivities at appropriate salinities of species that occupy this gradient. EPA's recommendations are reasonable given that (1) the database for most metals includes tests with saltwater and freshwater species that tolerate these salinities; (2) that salinities at a particular location change daily with tide and wind and seasonally; and (3) that at low salinities, freshwater and saltwater species mix. It is reasonable that the presence of both types of species in this transition zone require application of both freshwater and saltwater water quality criteria. Given the temporal variability of salinity in both the short and long term and the judgmental basis for EPA's recommendations, knowledge of the kinds of organisms at a site of concern will be particularly helpful in being confident that the appropriate criterion has been applied to the site.

The second commenter's suggestion is not supported by data or professional experience of EPA's scientists. For many metals, toxicity to saltwater species increases at low salinities. Therefore, underprotection would result from the use of an interpolation approach that would result in higher criteria at low or intermediate salinities.

5. Timing and Process

106. *Comment:* EPA should delay Federal promulgation until current State efforts to adopt water quality standards have been completed.

Response: Without sufficiently protective and defensible water quality standards, EPA and the States cannot effectively control discharges of toxic pollutants. While the Clean Water Act clearly gives primary authority for adopting water quality standards to the States, Congress clearly signaled its frustration with State delays in adopting criteria for toxics in the 1987 Clean Water Act amendments. Since the 1987 amendments, the States have had over five years to meet the statute's requirements for adopting water quality standards for toxic pollutants. Further delay is unacceptable. It is now time for EPA to exercise its oversight authority to ensure that human health and the environment are adequately protected.

107. *Comment:* Several comments were received relating to the general subject of State action during or subsequent to this rulemaking and on the processes EPA would use to withdraw Federal criteria applicable to a State. A related comment was that EPA should clarify that partial withdrawals are possible. Another comment questioned which criteria would apply in a situation where EPA approves State standards subsequent to the Federal promulgation.

Response: EPA is fully aware that several States are actively involved in reviewing and possibly revising their standards to meet the requirements of the Act simultaneously with the Agency's action to promulgate Federal standards. It is an objective of the Federal action to spur State action to complete their own administrative procedures so as to obviate the need for Federal promulgation. However, for the reasons stated earlier in the preamble as the basis for this rulemaking, EPA believes States have already had more than adequate time to respond to the statutory requirement and that EPA has a responsibility to act to put standards in place to serve as a basis for environmental control programs. Nevertheless, EPA encourages States to continue to adopt their own standards and thereby enabling themselves to make use of the flexibility inherent in the program through use of the various implementation processes even if such action will not be completed until after promulgation of this rule. EPA is committed to timely withdrawal of the Federal standards after State adoption and EPA approval of State standards.

The assertion that upon adoption of standards by the State, EPA's Federal criteria are no longer applicable within the State is not correct. The Federal criteria will continue to be the applicable water quality standards until withdrawn. Where the State standards are less stringent than the Federal standards, the Federal standards will be controlling until final action is taken to withdraw the Federal standards. In this situation, the permitting agency must use the more stringent standards in issuing permits. As a practical matter, it is assumed that permit holders would seek a stay of permit requirements pending the final decision of the Federal standards. While there may be a period in which there are both State and Federal standards in effect, the most stringent standards (either the State's or EPA's) would be controlling.

As described earlier in the preamble, EPA will act to withdraw this rule as applicable to a State, if the State completes action on adopting standards that adequately protect their waterbodies from toxic contamination and EPA approves those standards. The standards do not necessarily have to be exactly as those promulgated by EPA but they must meet the requirements of the Act and 40 CFR 131.11.

Many comments were received that EPA should not be required to receive comment and execute a rulemaking in order to withdraw State-adopted and EPA-approved standards that are less stringent than those promulgated by EPA. As described in Section E-3 of this preamble, EPA withdrawal action differs depending upon whether the State standards are equal to or more or less stringent than those promulgated in this rule.

While it would be administratively less cumbersome not to provide notice and comment in withdrawing a more stringent Federal water quality standard, EPA, however, is constrained by the provisions of the Administrative Procedures Act, 5 U.S.C. Section 551 (4) and (5) which we believe preclude the Agency from withdrawing a rule as suggested by the commenters. EPA will take timely action to withdraw the Federal rule in these cases. EPA has had experience in withdrawing the Federal rule covering each situation, i.e. standards equal to or more or less stringent than the Federal rule (51 FR 11581, April 4, 1986; 47 FR 53372, November 26, 1982; 56 FR 13592, April 3, 1991). It has not proven to be a practical problem. Consistent with the water quality standards guidance and historical operating policies, EPA confirms that partial approval of State standards and partial withdrawal of the

Federal rule is allowable. (See generally, Chapter 2, Water Quality Standards Handbook, December 1983)

There is an exception to this process. If a State adopts a 10^{-5} risk level when EPA promulgated 10^{-6}, the rule can be withdrawn without notice and comment because we raised the possibility of different risk levels in the proposal and we have accepted both risk levels as meeting the requirements of the Act.

108. *Comment:* EPA received comment that there is no procedural necessity for this rule because Congress did not set a specific deadline for State action to comply with section 303(c)(2)(B).

Response: For the reasons set forth elsewhere in this preamble, EPA has the requisite statutory authority to promulgate these criteria and that such criteria are necessary as a basis for water quality-based control programs designed to protect the public health and the environment.

Section 303(c)(2)(B) of the Act requires States action to address toxic pollutants "whenever a State reviews water quality standards pursuant to paragraph (1) of this subsection * * *". Paragraph (1) refers to the requirements to review and revise, if necessary, standards at least once each three year period—the triennial review cycle for standards.

Notwithstanding arguments concerning timeliness of EPA and State actions, the Agency has made a decision that toxics criteria for priority toxic pollutants should be in place. The Administrator's action has started the process described in CWA section 303(c)(4) for Federal promulgation. Thus, because of the Agency's action, the comment at this point is moot.

109. *Comment:* EPA received numerous comments concerning the 30-day public comment period. Some industries and municipalities expressed concern that the rulemaking was too extensive to allow meaningful comment within 30 days. Some commenters requested extensions up to six additional months. Several commenters noted that EPA had never before promulgated a final water quality standards rule within 90 days of proposal.

Response: EPA appreciates that 30 days is a short comment period but believes that it is fully consistent with section 303(c)(4) (33 U.S.C. 1313(c)(4)) which requires EPA to promulgate a final regulation within 90 days of proposal. The fact that EPA only met this requirement once in its nine final promulgation actions does not change the statutory requirement.

In most of those previous cases (and in 2 cases today) the Agency was in fact superseding a State rule. Pursuant to the Agency's regulation at 40 CFR 131.21(c) the State rule stayed in effect until EPA's final rule took effect. Today's action is different. Here, by and large, there are no State criteria for priority toxic pollutant in place and EPA is acting to fill that void. This EPA action has a greater sense of urgency and justifies the Agency's effort to meet the 90 day statutory time schedule in CWA section 303(c)(4).

The addition of section 303(c)(2)(B) to the Clean Water Act was a clear and unequivocal signal from Congress that it was dissatisfied with the slow pace at which States were adopting numeric criteria for toxic pollutants. This intent is made clear in the legislative history of that provision. It is the only time in the 26-year history of the program that Congress explicitly directed the States to address certain pollutants in their standards. Moreover, section 303(c)(4), which authorizes Federal promulgation has explicit deadlines and Congressional directives to act promptly. The intent of the Federal promulgation section of the Act is to accelerate human health and ecological protection by establishing water quality standards as a basis for pollution control programs. To achieve these objectives and meet the statutory deadline, we need sufficient time to review public comments and make any necessary revisions.

Although the State and pollutant coverage of this final rule is large, the issues involved are neither new nor numerous. The primary focus of this rule is the narrow issue of whether a State has adopted sufficient water quality criteria for toxic pollutants in State standards as necessary to support water quality-based control programs.

EPA alerted the public to its intentions and the planned contents of the proposal on April 19, 1990, in an announcement in the **Federal Register**. In addition, we notified the administrators of the State agencies responsible for the water quality standards program of each potentially affected State of our plans on April 9, 1990. In the April 19, 1990, notice, EPA described what would be in the proposal, including: Which pollutants, which States, the cancer risk level, and EPA's intention to update criteria using publicly available information in the Integrated Risk Information System. Since that notice, EPA has apprised the public of its intentions and status of its action through State and Regional meetings and quarterly newsletters on the criteria and standards program. EPA, through both its Headquarters and Regional Offices have met with the States, and the regulated community individual and public meetings and public hearings to discuss EPA's plans and progress. This lengthy lead time has allowed potential commenters to prepare for the proposal and should have facilitated preparation and submission of meaningful comments within the 30-day public comment period.

As discussed previously in this preamble and the preamble to the proposed rule, the methodology used to develop the criteria and the criteria themselves have previously undergone scientific peer and public review and comment and were revised as appropriate. Some human health criteria were updated by recalculating the criteria using revised reference dose information contained and publicly available in the Agency's Integrated Risk Information System. Information in this system was peer reviewed within EPA and, as a matter of policy, is the information which was recommended to the States for their use. Most of these reviews occurred before 1987. Congress acted to amend the Act with full knowledge of the EPA process for developing criteria and the Agency's recommendations under section 304(a). EPA believes it is consistent with Congressional intent to rely on existing criteria rather than engage in a time-consuming reevaluation of the underlying basis for water quality criteria. At some point in the standards setting process the States and EPA must act recognizing that scientific research leading to improved water quality information is an ongoing process. In the case of this rulemaking, EPA affirms that in addition to all the environmental, programmatic, and statutory factors supporting the rule, the basic criteria methodologies are scientifically sound as are the resulting criteria.

In the five years since the February 1987 enactment of section 303(c)(2)(B), most States have worked extensively to adopt water quality standards for toxics pollutants. The issues in this proposal are the same ones that States, dischargers, public interest groups, and EPA have discussed and debated in-depth during those deliberations. The comments prepared for State and EPA meetings and hearings are to a great extent the same as those to be made on this Federal action and made it easier for the commenters to prepare submissions on this rule. The arguments presented in the public comments that EPA's action is new or that the States are not in compliance because they are carefully reviewing their standards all tend to ignore the fact that many of the criteria were available as early as 1980. Because of a lack of State action, EPA made it a priority emphasis in the revision to the water quality standards regulation in 1983 and, most importantly of all, that section 303(c)(2)(B) was not the start of the process but the signal from Congress that delays had to cease. It is now eleven years after the criteria were first made available to the States, five years after Congress specifically directed the States to Act. Given this background, 30 days was sufficient for commenters to prepare and submit meaningful comments. The extensive nature of the comments submitted support this position. Further delay in the process is totally unwarranted for all of the above programmatic, health, ecological, and statutory reasons.

110. *Comment:* EPA should promulgate criteria only for those pollutants clearly shown to be interfering with designated uses.

Response: The record supporting this proposal contains extensive data on the toxic pollutant problem in each State. It shows the presence of numerous toxics in State waterbodies and it also contains information on impaired waterbodies. Earlier in this preamble, in section E-2 of this preamble, we described that rationale for why EPA could not undertake extensive studies in each State.

In responses to previous comments earlier in this section, we described EPA's legal authority to undertake this promulgation action including why it is not necessary for EPA to promulgate standards pollutant-by-pollutant, waterbody-by-waterbody. In summary: (1) EPA has sufficient data to indicate the widespread presence of toxic pollutants, (2) administratively, given the statutory schedule for promulgation, Congress clearly never intended EPA to conduct in-depth State analysis, (3) EPA, in its December 1988 guidance on options to meet the statutory requirement of section 303(c)(2)(B) indicated a policy position that "* * * the presence or potential construction of facilities that manufacture or use priority toxic pollutants or other information indicating that such pollutants are or may be discharged strongly suggests that States should set standards since such pollutants have the potential to or could be interfering with attaining designated uses", (4) neither the Act nor EPA's regulation limits the establishment of standards to a waterbody-by-waterbody, pollutant-by-pollutant approach, (5) as a matter of public policy to protect human health and the environment, it is the Agency's position that a more conservative approach is warranted, and (6) actual dischargers of such pollutants should expect to have control limits placed in their permits for such pollutants while other dischargers will not be affected.

111. *Comment:* Since EPA published a range of risk levels in its water quality criteria documents, it should allow a range in this rule or allow States to select the appropriate risk level.

Response: EPA's publication of a range of risk levels in individual water quality criteria documents was simply an illustration of how the criteria recommendations would be affected by adopting various risk levels. It was not intended to nor did it, in fact, establish a policy on risk levels.

Consistent with recognizing the primary authority of States to adopt water quality standards and that Agency policy allows States to select an appropriate risk level within the general range of 10^{-4} to 10^{-6}, EPA modified this final rule to apply the human health criteria at the risk level adopted or proposed by the State for all or a majority of toxic pollutants under applicable State water quality standards regulations, or in the case of Idaho, Nevada, and Rhode Island, on an expression of State preference. EPA notes that in a majority of cases, the 10^{-6} risk level is the one adopted by the States. In order for the human health criteria to be implemented in water quality programs, a single risk level must be chosen so that a specific numeric limit is established for a pollutant. The rationale for EPA's choice of a risk level for each State in this rule is contained in section G-1 of this preamble.

Any State adopting its own standards that meet the requirements of the Act may adopt a risk level other than that used by EPA in this rule. The ability of a State to select an alternative risk level is one of the reasons EPA encourages each State to adopt its own water quality standards rather than rely on Federal promulgation.

6. State Issues

Alaska, Washington, and Idaho

112. *Comment:* Alaska, Washington and Idaho have noted errors in the proposed rules. In some cases these errors were improper citations, or the inclusion of, or failure to include, certain criteria.

Response: EPA sought comments on the interpretation it had made of the various State water quality standards that were potentially affected by the proposed rulemaking. EPA expected and received comments on the appropriateness of the individual criteria groups applied to the State beneficial use designations.

In deciding which changes it can make to the proposed rules EPA notes that the preamble to the proposed rule laid out the intent and purposes of this action extensively. Beginning on page 58431 of the preamble to the proposed rule, EPA described the 12 "rules" or logic used to derive the criteria applicable to States judged not in compliance with CWA section 303(c)(2)(B). The gist of this rationale was for EPA to apply aquatic life criteria to State-defined designated uses providing even minimal support to aquatic life survival; and human health criteria to State-defined designated uses providing for public water supply and/or aquatic life consumption. Moreover, EPA provided in the matrix in proposed 40 CFR 131.36(b) all of the numeric levels that it proposed for application to the designated uses. Thus, EPA believes that sufficient notice was provided as to the purpose of the proposed rule, the types of affected State designated uses and the identification and stringency of the section 304(a) criteria to provide the Agency some latitude in deleting and adding criteria, especially when these changes are made because of comments made by the affected States and are necessary to correct unintended mistakes.

After discussing this comment with the State of Alaska, it was agreed that the following changes to the rule were necessary. These changes occur in 40 CFR 131.36(d)(16)(ii).

The State's current water quality standards (WQS) reference "Gold Book" criteria for all uses included in the rule except secondary contact recreation. Because the promulgated numbers are, in essence, revised Gold Book criteria, to be consistent with State WQS, EPA applied aquatic life and human health numbers to all uses except secondary contact. Secondary contact recreation is included because it is defined in the State's standards as including fishing. D1 criteria are applied to the drinking water use. D2 criteria are applied to all uses except drinking water for both fresh and marine waters. All acute aquatic life criteria are included in this rule. (See correspondence between the State and EPA in the record.) Also, all human health criteria for carcinogens based on the fact that the State has not adopted a risk level and therefore, cannot calculate or apply appropriate criteria for carcinogens. The chronic aquatic life criterion for selenium as it has been updated since publication of the Gold Book and made more stringent.

The seafood processing use (2)(A)(ii) was deleted from rule because it is an industrial use category to which the criteria promulgated today do not appropriately apply.

Additionally, in 40 CFR 131.36(13)(iii), the risk level for carcinogens was changed to 10^{-5} to reflect the State's July 1992, proposal to amend its water quality standards and to reflect an indication of State policy preference received on November 16, 1992.

The following changes were made with respect to the State of Washington. After discussion with the State, EPA has assigned appropriate criteria to use categories rather than to classes. The rule was revised as follows (see 40 CFR 131.36(d)(17)):

(22)(i) Fish and Shellfish
 Fish
 Water Supply (domestic)
 Recreation
(22)(ii) Fish and Shellfish; Fish
 B1 and B2—#2, 10
 C1—#2, 10
 C2—#2, 6, 10, 14
 Water supply (domestic)
 D1—All
 Recreation
 D2—All marine waters
 D2—freshwaters not protected for domestic water supply

The following changes were made with respect to the State of Idaho. After discussion with the State, EPA renumbered the use classifications to reflect the reorganization of the State standards and made the following changes in the criteria assigned (see 40 CFR 131.36(d)(18)):

1.b Domestic Water Supplies
 Remove cyanide and asbestos
3.a Primary Contact Recreation
 Remove B1—All
 Remove B2—All
 Add D1—All
3.b Secondary Contact Recreation
 Remove B1—All
 Remove B2—All

Alaska

113. *Comment:* EPA has incorrectly included CMC (acute) aquatic life criteria for freshwater and saltwater for Alaska in the proposed rule.

Response: EPA's inclusion of CMC aquatic life criteria in the rule is appropriate. Alaska's water quality standards state that, "Substances shall not * * * exceed criteria cited in EPA, Quality Criteria for Water." Whether or not the State has adopted both acute and chronic criteria by reference is ambiguous and requires clarification through this rulemaking, especially in light of language included in the following three documents issued by the State:

1. The State's Water Quality Standards Workbook, published in July 1991, and widely distributed in order to "understand what water quality standards and criteria are, how to interpret the Alaska water quality standards regulation * * *", states that, "* * * EPA has developed a two-number criterion for acute and chronic conditions. The state adopts only the chronic criterion."

In the same state WQS workbook, Table 1, "Alaska's Water Quality Criteria for Toxic Substances in Freshwater and Saltwater", is said to "represent the toxic substances criteria adopted by reference in the AWQS." This table does not include any acute values for the priority toxic pollutants.

2. An August 30, 1991 letter from John A. Sandor, Commissioner of ADEC, to Harold Geren, Chief of EPA Region 10's Water Permits and Compliance Branch, states, "The Department affirms its decision to continue to use "Gold Book" *chronic* criteria to establish receiving water criteria and effluent limits in NPDES permits." (emphasis added)

114. *Comment:* Alaska was not informed of EPA's intention to include acute criteria in this rulemaking.

Response: On November 4, 1991, EPA Region 10's Water Division Director sent via fax and hard copy, a letter to ADEC's Chief of Water Quality Management, notifying the State of EPA's intention to include acute criteria in this rulemaking. The letter stated, "These letters affirm Alaska's use of "Gold Book" chronic criteria for freshwater and marine systems and have convinced us that Alaska is in compliance * * * with the following exceptions: * * * Acute aquatic life criteria for all pollutants * * *."

115. *Comment:* The statement included in the rule that, "Alaska is included in today's proposal because although the State had previously adopted all section 304(a) criteria by reference, the State Attorney General has decided that the adoption by reference is invalid", is in error and should be deleted from the final rule.

Response: EPA concurs that the statement was in error and no such statement is included in this final rule.

Arkansas

116. *Comment:* Any promulgation of human health criteria for the State of Arkansas should be withdrawn from the rulemaking because the state has adopted such criteria.

Response: A State's standard must be reviewed and approved by EPA before the State can be removed from the rule. Arkansas formally submitted their water quality standards containing human health criteria to EPA on December 17, 1991. EPA's review found that the human health criteria were supportive of designated uses and therefore no human health criteria are promulgated in this rule. The State's criteria to protect human health were approved by EPA on January 24, 1992. EPA also disapproved Arkansas' water quality standards for failing to adopt the criteria for priority pollutants to protect aquatic life as required by section 303(c)(2)(B). Necessary aquatic life criteria are promulgated today and include the following: Cadmium, chromium, copper, lead, mercury, nickel, selenium, silver, zinc, and cyanide.

117. *Comment:* Arkansas is not required by the Act to adopt numeric criteria for metals because it has not been established that the metals listed "could reasonably be expected to interfere with those designated uses adopted by the State."

Response: EPA's policy is that the presence of any Section 307(a) pollutants raises an issue as whether they could reasonably be expected to interfere with designated uses. The presence in ambient waters and the discharge of metals is documented in several databases, including the Toxic Release Inventory, STORET, and discharge monitoring reports. The State could have submitted supporting documentation that demonstrates that the presence or discharge of these metals is not expected to interfere with designated uses. The State submitted no such information. In the absence of any demonstration to the contrary, EPA must conclude that the metals can reasonably be expected to interfere with designated uses.

118. *Comment:* The documentation on which EPA based its assertion that designated uses "could reasonably be expected to be interfered with" should be provided under this rulemaking process.

Response: The documentation that showed the widespread occurrence of metals in Arkansas' waters in concentrations exceeding EPA's recommended levels was part of the record for this rulemaking and was available for review at the Region 6 office as well as at EPA headquarters.

119. *Comment:* All pertinent data developed by EPA under the 304(1) process should be made available without special request to ensure its availability to potentially affected parties.

Response: The material developed by the States with respect to section 304(l) was publicly available at the time the list was compiled. A complete discussion of the relationship between the 304(l) list and today's rule is included earlier in this section. Moreover, because EPA did not rely on the State's section 304(l) materials for this rulemaking, it was unnecessary to place such materials in the record.

California

120. *Comment:* A commenter urged that the national rule should clarify that no criterion continuous concentration for selenium less stringent than 5 µg/l will be allowed in California's San Francisco Bay. Commenters suggested that the National Rule should direct Region IX to develop site-specific criteria for selenium in San Francisco Bay. It was further suggested that the National Rule should state that the 5 µg/l selenium criterion (B2) applies only to fish and aquatic invertebrates, not to more sensitive uses such as wildlife. The narrative standards should govern for the more sensitive uses.

Response: This rule promulgates EPA's freshwater criteria for selenium of a CCC of 5 µg/l (4 day average) and a CMC of 20 µg/l (1 hour average) for San Francisco Bay and Delta. In EPA's November 6, 1991 approval letter on California's Enclosed Bays and Estuaries Plan, EPA approved California's decision to allow regional water quality control boards (Regional Boards) to determine where in an estuary it is appropriate to apply freshwater or saltwater criteria. Although most Regional Boards have not yet specified the appropriate standard, EPA generally agrees with this process. However, the EPA standards approval letter specifically found that utilization of the saltwater criteria for selenium in the San Francisco Bay/Delta would be inappropriate. This finding is based on substantial scientific evidence that there are high levels of selenium bioaccumulation in San Francisco Bay and the saltwater criteria fails to account for food chain effects. Accordingly, in the absence of Regional Board action consistent with EPA's approval letter, EPA is promulgating the freshwater criteria for selenium for the San Francisco Bay/Delta. EPA's criteria for selenium in freshwater are derived from laboratory and field data on the effects of selenium on aquatic vertebrates, invertebrates and plants and should be protective of aquatic organisms under most conditions. The selenium criteria were not developed with the intent to address protection of wildlife such as waterfowl. EPA is in the process of developing wildlife criteria for selenium. Recent studies and analyses have enhanced our understanding of avian exposure to selenium in the field and have clarified the importance of food chain biomagnification and low level toxic effects on avian reproduction. Such information is, for the most part, new information available after the Water Quality Criteria for Selenium was published in 1987. EPA supports the efforts of the State to develop selenium criteria based upon food chain biomagnification. However, in the absence of a final wildlife criteria document, or other sufficient information, EPA is unable to promulgate a criterion more stringent than 5 µg/l as part of this rulemaking. The purpose of this rule is to establish Federal criteria for all waters that do not have EPA-approved state criteria. It is not appropriate to use this Federal rule as a mechanism for directing promulgation efforts of a region. Further, EPA's regulations, guidance documents, and the Preamble to the Federal rule clearly specify the steps to be taken when a state wishes to adopt site specific criteria. EPA believes that it is already clear that both the numeric and the narrative standards apply in all cases. This information is contained in EPA's guidance documents and does need not be reiterated in this rulemaking.

121. *Comment:* EPA should promulgate freshwater selenium criteria in California for the Sacramento-San Joaquin Delta, the inland surface waters including the San Joaquin River, and the Central Valley Wildlife refuges.

Response: The draft rulemaking proposed the national selenium criteria for all water bodies in California and included those listed above. On November 6, 1991, EPA approved California's Inland Surface Waters Plan which adopted EPA's selenium criteria for freshwater bodies with the exception of Salt Slough, Mud Slough, and the upper San Joaquin River. EPA approved the State's selenium criteria but did not approve these exceptions. Accordingly, the final national rule promulgates the EPA freshwater criteria for selenium for Salt Slough, Mud Slough, and the upper San Joaquin River. The State's freshwater selenium criteria will apply elsewhere in the Sacramento-San Joaquin Delta and San Joaquin River. The California Inland Surface Waters Plan also included a selenium criterion of 2 ppb for the inflow to Grasslands Area Wildlife Refuge in the Central Valley that is more protective than EPA's criteria. This selenium criterion was approved by EPA and, therefore, today's promulgation will not apply to the inflow to Grasslands Valley Wildlife Refuge.

122. *Comment:* Several commenters asserted that: (1) Past efforts to develop site specific objectives for San Francisco Bay demonstrate the technical difficulties, costs, and uncertainty of developing site specific criteria and; (2) those difficulties make site-specific criteria ineffective in amending inappropriate national criteria.

Response: EPA approved the water quality criteria adopted by California in the Enclosed Bays and Estuaries Plan on November 6, 1991. EPA has revised today's rule so that it does not include pollutants covered by those state-adopted, EPA-approved criteria, except for selenium as described in the previous comment and response. The San Francisco Bay is a highly complex estuarine system. In such cases, developing site specific criteria may be difficult. In October 1991, EPA made technical comments on the site specific objectives proposed for San Francisco Bay. The site specific criteria for San Francisco Bay have not yet been adopted by the State and, therefore, it is premature to evaluate their effectiveness. EPA has approved site specific criteria in several States and recommends that site specific criteria be developed where physical or chemical characteristics of the site alter the biological availability of the chemical or where species at the site are more or less sensitive than those species used in the development of national criteria. Please see Science and Implementation under general comments.

123. *Comment:* A commenter indicated that Region IX has placed impediments on the adoption of site-specific criteria which make future adoption of site-specific criteria an unrealistic alternative.

Response: There is no indication what "impediments" the commenter refers to, or the action by which Region 9 allegedly created such impediments. Please see Implementation under general comments about requirements for site-specific criteria.

124. *Comment:* EPA also received comments that the proposed rule would establish inappropriate and technically unsupported criteria for copper, nickel, lead, and mercury for South San Francisco Bay.

Response: The final rule has been amended to reflect EPA's November 6, 1991 action on California's Enclosed Bays and Estuaries Plan and does not include criteria for copper, nickel, mercury or lead for San Francisco Bay. EPA generally approved California's approach directing regional boards to choose between two sets of criteria (freshwater or saltwater) in an estuary. California's saltwater and freshwater criteria are approved by EPA. At this point, EPA does not have sufficient information to conclude that this approach of allowing Regional Boards to choose between the two sets of criteria is inappropriate for copper, nickel, lead, and mercury in the South Bay. Therefore, criteria for these metals are not included in this final rule.

125. *Comment:* Several commenters questioned the appropriateness of promulgating EPA criteria for special water bodies such as ephemeral streams, constructed agricultural drains, effluent-dominated streams, irrigation-flow dominated streams, or evaporation ponds.

Response: The criteria contained in this rule apply to all "waters of the United States" as defined in the Clean Water Act and implementing regulations except where State-adopted/EPA-approved criteria apply. Waters of the U.S. may include human-constructed water bodies. Waters of the U.S. does not include waters that fall under EPA's waste treatment system exemption. California deferred adopting water quality standards for certain effluent-dominated streams and irrigation-flow dominated streams. This deferral was disapproved by EPA in its letter dated November 6, 1991 on the basis that it did not protect the water bodies from toxics that are reasonably expected to interfere with designated uses. EPA Region IX agrees with California that site specific criteria would be appropriate for many waters in these categories. If California adopts and EPA approves site-specific criteria that protect the designated uses, criteria for those waters will be removed from this final rule.

126. *Comment:* Several commenters found it impossible to comment on the proposed rule in the short comment period provided. Specifically, commenters noted that the thirty-day comment period is unreasonable and unfair for California given Region IX's delay in acting on California's own water quality standards.

Response: Commenters had more than five weeks to review Region IX's November 6, 1991 action, including thirty days to compare it to the proposed Federal rule. Also, please see general comments under Timing and Process.

127. *Comment:* EPA was not mandated to propose standards for California at this time, especially in light of Region IX's November 6, 1991 action on California's standards. The Clean Water Act contains no specific deadline for EPA to propose standards and does not require standards to be proposed for the entire nation at once. California could be separated from other states in order to allow reasonable time to evaluate both actions.

Response: On November 6, 1991, Region IX disapproved California's failure to adopt numerical criteria for all 307(a) pollutants for all "waters of the U.S." in California. According to EPA's water quality standards regulations (40 CFR part 131), the State has a 90-day opportunity to correct any deficiencies and EPA may then approve adequate corrections. If the State does not adopt the necessary corrections (or additions) within that period, then EPA must "promptly" propose and promulgate Federal standards in place of those deficient State standards. (Clean Water Act, section 303(c)(4)(A); 40 CFR 131.22.) In this instance, Federal promulgation occurred more than 90 days after November 6, 1991, and took into account any and all changes adopted by the State during those ninety days. To further delay promulgation for California when EPA is prepared to act on California's standards concurrent with other States is unnecessary. As to the adequacy of time to evaluate both actions, see response to preceding comment.

128. *Comment:* California commenters stated that it is unclear whether Federal or State criteria would apply to waters which California exempted, since EPA disapproved this exemption.

Response: California, by exempting certain waters from its 303(c)(2)(B) criteria, failed to adopt such criteria for those waters. EPA's disapproval of the exemptions did not bring about an adoption which the State never made. With this rulemaking, EPA adopts criteria for all 307(a) priority pollutants for those exempted waters which are Waters of the U.S. See additional comments below.

129. *Comment:* It is unclear which of California's use classifications are considered aquatic life or human health classifications. The proposed rule equates aquatic life protection with aquatic life consumption and states that waters with any aquatic life designation must meet human health criteria. A commenter indicated that assigning fish consumption for any aquatic life segment is equivalent to Federal promulgation of new designated uses and should not be done in this rulemaking.

Response: California's basin plans identify specific aquatic life and human health uses that are to be protected in a particular waterbody. EPA has no intention of changing designated uses in this rulemaking. As stated in the proposed rulemaking, *States may* remove the human health use classification for waters which have aquatic life but no existing aquatic life consumption uses. California, however, applies human health protection for fish consumption statewide to all navigable waters through the Inland Surface Waters Plan, Enclosed Bays and Estuaries Plan, and Ocean Plan. Therefore, the Federal rule is based on the presumption that, for all navigable waters of the State, aquatic life is present, fish or other aquatic life are being caught and consumed, and human health protection for fish consumption is necessary. It is consistent with EPA's established water quality standard regulations to require States to include all uses identified in Section 101(a) of the Act for all waters unless removed through an approved use attainability analysis. (See 40 CFR 131.10(j)). In this rulemaking EPA has not included the human health criteria (based on fish consumption) for any segments for which a State has conducted, and EPA has approved, a use attainability analysis to remove fish consumption as a use. Please see Legal Authority under general comments.

130. *Comment:* EPA's claim on 56 FR 58422 at p. 58431 that comprehensive Federal promulgation of standards place "no undue or inappropriate burden on States or dischargers" is unsubstantiated and believed to be untrue in California. The economic impacts of complying with Federal criteria are believed to be enormous particularly for publicly owned treatment works (POTWs) and are likely to discourage water reclamation projects.

Response: The commenter provides no explanation as to why complying with Federal criteria will discourage water reclamation projects. EPA is unconvinced that this would be the case. Please see Economics under general comments in response to economic impact concerns.

131. *Comment:* The commenter is concerned about the use of 10^{-6} risk level criteria as opposed to MCLs for protection of drinking water.

Response: California does not have any water bodies where drinking water is the sole exposure pathway. Therefore, MCLs may not be sufficient to protect human health from exposure to toxics from combined drinking water and fish consumption pathways. See section F-5 for a more detailed discussion of risk levels included in this rule.

132. *Comment:* The commenter is concerned that State schedules of compliance will not apply to Federal criteria.