DEPARTMENT OF
ECOLOGY
State of Washington

Responses to Public Comments on Fish Consumption Rate Issues

September 2012
Publication No. 12-09-055

Publication and Contact Information

This report is available on the Department of Ecology's website at:
https://fortress.wa.gov/ecy/publications/SummaryPages/1209055.html

Additional fish consumption related information is available at:
http://www.ecy.wa.gov/toxics/fish.html

For more information contact:

Toxics Cleanup Program
P.O. Box 47600
Olympia, WA 98504-7600

Phone: 360-407-7170

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

If you need this document in a format for the visually impaired, call the Toxics Cleanup Program at 360-407-7170. Persons with hearing loss can call 711 for Washington Relay Service. Persons with a speech disability can call 877-833-6341.

Responses to Public Comments on Fish Consumption Rate Issues

Toxics Cleanup Program
Washington State Department of Ecology
Olympia, Washington

This page purposely left blank for duplicate printing.

Table of Contents

Page

Acronyms and Abbreviations

APA	Administrative Procedure Act
API	Asian and Pacific Islander
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	Ambient Water Quality Criteria
BAF	bioaccumulation factor
BCF	bioconcentration factor
BW	body weight
BRFSS	Behavioral Risk Factor Surveillance System
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CRITFC	Columbia River Inter-Tribal Fish Commission
CSF	cancer slope factor
CSFII	*Continuing Survey of Food Intakes by Individuals*
CTCR	Confederated Tribes of the Colville Reservation
CTUIR	Confederated Tribes of the Umatilla Indian Reservation
CWA	Clean Water Act
DDT	dichlorodiphenyltrichloroethane
DOH	Washington State Department of Health
DRCC/TAG	Duwamish River Cleanup Coalition/Technical Advisory Group
Ecology	Washington State Department of Ecology
EPA	U.S. Environmental Protection Agency
g/day	grams per day
g/kg	grams per kilogram
FDF	fish diet fraction
FOIA	Freedom of Information Act
Hg	mercury
IHS	Indian Health Service
LDW	Lower Duwamish Waterway
LEKT	Lower Elwha Klallam Tribe
µg/kg	micrograms per kilogram
µg/L	micrograms per liter
µg/mg	micrograms per milligram
MOA	modes of action
MTCA	Model Toxics Control Act
NCP	National Contingency Plan
NHANES	National Health and Nutrition Examination Survey

Oregon DEQ	Oregon Department of Environmental Quality
OFM	Office of Financial Management
PAH	polycyclic aromatic hydrocarbon
PBDE	polybrominated diphenyl ether
PBT	persistent bioaccumulative toxic
PCB	polychlorinated biphenyl
PLP	potentially liable party –*or*– potentially liable person
PRP	potentially responsible party
POP	persistent organic pollutants
ppt	parts per trillion
QA/QC	quality assurance/quality control
QAPP	quality assurance project plan
RCRA	Resource Conservation and Recovery Act
RfD	reference dose
RME	reasonable maximum exposure
RSC	relative source contribution
SAB	Science Advisory Board
SaSI	salmon stock inventory
SMS	Sediment Management Standards
TEF	toxicity equivalence factor
TEQ	toxicity equivalence
TSD	Technical Support Document Version 1.0 (October 2011) –*or*–
TSD	Technical Support Document Version 2.0 (Fall 2012)
USDA	U.S. Department of Agriculture
U&A areas	Usual and Accustomed areas
WAC	Washington Administrative Code
WDFW	Washington Department of Fish and Wildlife
WRIA	water resource inventory area
WQS	Water Quality Standards for Surface Waters

Chapter 1: Introduction and Purpose

1.1 Overview

In October 2011, Washington State Department of Ecology distributed *Fish Consumption Rates Technical Support Document Version 1.0* for public review (Publication No. 11-09-050). The document was prepared to support discussions on whether and how to revise the fish consumption rates in current state rules. The technical evaluations in the document were modeled on similar evaluations completed by the Environmental Protection Agency (EPA, 2011) and the Oregon Department of Environmental Quality (Oregon DEQ, 2008).

Ecology held several meetings with interested parties to discuss the report between October 2011 and March 2012. The agency also sponsored workshops in Seattle, Spokane, Ellensburg and Tacoma, Washington.

Ecology received several hundred comments on Version 1.0 of the Technical Support Document. The Department has reviewed those comments and prepared written responses that are compiled in this Responses document. As part of that review, Ecology also performed additional technical analyses to address several issues raised during the public comment period. Ecology considered the comments and analyses when preparing Version 2.0 of the Technical Support Document. Ecology distributed Version 2.0 for public review in August 2012.

In July 2012, Ecology decided not to propose a default fish consumption rate in the Sediment Management Standards (SMS) rule (Chapter 173-204 WAC). Ecology also decided to initiate the process to adopt human health criteria in the Water Quality Standards for Surface Waters of the State of Washington (Chapter 173-201A WAC).

1.2 Purpose of this document

The purpose of this Responses document is to:

- Compile issues raised during the public comment period,
- Provide Ecology's evaluation and response to those comments, and
- Identify how Ecology has taken those issues into account when preparing the revised Technical Support Document Version 2.0.

1.3 Relationship to other Ecology documents and processes

Ecology began preparing the Technical Support Document in 2009 to support decisions on revisions to the Model Toxics Control Act (MTCA) rule. In November 2010, Governor

Christine Gregoire signed Executive Order 10-06 which established a one-year rule moratorium that included a process for agencies to obtain exemptions.

In December 2010, Ecology decided to stop work on the MTCA rule revisions, but elected to continue work on updating the SMS rule. One of Ecology's SMS rulemaking objectives is to establish clear methods and policies for selecting sediment cleanup standards based on human health risks. As part of its response to the Governor's rule moratorium, Ecology announced it would explore options for establishing a default fish consumption rate in Part V (Sediment Cleanup Standards) of the SMS rule.

Ecology distributed the *Fish Consumption Rates Technical Support Document Version 1.0* for public review in early October 2011. The document was designed to support discussions on whether to include one or more default fish consumption rates in the SMS rule. As noted above, the Department received over 300 written comments on Version 1.0.

In July 2012, Ecology decided to revise the approach for addressing fish consumption rates. The revised approach includes the following elements:

1. *Complete the Technical Support Document.* Ecology has performed additional evaluations and revised Version 1.0 of the draft report in response to public comments. These independent assessments are provided in the following separate issue papers: (*in* Ecology, 2012)

    - *Statistical Analysis of National and Washington State Fish Consumption Data*
    - *Estimating Annual Fish Consumption Rates Using Data from Short-Term Surveys*
    - *Recreational Fish Consumption Rates*
    - *Health Benefits and Risks of Consuming Fish and Shellfish*
    - *Chemical Contaminants in Dietary Protein Sources*
    - *Salmon Life History and Contaminant Body Burdens*

    Prior to finalizing the report in late 2012, Ecology will convene a series of meetings to discuss several technical issues related to the Technical Support Document.

2. *Distribute written response to public comments.* Ecology has prepared a written response to comments on Version 1.0 of the Technical Support Document (this Responses document).

3. *Complete the SMS rule revisions.* Ecology proposed revisions to the SMS rule on August 15, 2012.[1] Ecology decided not to include a default fish consumption rate in the proposed SMS rule revisions. Under the proposed rule, site-specific sediment cleanup standards will continue to be based on a reasonable maximum exposure. Ecology will consider information in the *Fish Consumption Rates Technical Support Document Version 1.0* and other technical publications when establishing site-specific sediment cleanup standards.

4. *Initiate the process to adopt water quality standards based on human health protection.* Ecology will initiate the rulemaking process to adopt human health criteria in the WQS rule. Ecology plans to evaluate those changes concurrently with revisions to the procedures for implementing the numeric criteria.

1.4 Revisions to the Technical Support Document in response to public comments

Ecology has made a number of changes to the Technical Support Document in response to public comments and the revised regulatory strategy announced in July 2012. There are two major differences between the revised report (Version 2.0) and the document that was distributed for public review in October 2011 (Version 1.0).

First, Ecology revised the document to focus more clearly on the scientific and technical issues associated with estimating the amount of fish and shellfish eaten by people in Washington. Several people commented that they thought the recommendations in the October 2011 document embodied a number of policy choices that should be decided in public rulemaking process. After evaluating those comments, Ecology agrees that such decisions are appropriately addressed during the process to adopt human health criteria in the state's water quality standards or through the preparation of cleanup action plans for individual sites. Consequently, Ecology decided to remove the recommendations on selecting a default fish consumption rate (Chapter 7) from the revised report. Other sections have been revised to better distinguish scientific issues and regulatory decisions associated with using the scientific data.

Second, the revised document includes new information that was added in response to public comments. These revisions include:

- *General population studies.* Several people recommended that Ecology provide information on fish consumption rates for the general population. Ecology has worked with the University of Washington to review national dietary surveys that provide

[1] Information on the proposed SMS rule revisions can be obtained at http://www.ecy.wa.gov/programs/tcp/regs/2011-SMS/2011-SMS-hp.html. Ecology has scheduled five public hearings on the proposed revisions that will be held in late September and early October, and the public comment period runs through October 15, 2012.

information on fish consumption rates for the general population, and has included the results of that review in the revised Technical Support Document. A separate document (Polissar et al, 2012) details the statistical methodology applied to the national dataset (2003–2006 National Health and Nutrition Examination Survey).

- *Recreational fisher studies.* Several people recommended that Ecology provide information on fish consumption rates for recreational fishers. Ecology reviewed available studies on recreational fishers, then assessed the recreational fish consumption studies conducted in Washington.(*in* Ecology, 2012). Ecology has summarized the results of that review in the revised Technical Support Document.
- *Asian and Pacific Islander (API) studies.* Several people recommended that Ecology consider additional information on the fish dietary habits of API populations. Ecology has incorporated additional information on API populations into the revised Technical Support Document.
- *Estimating long-term averages.* Several people expressed concerns about using the results from short-term episodic dietary studies to estimate how much fish people eat over longer periods of time. Ecology reviewed and evaluated methods for adjusting short-term episodic dietary information to provide fish consumption estimates and percentiles for longer periods of time. Ecology used these statistical methods to estimate annual fish consumption rates for the general population from 2-day national survey data.
- *Salmon.* Ecology received a wide range of comments on salmon, their life cycles and survival strategies, and salmon contaminant body burdens. Ecology has revised the report to present fish consumption estimates with and without salmon from several of the regional-specific fish dietary surveys. Ecology has also compiled additional information on salmon contaminant body burdens which is provided in the Technical Issue Paper titled *Salmon Life History and Contaminant Body Burdens*.
- *Analysis of regional fish dietary information*. Several people recommended that Ecology consider additional information on fish groups (shellfish, anadromous, non-anadromous species consumed) and whether people obtained their fish from local or non-local harvests. Ecology reviewed these comments and has further evaluated the regional-specific fish dietary information to provide percentile estimates for several fish species groups. Ecology has included this information in the revised Technical Support Document with further details provided in the Technical Issue Paper titled *Statistical Analysis of National and Washington State Fish Consumption Data (*Polissar et al, 2012).
- *Uncertainties and Variability*. Version 2.0 includes a new Chapter 5 that summarizes sources of uncertainty and variability in current fish consumption rate information.
- *Using Scientific Data to Support Regulatory Decisions*. Version 2.0 includes a new Chapter 6 that highlights (but does not attempt to resolve) key policy choices that are

needed when using the scientific information on fish consumption rates to support regulatory decisions.

1.5 Organization of this document

This Responses document includes nine chapters that are organized around the public comments on the Technical Support Document Version 1.0. Each chapter includes (1) a summary of the main issues associated with a particular topic, (2) examples[2] of comments to illustrate issues and concerns, and (3) Ecology's evaluation and response to those issues.

- Chapter 1 – Introduction. Chapter 1 provides background information and summarizes the purpose and organization of this Responses document.
- Chapter 2 – General Comments. Ecology received a number of comments supporting or opposing Ecology's decision to consider revisions to default fish consumption rates, the content and quality of the Technical Support Document, the need for additional evaluations, and the timeline for completing the document. This chapter summarizes and responds to these comments.
- Chapter 3 – Policy Issues Associated with Protection of Population Groups. When developing a regulatory standard based on health protection, agencies must decide what population groups that standard is designed to protect. Ecology received a number of comments related to this choice. This chapter summarizes comments on this issue. However, Ecology decided not to provide broadly applicable responses to these comments because of the revised regulatory strategy announced in July. Chapter 8 provides Ecology's evaluation and response to these comments within the context of defining reasonable maximum exposures under the Model Toxics Control Act.
- Chapter 4 – Comments on Salmon Issues and Considerations. Ecology received a number of comments on whether and how consumption of salmon should be taken into account when developing default and/or site-specific fish consumption rates. This chapter summarizes these comments. However, Ecology decided not to provide broadly applicable responses to these comments because of the revised regulatory strategy announced in July. Chapter 8 provides Ecology's evaluation and response to these comments within the context of defining reasonable maximum exposures under the Model Toxics Control Act.
- Chapter 5 – Comments on "Washington Fish Resources and Fish-Consuming Populations." Ecology presented information on Washington's fish resources and fish

[2] On most issues, several people provided similar comments and/or raised similar concerns. In some cases, one person included references or support for points raised in another person's comments. For purposes of this document, Ecology selected representative examples of comments to illustrate key recommendations and concerns.

consumers in Chapter 2 of the Technical Support Document. Several people provided comments on Ecology's definition and estimates for "high fish consumers." This chapter summarizes and responds to these comments.

- Chapter 6 – Comments on "Methodology for Assessing Fish Consumption Rate Information." Ecology reviewed available survey methods and identified measures of technical defensibility in Chapter 3 of the Technical Support Document. Several people provided comments on the measures of technical defensibility. This chapter summarizes and responds to these comments.
- Chapter 7 – Comments on "Fish Consumption Survey Data Applicable to Washington Fish Consumers." Ecology identified and evaluated four Pacific Northwest fish consumption surveys in Chapter 4 of the Technical Support Document. Many people provided comments on the individual studies and suggestions for additional evaluations. This chapter summarizes and responds to these comments.
- Chapter 8 – Comments on Issues Related to "Regulatory Context for Using Fish Consumption Rates" and "Site-Specific Fish Consumption Rates." Ecology summarized how fish consumption rate information was used in several regulatory programs (Chapter 5 of the Technical Support Document) and discussed key issues associated with establishing site-specific fish consumption rates (Chapter 6). Ecology received a number of comments and questions on available information that would be used to support decisions under the Model Toxics Control Act (MTCA). This chapter summarizes and responds to these comments.
- Chapter 9 – Recommendations for Default Fish Consumption Rates. Ecology identified a recommended range of fish consumption rates (157 g/day to 267 g/day) in Chapter 7 of the Technical Support Document. Ecology received a number of comments with recommendations on specific default rates and/or factors that Ecology should consider in selecting a default rate. As noted above, Ecology has revised its strategy for developing a new default fish consumption rate. This chapter summarizes the range of comments and recommendations. Ecology will consider these comments when making decisions on revising the human health criteria and/or site-specific cleanup decisions.

Chapter 2: General Comments

2.1 Overview

Ecology distributed the *Fish Consumption Rates Technical Support Document Version 1.0* for public review in early October 2011. The document was prepared to support discussions on whether and how to revise the fish consumption rates in current state rules. The technical evaluations in the document were modeled on similar evaluations completed by the Environmental Protection Agency (EPA, 2011) and the Oregon Department of Environmental Quality (Oregon DEQ, 2008).

The Technical Support Document was organized into seven main chapters:

Chapter 1: Introduction and Purpose

Chapter 2: Washington Fish Resources and Fish-Consuming Populations

Chapter 3: Methodology for Assessing Fish Consumption Rate Information

Chapter 4: Fish Consumption Survey Data Applicable to Washington Fish Consumers

Chapter 5: Regulatory Context for Using Fish Consumption Rates

Chapter 6: Site-Specific Fish Consumption Rates

Chapter 7: Recommendations

Ecology received a number of comments on the contents and quality of the Technical Support Document, the need for additional evaluations and the timeline for completing the document. Ecology has compiled and evaluated those comments in this chapter.

2.2 General comments on the Technical Support Document

Many people concluded that the report was well-written and provided a sound basis for agency decisions. Many of these people thanked Ecology and commended the agency's work on this report. For example:

> *I am highly supportive of the effort undertaken to recognize that fish ingestion is much greater than previously acknowledged. I am likewise highly supportive of the philosophy behind this report and the quantification methods employed. Having been knowledgeable in this topic and the scientific and technical aspects involved, I can say that this report represents a robust, scientific-based assessment that is both clear and transparent. This report provides an invaluable contribution and major step forward in the protection and preservation of fish and shellfish resources for the people of Washington State.* ***(Faustman (Univ. of Wash.))***

****

CRITFC commends Ecology's efforts to compile this report and respond to tribes' requests for information. The report provides a thorough examination of relevant regional fish consumption rate studies and concludes by recommending that Washington State make significant changes to their default fish consumption rates. ***(Lumley (CRITFC))***

****

In the fish consumption TSD, Ecology provides a useful and informative review of fish consumption survey data available for the Pacific Northwest, building on and adapting the analysis done for the Oregon Department of Environmental Quality (2008). We agree that this information helps to characterize fish consumption habits and rates for different State population groups with regard to how much fish is consumed, what kinds of fish are consumed and where the fish is obtained. This information is also likely to be useful in development of site-specific fish consumptions rates. However, we question Ecology's conclusion that these data may be used to derive a state-wide default fish consumption rate applicable to a variety of regulatory requirements. ***(Barrette (PCSGA)/Schoof (Environ))***

****

Report overall. *Overall, the report is excellent. We appreciate the level of technical detail and the clarity of the report. We generally agree with the conclusions.* ***(Trim (PFPS)/Bell (NWEA))***

However, several other people concluded that the document does not provide an adequate basis for agency decision-making on this issue. There appeared to be two main concerns.

- **Scope of the Technical Support Document**: Many people stated that the document did not include all of the information needed to reach a decision on this issue. Ecology's evaluation and responses to these comments are provided in Section 2.3 below.
- **Scientific Bases for the Technical Support Document**. Several people identified problems with the scientific information and analyses and/or assumptions used to prepare the technical report. Ecology's evaluation and responses to these comments are provided in Section 2.4 through 2.6 and other chapters in this Responses document.

Several people stated that Ecology must prepare a revised document and explain how the agency addressed issues raised in the public comments. For example:

King County recognizes that the purpose of the new default fish consumption is to estimate exposures from individual waterbodies. Because it is unclear how the requested recalculations described above may influence conclusions about differences in exposure, King County requests that Ecology reissue the technical document with these issues addressed. ***(True (King County DNRP))***

****

…Although admittedly not typical of guidance documents, Weyerhaeuser's request is that Ecology respond in writing to the substantive science and technical and risk management issues that are presented. An incomplete exchange on science/technical questions now will

simply move the issues into the next phase of the upcoming administrative/rule development processes. ***(Johnson (Weyerhaeuser))***

****

It is for these reasons that we believe and insist that Ecology must review, consider and respond in writing to the NCASI comments – and all other comments – received from stakeholders during the comment period. Any decision made by Ecology must be made based on sound science. If this process is not based on a sound scientific and technical review, it will undermine the credibility of the entire process. ***(McCabe (NWPPA))***

Ecology's Evaluation and Response: Ecology appreciates the feedback on the Technical Support Document Version 1.0. After evaluating the public comments, we believe there are several areas where the document can be strengthened or clarified. Consequently, Ecology has decided to prepare a revised report (Version 2.0) and a written response to comments.

Chapter 1 of this Responses document includes a summary of the major revisions. The revised Technical Support Document (Version 2.0) still provides an evaluation of scientific information on fish consumption rates. We have incorporated several new evaluations that Ecology has prepared in response to public comments.

We have also revised the Technical Support Document to focus more clearly on the scientific and technical issues associated with estimating the amount of fish and shellfish eaten by people in Washington. Several people commented that they thought the recommendations in the October 2011 document embodied a number of policy choices that should be decided in public rulemaking process rather than in an agency technical document. After reviewing those comments, Ecology agrees that such decisions are more appropriately addressed during the process for revising the state's water quality standards or through the preparation of cleanup action plans for individual sites. Consequently, Ecology decided to remove the recommendations on selecting a default fish consumption rate (Chapter 7) from the revised report. Other sections have been revised to better distinguish scientific and regulatory decisions associated with using the scientific data.

Ecology will also convene a series of technical meetings to discuss the new evaluations and specific technical issues prior to finalizing the Technical Support Document Version 2.0 report in late 2012.

2.3 Scope of the Technical Support Document

The Technical Support Document was prepared to support discussions regarding a fish consumption rate (or rates) appropriate for use as a default value in a regulatory context. The document included the following statement:

This report does not examine the implications or results of updating the fish consumption

rates in these various regulations. This report is focused solely on the data available on fish consumption in the state of Washington. Other materials being prepared concurrently will examine in detail the policy considerations and implications. [Ecology, 2011]

Many people found it difficult to fully evaluate the Technical Support Document without more information on how a revised fish consumption rate would be used to support various regulatory decisions. For example:

….many of the concerns raised in these comments stem from the lack of any indication on the part of Ecology about how these fish consumption rates will be used. The fish consumption rates cannot be fairly evaluated in a vacuum. It will only be possible to consider the full implications of the adoption of these fish consumption rates once Ecology has explained how they intend to use them. ***(McKrone)***

Many people providing comments on regulatory choices and implications expressed concerns that a new fish consumption rate would result in requirements that are difficult and/or infeasible to achieve. They urged Ecology to address these types of regulatory issues before adopting an updated fish consumption rate. For example:

A discussion should be provided in Chapter 7 regarding the impact that fish consumption rates have on the establishment of site cleanup criteria to background levels and the impact this has on developing site boundaries. ***(Johns and Garry (Exponent))***

****

King County agrees that the recommended 157-267 gm/day consumption range characterizes the upper percentile of "high end seafood consumer" exposure. However, we believe that values in this range are not applicable for all waterbodies on a statewide basis as elaborated below. We also have concerns regarding the technical feasibility of implementing these rates that will ultimately need to be addressed. ***(True (King County DNRP))***

Several people stated that Ecology needs to assess the economic impacts associated with updating the current default fish consumption rates. For example:

We are also concerned about the economic impacts from this proposal. Higher fish consumption rates mean few toxic pollutants would be allowed in state waters and result in stricter environmental standards. We want to ensure that stricter environmental standards are scientifically justified and do not negatively impact our state economy. ***(Hewitt et al. (Republican Senate Caucus))***

Several people urged Ecology to assess the human health risks associated with the current default rates and describe the benefits of changing the current default FCRs in terms of public health benefits. For example:

The TSD document fails to provide an assessment of relative human health risks associated with the existing FCRs and the default FCRs in the TSD or to what degree health risk would be reduced by changing the FCR. Ecology must accordingly defer any FCR determination to full rulemaking under the APA with adequate public notice and an opportunity to comment on these and other aspects of the FCRs. ***(Tupper (on behalf of IEP))***

****

The TSD lacks a specific discussion on the potential changes to actual risk for state wide or high consumers because of the higher FCR. While the change in FCR may fulfill legal or policy objectives the actual risks presently experienced in the state due to fish consumption may not change for a very long time. Quantification of the actual risk change due to the proposed FCR should be addressed. ***(Perlwitz (Nippon Paper))***

****

Ecology should present a coherent assessment of health risks represented by the current default FCRs to the general population and high-end consumers, and contrast them with the health risks that would result if the default FCRs were increased as recommended in the TSD. This assessment should also embody components of health risk attributable to other exposure vectors as well as conservative assumptions already used in such risk calculations. This analysis is imperative as it represents the only available comparator for the costs that will be borne by both Ecology and the regulated community to respond to lowered water quality criteria. ***(Louch and Stratton (NCASI))***

Ecology's Evaluation and Response: Ecology acknowledges the difficulties that some people experienced in providing comments on the Technical Support Document without relevant regulatory analyses. This was one of the factors that Ecology considered when modifying our strategy for addressing fish consumption rate issues in July 2012.

The Administrative Procedure Act requires agencies to evaluate the likely costs and benefits of "significant legislative rules." The Technical Support Document was prepared to support discussions on rule revisions. Ecology did not intend to use the document to establish legally-binding requirements in lieu of a formal rulemaking process.

Several people correctly noted that adopting a default fish consumption rate in the SMS rule, the MTCA rule or the Water Quality Standards rule, would be defined as a "significant legislative rule." For such rules, Ecology prepares a preliminary cost/benefit analysis that is published with the proposed rule changes. Ecology considers public comments on the preliminary analysis when preparing a final cost-benefit analysis prior to adopting a new or revised rule.

Ecology proposed revisions to the SMS rule on August 15, 2012. As discussed above, Ecology decided not to include a default fish consumption rate in the proposed SMS rule revisions. The proposed rule clarifies that site-specific sediment cleanup standards will continue to be based on a reasonable maximum exposure scenario.[3] Ecology will consider information in the revised Fish Consumption Rates Technical Support Document Version 2.0 and other technical publications when establishing site-specific sediment cleanup standards.

[3] It is also important to understand that the fish consumption rate is only one of several factors considered when selecting sediment cleanup standards. Decisions on cleanup standards take into account a wide range of factors including chemical toxicity, background concentrations, net environmental impacts and analytical limits. Final decisions on sediment cleanup standards are made concurrently with the selection of a cleanup action which takes into account other factors such as cost, permanence, restoration timeframes, etc.

Ecology has prepared a preliminary cost-benefit analysis for the proposed SMS rule amendments. Ecology will consider comments on the preliminary cost-benefit analysis and prepare a final cost-benefit analysis that will be included in the rule-making record when the final SMS rule revisions are adopted. Since Ecology is not proposing a default fish consumption rate, the analysis does not provide a detailed evaluation of the costs and benefits of adopting a different default fish consumption rate.

Ecology has also prepared a draft Environmental Impact Statement (EIS) that evaluates the human health and ecological impacts associated with different rulemaking alternatives. Ecology will consider all comments on the draft EIS before preparing a final document.

The proposed SMS rule revisions and supporting documents are available for public review. They are available at the following webpage:

http://www.ecy.wa.gov/programs/tcp/regs/2011-SMS/2011-SMS-hp.html

Ecology has also decided to initiate the process to adopt human health criteria that take into account new scientific information on fish consumption rates and toxicological information. During that process, Ecology will comply with the requirements for Significant Legislative Rules.

2.4 Scientific analyses

One of Ecology's overarching goals is to develop requirements that are scientifically defensible. When preparing the Technical Support Document, Ecology reviewed the scientific literature and consulted with scientists experienced in exposure assessment, toxicology and statistics. Where conflicting opinions or recommendations exist, Ecology attempted to reconcile the various positions to arrive at a scientifically defensible approach.

As noted above, a number of people concluded that the report was well-written and provides a sound basis for agency decisions. For example:

> *I am highly supportive of the effort undertaken to recognize that fish ingestion is much greater than previously acknowledged. I am likewise highly supportive of the philosophy behind this report and the quantification methods employed. Having been knowledgeable in this topic and the scientific and technical aspects involved, I can say that this report represents a robust, scientific-based assessment that is both clear and transparent. This report provides an invaluable contribution and major step forward in the protection and preservation of fish and shellfish resources for the people of Washington State.* ***(Faustman (Univ. of Wash.))***
>
> **********
>
> *This document provides a strong framework for your upcoming process to choose a fish consumption rate that more accurately reflects the fish and shellfish consumed by people in Washington. In turn, this rate may be used to adopt criteria that protect the health of those*

consumers. You and your staff should be commended for the quality, substance and readability of the document. ***(Jennings (EPA))***

Ecology also received a number of comments questioning the scientific integrity of the Technical Support Document. For example:

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. ***(Louch and Stratton (NCASI))***

****

Ecology's analysis of the data from the fish consumption studies used to develop the proposed FCRs is significantly flawed. ***(McCabe (NWPPA))***

****

The TSD document provides a superficial analysis of complex scientific issues and a number of policy determinations that are not appropriate for a technical guidance document. ***(Tupper (on behalf of IEP))***

Several people also raised scientific concerns associated with establishing a single statewide default fish consumption rate. In particular, they expressed concerns that a "one-size-fits all" approach was not scientifically supportable. They noted that such an approach failed to take into account the variability in environmental conditions, fish consumption habits of different population groups, chemical uptake by different species of fish and shellfish, etc. For example:

Ecology's notion that one default fish consumption rate can be derived to support a range of regulatory actions does not appear to be scientifically supportable. This is not due to scientific flaws in the fish survey data, but to the narrow focus of many regulations. Each regulation has different goals that are likely to require separate assessments of fish consumption. While a common goal of most regulations is to reduce chemical concentrations in fish, water quality criteria are focused on chemicals in water, while sediment quality standards are focused on contaminated sediments. ***(Barrette (PCSGA)/Schoof (Environ))***

****

One Fish Consumption Rate Does Not Fit Every Site. MTCA (WAC 173-340) is an excellent set of regulations that outlines a relatively streamlined approach which could also be of value if applied to the question of appropriate FCRs. One of the core principles of this approach is its built-in flexibility to allow cleanups to be addressed on a site-specific basis, based on each site's unique risk profile… Other regulations within the State encourage site-specific evaluation to determine appropriate site specific risk profiles and associated cleanup levels. This risk-based approach is the basis for MTCA and the SMS. We recognize that there are some water bodies that are more heavily utilized for subsistence fishing. Similarly, there are other water bodies that have remained primarily industrial with little to no subsistence fishing since they were first modified over 100 years ago, and other water courses with limited access to allow subsistence fishing. To assume that one FCR, based on

a tightly focused consumption survey of 0.02% of the state's population, fits every water body within the State is not realistic based on current and projected site use, and is not consistent with previous Ecology decisions. Simply put, the focused population survey is not representative of the "reasonable maximum exposure" for every water body in Washington. ***(Graham (Schnitzer Steel))***

The issue of geographic variability is discussed in other parts of this document.

Ecology's Evaluation and Response: Ecology has reviewed the public comments on this issue and continues to believe that the Technical Support Document provides a solid scientific foundation for regulatory decisions. The rationale for this conclusion includes:

- The scientific information, analyses and conclusions in the Technical Support Document are consistent with the information, analyses and conclusions in other technical documents prepared by EPA and Oregon. Ecology modeled the Technical Support Document on work performed by EPA (2011) and Oregon DEQ (2008). These agencies also conducted extensive multi-year evaluations of the scientific evaluations of the information considered by Ecology when preparing the Technical Support Document.
- Ecology consulted with scientific experts when preparing the Technical Support Document. Ecology developed the Technical Support Document over a three-year time span. During that timeframe, Ecology consulted with experts in fisheries biology, statistics and exposure assessment. Ecology distributed preliminary drafts of the Technical Support Document and individual chapters for review by these experts.
- The MTCA Science Advisory Board[4] reviewed preliminary analyses prepared by Ecology and concluded that the information was consistent with current scientific knowledge on these issues. Ecology has consulted with the MTCA Science Advisory Board on two site-specific fish consumption rate issues. In 2005, Ecology sought advice from the Board on issues surrounding fish consumption rates for Asian and Pacific Islanders at the Lower Duwamish Waterway site. From 2007 to 2008, Ecology sought advice from the Board on issues surrounding tribal fish consumption rates at the Rayonier site in Port Angeles Harbor. The Board provided several conclusions and recommendations.[5] For example, the summary of

[4] The Model Toxics Control Act Science Advisory Board (SAB) was established by Chapter 70.105D RCW. The Board provided advice to Ecology on hazardous substances and cleanup-related scientific issues from 1988 through 2009. The legal mandate for Ecology to maintain a Science Advisory Board was removed from law during the 2009 Legislative session (Senate Bill 5995).

Consistent with the intent of that legislation, Ecology will continue to seek scientific input and advice on a wide range of technical issues related to the cleanup of contaminated sites. One method Ecology will solicit this input is through a "Science Panel," appointed by the Director of the Department of Ecology. Panel members are invited by the Toxics Cleanup Program to meet 2 to 4 times a year to provide advice on scientific issues related to site cleanup posed by the Program. These meetings are open to public attendance. See the Public Meeting page for dates and agendas.

[5] http://www.ecy.wa.gov/programs/tcp/SAB/SAB_mtg_info/mtg_info.htm

the meeting held on the March 11, 2008, includes the following recommendations from the Board:

- The Board agreed with Ecology's conclusion that the MTCA exposure parameters do not provide a reasonable basis for estimating fish consumption exposures for members of the Lower Elwha Klallam Tribe (LEKT) and that this conclusion is consistent with current scientific information.
- The Board concluded that it is scientifically defensible to use consumption surveys from other tribes with similar dietary habits to estimate fish and shellfish consumption exposures for members of the LEKT.
- The Board concluded that it is scientifically defensible to use the fish consumption survey completed by the Suquamish Tribe to estimate fish and shellfish consumption exposures for members of the LEKT.

Ecology and the Board used the criteria for quality of information as specified in the MTCA Cleanup Regulation (See WAC 173-340-702(16)). These criteria are similar to the technical defensibility criteria used when preparing the Technical Support Document. The MTCA quality of information criteria are:

- Whether the information is based on a theory or technique that has widespread acceptance within the relevant scientific community.
- Whether the information was derived using standard testing methods or other widely accepted scientific methods.
- Whether a review of relevant scientific information, both in support of and not in support of the proposed modification, has been provided along with the rationale explaining the reasons for the proposed modification.
- Whether the assumptions used in applying the information to the facility are valid and would ensure the proposed modification would err on behalf of protecting human health and the environment.
- Whether the information adequately addresses populations that are more highly exposed than the population as a whole and are reasonably likely to be present at the site.
- Whether adequate quality assurance and quality control procedures have been used, any significant anomalies are adequately explained, the limitations of the information are identified and the known or potential rate of error is acceptable.

2.5 Distinguishing between matters of science and matters of policy

Ecology received a wide range of comments on the scientific analyses in the Technical Support Document. In some cases, the comments appeared to be less about the scientific information itself and more about Ecology's interpretation or intended use of that information to implement

certain policy/regulatory decisions. Some people questioned whether it was appropriate to include policy determinations in a technical guidance document. For example:

> *The TSD document provides a superficial analysis of complex scientific issues and a number of policy determinations that are not appropriate for a technical guidance document.* ***(Tupper (on behalf of IEP))***

Ecology's Evaluation and Response: Ecology believes that some of the comments on the scientific merits of the Technical Support Document reflect concerns about the policy choices surrounding the use of that information. In particular, several people were concerned that the recommendations for selecting a range of default fish consumption rates embodied a number of policy choices on the appropriate way to manage uncertainties and variability.

The Conservation Foundation has stated that it is important that environmental agencies distinguish between scientific and policy choices when making regulatory decisions:

> *A key to understanding the risk assessment process is to distinguish between those aspects of the process that are scientific and those that are matters of policy or personal values, and to appreciate their complex interrelationships …. A risk assessment process that is defensible from both a scientific and a policy standpoint must accurately identify which aspects of the assessment are policy and which are science. The difficulty is that both scientists and policy makers tend to define their realm in the broadest terms. (Conservation Foundation, 1984)*

However, the interaction between science and policy in regulatory decision-making is complicated. There are often several equally plausible scientific options for resolving a particular issue.[6] In these situations, the regulatory decision essentially represents a policy choice that must take into account statutory directives, implementation issues, and value judgments on how to deal with scientific uncertainty and variability in exposure and susceptibility. As Victor Hugo once wrote, "Science says the first word on everything, and the last word on nothing." (Hugo, 1907)

In Version 2.0 of the Technical Support Document, Ecology has sought to reinforce this distinction by focusing on the scientific information on fish consumption in Washington State. As noted above, we have removed the recommendations on selecting one or more default fish consumption rate for statewide use. Version 2.0 includes a new Chapter 6 ("Using Scientific Data to Support Regulatory Decisions") that highlights some of the policy choices that are needed when using the scientific information on fish consumption rates to support programmatic and site-specific regulatory decisions.

[6] The complicated relationships between scientific information and regulatory choices have been discussed and evaluated in a series of reports prepared by the National Academy of Sciences (NAS)/National Research Council (NRC) over the last 30 years. (NAS, 1983; NRC, 1994; NRC, 1996; and NRC, 2009).

2.6 Scientific review of the Technical Support Document

Several people emphasized the importance of scientific peer review. They acknowledged that the document provided important factors that must be considered when evaluating scientific integrity of individual studies. However, they concluded that such evaluation factors were not an adequate substitute for a rigorous peer review of individual studies. For example:

> *…we urge Ecology to follow the rulemaking process identified above so that the science on this issue is thoroughly vetted before the rates are set. This approach will have the benefit of giving credibility to future rulemaking on water quality and pollution control standards.* ***(Hewitt et al. (Republican Senate Caucus))***
>
> **********
>
> *The FCR Studies should be Scientifically Peer-Reviewed by an Independent Third Party. Peer review plays an important role in evaluating data, conclusions, and recommendations in any publication; especially a scientific document that could be used to develop regulations or guidelines. The peer reviewed document becomes the foundation by which the regulations are built upon. The fish consumption surveys conducted from 1994 through 2000, and used for this FCR report, should be peer reviewed by an independent third party selected by an unbiased neutral party to determine the scientific validity of the study conducted and the appropriateness of its conclusions. The FCR report should also undergo a similar scientific peer review process. It is critical that the peer reviewer(s) be a third party without ties to the primary author or group to avoid any potential biases. It is unclear based on the information provided in the FCR if the older fish consumption surveys were appropriately peer reviewed, and if so, what the findings of the peer reviews were.* ***(Graham (Schnitzer Steel))***

Ecology's Evaluation and Response: Ecology's overall goal is to produce a final Technical Support Document that provides a credible and balanced evaluation of the current scientific information on fish consumption rates in the Pacific Northwest.

Ecology believes that the available scientific data has been thoroughly evaluated in a credible and objective manner through multiple review processes.

- Review of the Technical Support Document. Ecology conducted literature reviews and consulted with subject matter experts when preparing the Technical Support Document. Scientists from the University of Washington, Environmental Protection Agency, Department of Health and other agencies reviewed specific topics according to their areas of expertise. The list of reviewers is provided in the Technical Support Document. Ecology staff made presentations and received feedback at numerous technical meetings.

- Review of the *Exposure Factors Handbook*. EPA recently published an updated *Exposure Factors Handbook* (EPA, 2011). Chapter 10 of the EPA document provides evaluations and recommendations on fish consumption rates. With respect to the tribal and API studies, EPA reached conclusions similar to those in Ecology's *Fish*

Consumption Rates Technical Support Document Version 1.0. EPA conducted extensive evaluations to support revisions to the handbook. EPA distributed the draft document for public review and convened a peer review panel in March 2010.

- Review of Early Ecology Evaluations. The MTCA Science Advisory Board provided independent scientific review of fish consumption rates as part of site-specific evaluations in Port Angeles Harbor and the Lower Duwamish Waterway.

- Review of the Oregon Water Quality Standards. The Oregon Department of Environmental Quality formed a scientific review group (the Human Health Focus Group). The group evaluated available fish consumption studies and provided recommendations to the Oregon DEQ.

However, people raised several important technical issues that Ecology believes would benefit from further technical discussions. Consequently, Ecology has decided to convene a technical committee to focus on particular technical and scientific issues related to the report. Specifically, Ecology will be asking scientists to provide comments and advice on the following topics:

- Additional evaluations. Ecology completed several additional studies that have been incorporated into the revised Technical Support Document. We are specifically interested in comments on (1) the evaluation of regional studies to estimate species-specific rates and (2) the evaluation of the national fish consumption data using methods developed by the National Cancer Institute to account for temporal variations in fish consumption rates.

- Regional surveys. Ecology received numerous comments on the regional surveys. Ecology has identified a limited number of specific issues that we would like to discuss with other scientists.

- Use of fish consumption information to estimate exposure. Ecology uses information on fish consumption rates to prepare exposure estimates that reflect different types of exposure scenarios. Ecology is interested in receiving advice from scientists on issues associated with using regional and national data to estimate chronic and sub-chronic exposures.

2.7 Environmental justice issues

Several people expressed concerns that the document largely omitted any discussion of environmental justice issues that should be considered when establishing a default fish consumption rate. For example:

> *We have reviewed the technical support document and think that it is, overall, a well crafted document. However, there are a few issues not fully addressed in the technical document that further support the proposed fish consumption rates, and possibly support consumption rates that are even higher than proposed: As a result of Substitute Senate Bill 6197 and RCW 43.20.270, Governor Gregoire has initiated a State Policy Action Plan to eliminate health*

disparities in Washington State (http://healthequity.wa.gov/). One of the policy papers being issued in early 2012 addresses environmental exposures and hazards. Environmental exposures and hazards are not uniformly distributed across populations; low income communities and communities of color are at disproportionately high risk for environmental health disparities, including disease and death. One area of concern is the relatively new field of epigenetics – defined as changes that do not alter the DNA sequence but do cause biological changes in the body. Environmental exposures that may cause biological changes include endocrine disruptors, metals, benzene, polycyclic aromatic hydrocarbons, polychlorinated biphenyls, diet, and social influences such as stress. Ecology's proposed fish consumption rates will help to protect low income, minority populations by supporting actions which reduce contaminant levels in seafood, which will ultimately reduce health disparities. ***(Rasmussen (DRCC/TAG))***

Ecology's Evaluation and Response: Ecology agrees that environmental justice is an important consideration when establishing environmental policies and standards. While this issue was not explicitly discussed in the Technical Support Document, many of the analyses and recommendations in the document were consistent with approaches supported by environmental justice organizations. For example, the National Environmental Justice Advisory Council (NEJAC) is a federal advisory committee that provides independent advice, consultation, and recommendations to the EPA administrator on matters related to environmental justice. NEJAC has criticized EPA for including survey respondents who reported eating no fish during the survey period when calculating fish consumption rate for Tribal populations (EPA, 2002). The analyses in the Technical Support Document were developed using "consumer-only" data.

2.8 SMS rule schedule

Several people urged Ecology to revise the schedule for updating the default fish consumption rate in order to provide more time to evaluate scientific and implementation issues and concerns. For example:

IEP urges Ecology to suspend development of default statewide fish consumption rates (FCRs) until a more thorough scientific evaluation can be performed to assess any public health benefits. ***(Tupper (on behalf of IEP))***

****

Ecology proposes to have the default fish consumption rates finalized in Washington by Fall 2012 after publishing the technical support document in September 2011. This time frame must be extended. In addition, rushing to a final fish consumption rate only one year after the draft technical support document is published is unnecessary. The City of Spokane asks that Ecology develop a timeframe that would at least permit meaningful observation and lessons learned" from Oregon's process. ***(Arnold, City of Spokane)***

However, other people urged Ecology to maintain the current schedule and move expeditiously to update the default fish consumption rate for Washington. For example:

EPA urges Ecology to continue the process of revising Washington's human health criteria in a timely manner. However, EPA recognizes that several key questions still need to be decided. For example, Ecology will need to decide on implementation tools in order to put into practice revised human health criteria and Ecology will need to decide if a consistent number will be chosen for the state's SMS and WQS. Nonetheless, EPA believes the information is currently available to make decisions on these matters and requests Ecology to quickly move through the process necessary to do so. EPA remains committed to working with Ecology, the Tribes and Washington's stakeholders to facilitate the adoption of water quality criteria that reflect appropriate fish consumption rates for Washington's waters and are protective of human health. ***(Jennings (EPA))***

****

An update must occur. *Currently, the default rates in place do not protect either the general population or the high user groups. This is contrary to both state and federal law that standards must adequately protect human health. For this reason, we urge a speedy process to update the default fish consumption rates for both sediment and water quality standards.* ***(Trim (PFPS)/Bell (NWEA))***

Ecology's Evaluation and Response: Ecology proposed revisions to the SMS rule on August 15, 2012. Information on the proposed SMS rule revisions can be obtained at http://www.ecy.wa.gov/programs/tcp/regs/2011-SMS/2011-SMS-hp.html. Ecology has scheduled five public hearings on the proposed revisions that will be held in late September and early October 2012. The public comment period runs through October 15, 2012.

As discussed above, Ecology decided not to propose a default fish consumption rate in the SMS rule revisions. The proposed rule clarifies that site-specific sediment cleanup standards will continue to be based on a reasonable maximum exposure. Ecology will consider information in the revised Fish Consumption Rates Technical Support Document (Version 2.0) and other technical publications when establishing site-specific sediment cleanup standards.

2.9 Strategy for revising the Water Quality Standards for Surface Waters

In October 2011, Ecology announced strategy for adopting fish consumption rates in both the SMS and WQS rules. Under that approach, Ecology planned to incorporate a new fish consumption rate into the SMS rule revisions by December 2012. Ecology also planned to adopt revisions to the WQS that would have established additional compliance tools and longer timelines by the end of 2012 (Phase I revisions). Once those changes were adopted, Ecology planned to begin the process to revise the water quality criteria for human health protection (Phase II revisions). As discussed below, Ecology has modified this approach to address public comments and concerns.

Ecology received a number of comments on the phasing approach. Several people expressed support for Ecology's plan to amend the Water Quality Standards (WQS) rule in two phases. For example:

> *Lawful and efficient regulatory mechanisms need to be identified and promoted to allow wastewater dischargers and PLPs to be confidently compliant with the Clean Water Act, assuming good faith efforts and application of AKART. The Department of Ecology needs to demonstrate competence and a willingness to employ these mechanisms to achieve rational outcomes.* ***(McCabe (NWPPA))***

Several people urged Ecology to combine Phase I and II and complete the combined rulemaking by the end of 2012. For example:

> *Further, we strongly recommend that Ecology bundle the fish consumption/human health criteria rulemaking with the "implementation tools" rulemaking rather than loosening regulatory controls prior to adopting appropriate fish consumption rate-based criteria.* ***(Trim (PFPS)/Bell (NWEA))***
>
> **********
>
> *I am deeply concerned about what Jim Pendowski, Program Manager of the Toxics Cleanup Program (TCP), referred to at the first meeting of the Sediment Management Standards Advisory Committee as the "parallel" rule-making approach that Ecology's two programs are taking in promulgating water quality and sediment cleanup standards. This approach is certainly NOT parallel, but is sequential, at best….It is time for the WQP to take a similar "can do" to approach TCP, deal with this thorny issue straight on, and promulgate water quality standards* ***simultaneously*** *with the TCP cleanup standards.* ***(Winters)***

Ecology's Evaluation and Response: In July 2012, Ecology decided not to adopt a default fish consumption rate in the Sediment Management Standards (SMS) rule. Ecology also announced that the Water Quality Program was initiating the process to adopt human health criteria in the Water Quality Standards rule. The Water Quality Program will conduct both the implementation tools rule-making and the human health-based criteria development rule-making during roughly the same time frames. Compared to the approach being commented on, this will result in earlier adoption of human health-based criteria, and slightly delayed adoption of new implementation tools.

2.10 Impact on listings of impaired water bodies

Several people expressed concerns about how a revised fish consumption rate would impact the identification and listing of impaired waterbodies. A number of people predicted that using a fish consumption between 157 and 267 grams/day would result in practically all waters of the state being included on the 303(d) list of impaired waters. For example:

> *Another concern is that Ecology could set standards so low that our fish and shellfish industry would be impacted because we could end up listing all our waters as impaired for*

human health criteria. For example, Ecology is already listing many of NOAA's mussel watch sites in the state as impaired due primarily to PAH levels in mussels with the thresholds of concern being derived from the human health surface water quality criteria. If criteria become more stringent, then probably all mussel watch sites will need to be listed. ***(McClellan (Everett Public Works))***

Ecology's Evaluation and Response: In July 2012, Ecology announced that the Water Quality Program was initiating the process to adopt new human health criteria in the Water Quality Standards rule. Given Ecology's revised strategy, we decided not to provide broadly applicable responses to these comments at this time. Comments on this issue will be addressed during the process to adopt new human health criteria in the Water Quality Standards rule.

2.11 Impacts on permit limits for industrial and municipal dischargers

Many people expressed concerns about how a revised fish consumption rate would impact requirements for industrial and municipal dischargers. Most of these people emphasized the importance of adopting workable compliance methods for dealing with extremely low discharge requirements. For example:

Similarly, high fish consumption rates may drive water quality criteria for bioaccumulative contaminants to background or even laboratory detection limits. The cost for any entity with a wastewater discharge (i.e., not only industries, but also municipalities) to have to try to achieve such concentrations in their discharge will be enormous, and it is may not even be technically feasible to treat water to such low levels. I understand that Ecology intends to conduct an economic impact assessment for the current revision of the Sediment Management Standards only once a draft rule has been completed. I believe that it is incumbent on Ecology to consider the economic implications much earlier in the process; given the potential ramifications of the fish consumption rates on not only sediment standards, but also surface water quality criteria and surface water cleanup standards, such consideration of economic implications should occur now. ***(McKrone)***

****

Any application of the revised FCR to water quality standards must be accompanied by a set of tools that allow dischargers to be in compliance. These tools should consider both the regulatory methods allowable by EPA as bona fide compliance pathways and the likely technical and economic methods available to treat discharges to extremely low levels. Without a clear path forward municipal and industrial dischargers will be out of compliance immediately because discharge levels of certain pollutants will be driven to near zero by the high FCR. ***(Perlwitz (Nippon Paper))***

Ecology's Evaluation and Response: In July 2012, Ecology announced that the Water Quality Program was initiating the process to adopt new human health criteria in the Water Quality

Standards rule. Given Ecology's revised strategy, we decided not to provide broadly applicable responses to these comments at this time. Comments on this issue will be addressed during the process to adopt new human health criteria in the Water Quality Standards rule.

2.12 "Significant Legislative Rules" under the Administrative Procedure Act

Many people stated that a statewide fish consumption rate must be adopted as a "Significant Legislative Rule" which requires Ecology to perform several types of regulatory analyses. For example:

> *This is problematic for a couple of reasons. First, the fish consumption default rates will be the basis for determining the appropriate level of environmental protection that is needed when updating these regulations and need to be thoroughly vetted before adoption. Second, formal rulemaking would require Ecology to follow certain procedures that we do not believe are being followed currently for this proposal. Examples are: responding in writing to all comments (including on the science), justifying its final decision in writing, analyzing whether its standard is stricter than federal law, and performing a cost-benefit analysis.* ***(Hewitt et al. (Republican Senate Caucus))***
>
> **********
>
> *FCR is complex and this will be a significant change in Washington. This TSD will become the basis for rulemaking in the Sediment Management Standards and in the Surface Water Quality Standards. Therefore we urge Ecology to be considerate and responsive to comments made on the TSD. No doubt this will be a Significant Legislative Rule (SLR) (RCW 34.05.328) and require careful adherence to the elements necessary for promulgation of an SLR.* ***(Perlwitz (Nippon Paper))***
>
> **********
>
> *The Adoption of Default FCRs is Subject to APA Rulemaking Requirements for Significant Legislative Rules Statewide default FCRs must be adopted as significant legislative rules as defined in RCW 34.05.328. The APA requires Ecology to prepare a statement of the goals and specific objectives for the default FCRs. Ecology is also required to provide, at the time it issues public notice of rulemaking, a cost benefit analysis that documents the alternatives considered by the department, including a determination that the selected standard is the least burdensome alternative. There must be substantial evidence in the record that explains how the rule meets the goals and specific objectives of the department. This documentation must be sufficient to persuade a reasonable person that the determinations are justified. Finally, RCW 34.05.328 requires Ecology to include an implementation plan with the notice of rulemaking.*
>
> *It is not reasonably possible to comment on the merits of the recommended FCRs in the TSD document without the required disclosure for significant legislative rules. Nor would it be appropriate for Ecology to adopt statewide default FCRs without a cost benefit analysis and implementation plan for the resulting standards.* ***(Tupper (on behalf of IEP))***

Ecology's Evaluation and Response: The SMS rule revision is a "Significant Legislative Rule" as defined under the Administrative Procedure Act. As noted by numerous people, this law requires Ecology to prepare several regulatory analyses prior to publishing a proposed rule.

The APA requirements include, but are not limited to: (1) an analysis of the incremental costs and benefits of proposed rule revisions, (2) an evaluation of alternatives to determine whether the proposed rule revisions represent the least burdensome alternative, and (3) an evaluation and justification for any requirements that are more stringent than applicable federal requirements.

Ecology will fully comply with the "Significant Legislative Rule" requirements when preparing the revisions to the SMS rule. Ecology prepared a preliminary cost-benefit analysis and least burdensome alternative analysis for the proposed SMS rule revisions. These analyses have been posted on Ecology's website.[7] Ecology will review public comments on the preliminary analyses and prepare final analyses before formally adopting the SMS rule revisions. Ecology will also evaluate the other "Significant Legislative Rule" criteria (including an evaluation and justification for any requirements that are more stringent than applicable federal requirements) before adopting the final SMS rule revisions.

2.13 Guidance for site-specific fish consumption rates

Ecology received several comments on the use of guidance documents to address the fish consumption rate issue. Some people appeared to support an approach where Ecology would adopt guidance for establishing higher rates on a site-specific basis instead of adopting a default fish consumption rate through the rulemaking process. For example:

> *MTCA already provides sufficient flexibility to address the protection of high-consuming populations, so rule changes are not necessary. If the Department's goal is to clarify agency expectations and streamline cleanup decisions, then this can be addressed with an updated narrative standard accompanied by development of appropriate regulatory guidance.* ***(Hellman (WPPA))***

Other people expressed concerns with such an approach. They stated that adopting a default fish consumption rate in a guidance document would circumvent the rulemaking requirements in the Administrative Procedure Act. They stated that Ecology must comply with the APA requirements for significant legislative rules if the Department intends to uniformly apply the default fish consumption rate. For example:

> *Ecology may not lawfully use a Guidance Document to Circumvent APA Rulemaking Requirements*

[7] http://www.ecy.wa.gov/programs/tcp/regs/2011-SMS/2011-SMS-hp.html.

Ecology should recognize that it cannot bypass rulemaking requirements by adopting default FCRs in a guidance document. Washington Courts have been clear that adoption of a substantive rule requires compliance with APA rulemaking requirements. In Simpson Tacoma Kraft Co. v. Ecology, 119 Wn.2d 640, 835 P.2d 1030 (1992), the Court invalidated Ecology's promulgation of dioxin numeric water quality standards because Ecology did not utilize APA rule-making procedures. The Court emphasized the important purpose of rule-making procedures in providing the public with notice and an opportunity to comment. See also Hillis v. Ecology, 131 Wn.2d 373, 932 P.2d 139 (1997)(internal agency procedure for processing water rights had to be adopted by rule).

*Federal courts have similarly held that EPA cannot bypass public participation requirements through the use of "guidance" documents. See National Mining Assoc. v. Jackson, No. 10-1220, 2011 WL 124194 (D. D.C. Jan. 14, 2011). The Court held: "If an agency adopts a new position inconsistent with an existing regulation, or effects a substantive change in the regulation, notice and comment are required." Id. at *8. The Court found that because EPA was treating the Guidance Memorandum as binding, and it had a practical impact on permit applicants, the memorandum was a legislative rule—an "agency action that has 'the force and effect of law'", and thus public notice and comment was required. Id. at *5, 6, 8.1 See also Appalachian Power Co. v. EPA, 208 F.3d 1015 (D.C. Cir. 2000); Crop Life America v. EPA, 329 F.3d 876 (D.C. Cir. 2003.*

Conclusion: Ecology should commit to respond to all comments received on the TSD document and agree to further suspend development of default FCRs until a proper and thorough scientific assessment can be performed to validate any public health benefits. Ecology should further commit to subjecting any default FCRs to rulemaking as significant legislative rules. ***(Tupper (on behalf of IEP))***

One person recommended that Ecology clearly identify any guidance document on fish consumption rates. They recommended that Ecology consider the Office of Management and Budget (OMB) guidelines if Ecology decided to develop guidance on this issue.

EPA Region 10 has been very careful not to refer to their framework document as a "guidance document", perhaps being aware that an EPA "guidance document" would be subject to considerably more scrutiny than this document was ever expected to receive. Indeed, the Office of Management and Budget (OMB) requires that a guidance document must be: (1) developed with appropriate review and public participation, (2) accessible and transparent to the public, (3) of high quality, and (4) not improperly treated as legally binding requirements. Among other things, a guidance document must also include the term "guidance" or its functional equivalent in the title, have a document identification number, and a citation to the statutory provision or regulation it interprets or to which it applies. The agency must post the guidance document on the section of its website designated for significant guidance documents, provide for public comment, and provide a link from the guidance document to the public comments. The agency must also designate an office to receive and address complaints by the public that the agency is not following the procedures required by the OMB. EPA Region 10 apparently did none of these things in developing the framework document and therefore it should not be considered to be guidance. ***(Johns and Garry (Exponent))***

Ecology's Evaluation and Response: Ecology prepared the Technical Support Document to facilitate discussions on whether and how to update the current default fish consumption rates. Consequently, people were mistaken if they viewed the Technical Support Document as a stand-alone guidance document.

However, the comments on this issue highlight an important rulemaking dilemma: What is the appropriate balance between rule specificity and site-specific flexibility? With the SMS rule, Ecology has worked to create a predictable decision-making framework for making cleanup decisions based on human health protection. In general, greater predictability requires greater specificity in individual rules.

However, many people providing comments on the Technical Support Document discussed the large geographic variability in fish habitat, chemical contaminants and population groups. They emphasized the need for site-specific flexibility.

With the SMS rule revisions, Ecology has tried to balance the goals of regulatory consistency, predictability, and efficiency with the need to provide flexibility to address individual site situations. In many cases, we are proposing to achieve this balance by establishing general rule requirements that would be supplemented with guidance to support site-specific decisions.

Ecology has prepared a draft guidance document to support site-specific sediment cleanup decisions (*Sediment Cleanup Users Manual II*). The draft document provides methods for establishing risk-based cleanup standards and modifications based on background concentrations and analytical limits. Information on the draft Technical Support Document (Version 2.0) will be used to supplement that guidance.

Ecology plans to post a copy of the draft guidance in early September. This approach differs from other guidance documents that are usually developed after final rules are formally adopted. Based on comments made on the preliminary draft SMS rule language, Ecology decided it was important to provide people with the draft guidance as they prepare comments on the proposed rule language. However, Ecology is not seeking comments on the draft guidance at this time. Ecology plans to work on the guidance materials during the time between the rule adoption date and rule effective date. We anticipate that this time period will be longer than the minimum 30 days required under the Administrative Procedures Act. For example, Ecology provided a six month time period between rule adoption and the effective date for the 2001 amendments to the Model Toxics Control Act Cleanup Regulation (Chapter 173-340 WAC)

Chapter 3: Comments on Issues Associated with Population Groups

3.1 Overview

When developing a regulatory standard based on health protection, agencies must decide what population groups that standard is designed to protect. This is a policy choice that can be made on a programmatic (or statewide) or site-specific basis. The need for this choice arises because there are wide variations in fish consumption rates among different population groups and individuals within those groups. This choice has large implications given the wide range of fish consumption habits and patterns.

The Technical Support Document included a recommended range that was based on studies from high exposure population groups. The lower and upper ends of the range corresponded to the 80th and 95th percentiles of the distribution of fish consumption rates, respectively.

The key aspects of the underlying policy choice are reflected in the following two questions posed by one person who provided comments on the draft Technical Support Document:

- *Should the default fish consumption rate be based on the 90th/95th percentile of the entire population of Washington State fish consumers? Or*
- *Should the default fish consumption rate be based on the 90th/95th percentile of high-end consumers?* ***(Waldron (PTC))***

Ecology received numerous comments related to these questions. For purposes of this Responses document, Ecology has organized those comments into the following categories:

- Establishing fish consumption rates based on high exposure population groups.
- Establishing fish consumption rates based on the general population.
- Selecting values from the distribution of individual rates in the chosen population group.

In July 2012, Ecology decided not to propose a default fish consumption rate in the Sediment Management Standards (SMS) rule. Ecology also announced that the Water Quality Program was initiating the process to adopt human health criteria in the WQS rule.

Given Ecology's revised strategy, we decided not to provide broadly applicable responses to these comments. Instead, this chapter compiles and summarizes comments on this issue. Chapter 8 of this Responses document provides Ecology's evaluation and response to these comments within the context of defining reasonable maximum exposures under the Model Toxics Control Act.

Ecology will also consider these questions and comments when developing the human health criteria in the WQS rule.

3.2 High exposure population groups

Several people recommended that Ecology develop a default fish consumption rate that protects all Washington residents including those population groups that eat more fish than the general population. For example:

> *The Washington Waterkeepers support adopting a fish consumption rate that protects the vast majority of people who regularly eat Washington-caught fish which is reflected by the upper range of the Report's recommended fish consumption rate.* ***(VandenHeuvel et al. (Waterkeepers))***

Those who recommended that Ecology establish a default fish consumption rate based on protecting high exposure groups identified several reasons for their recommendations.

Available studies on high exposure population groups

Several people stated Ecology should establish the default fish consumption rate using information from high exposure population groups because studies have shown that many of these groups consume much larger amounts of fish than the general population. For example:

> *Similarly, the state of Washington establishes fish consumption rates for Washington residents. Dietary surveys cited in the Technical Support Document indicate that Washington residents consume fish and shellfish at rates that are likely higher than national averages. Specific groups of Washington residents, such as tribes and Asian/Pacific Islanders, consume fish and shellfish at even higher rates. The state must consider these fish consumption rates in determining standards for water quality and toxic cleanup that are sufficiently protective of all people in Washington. We would like to emphasize that the proposed rates will be state standards, and tribes will continue to set their own standards based on their own fish consumption and availability.* ***(Frank (NWIFC))***
>
> ***************
>
> *We believe it is vital that the end-result of cleanups be the protection of high-rate seafood consumers..* ***To this end, we ask that a reassessment of subsistence fishers be conducted to ascertain a consumption rate protective of high-rate consumers.*** *In reviewing the literature and in speaking with members of subsistence and indigenous groups, we believe the seafood consumption rate should be set close to 300 g/day, if not higher. The setting of a subsistence rate for non-tribal peoples should be in no way construed as a substitute for individual tribal consumption rates. The LEKT rate is appropriate for LEKT, as other tribal rates, as determined through consultation with the tribes themselves will be appropriate for them. Because non-tribal subsistence fishers often obtain seafood in the Usual and Accustomed Areas (U&A) of tribal members,* ***consumption rates protective of high-rate subsistence fishers should be considered the minimum consumption rate throughout Puget Sound****. In respecting treaty rights, we recognize that indigenous tribes and nations will negotiate fish consumption appropriate for their U&A's.* ***(Branch et al. (Environmental Coalition))***

However, several people concluded that the recommended range of fish consumption rates presented in the Technical Support Document did not fully reflect the amount of fish and shellfish eaten by some groups. For example:

> ***Subsistence fishers**. The lack of studies of subsistence fish consumption rates is disappointing. The rates being considered by Ecology, therefore, exclude this population which historically has been ignored. **(Trim (PFPS)/Bell (NWEA))***
>
> **********
>
> *The fish consumption rate Washington currently uses does not reflect fish consumption rates for Yakama tribal members and therefore does not adequately protect the health of those who consume many times that amount. Ecology's proposed rate range of 157-267 grams of fish per day is based on percentiles (80^{th} – 95^{th} percentile) of a model that represents "high fish consumption" populations of the state. While certainly a more defensible proposal than the status quo, this protocol ensures that a significant portion of the tribal population most in need of protection will be exposed to health risk. It is unclear how WDOE reconciles its choice to knowingly allow a portion of a population to be subjected to risk with its stated mission "…to protect, preserve and enhance Washington's environment, and promote the wise management of our air, land and water for the benefit of current and future generations." Ecology needs to select a fish consumption rate that is protective of all Yakama tribal members, not just a portion of them. **(Smiskin (Yakama Tribal Council))***

Tribal treaty rights

Several people stated Ecology should establish the default fish consumption rate using information from high exposure population groups because tribes have legally- protected rights to safely consume fish at subsistence levels. For example:

> *In ceding large portions of their aboriginal lands to the United States, the CRITFC tribes reserved the right to continue to fish at all usual and accustomed sites for ceremonial, subsistence, and commercial purposes. As demonstrated in the CRITFC fish consumption study fish remain a mainstay of tribal diets throughout the Pacific Northwest. Tribes have legally protected rights to safely consume fish at subsistence levels and the standards set by the state of Washington must consider these rights when it issues standards that so directly impact the safety of tribal populations. **(Lumley (CRITFC))***
>
> **********
>
> *Tribes comprise distinct peoples with inherent rights. Tribes' status as self-governing, sovereign entities pre-dated contact with European settlers. This status, nonetheless, was affirmed by the nascent United States. Among other things, the United States viewed the Indian tribes as nations, capable of entering into treaties. Today, tribes are recognized to have a unique political and legal status - a status that sets them apart from every other "subpopulation" or group that might warrant particular consideration in a risk assessment or in decisions about environmental standards more broadly. Tribes' rights and interests, moreover, are protected by a constellation of laws and commitments that are unique among groups affected by Ecology's decisions. These include protections secured by treaties, laws, and executive orders that speak to the rights of tribes and their members. **(O'Neill (Seattle Univ.))***

However, several people emphasized the importance of distinguishing between tribal fish consumption rates and rates adopted in state regulations. For example*:*

The tribes would like to emphasize the difference between tribal fish consumption rates and the default rates which will be established by the state of Washington.

Tribal governments have the ability to set their own fish consumption rates based on data they collect about the dietary habits of their tribal people. Tribal fish consumption rates are used for establishing standards on the lands and waters that the tribes govern. Tribes with water quality standards are responsible for monitoring, enforcement, and cleanup duties according to the standards they adopt. [CITATION]

Consistency with EPA guidance and Oregon water quality standards

Several people stated Ecology should establish the default fish consumption rate using information from high exposure population groups because this approach complies with EPA guidance and is consistent with the approach used in Oregon. For example:

The water quality standards regulation at 40 C.F.R. 131.11 (a) requires states to adopt water quality criteria to protect all designated uses. Such criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use. In 2000, EPA updated its methodology for deriving human health criteria (2000 Methodology). In that document EPA urges states and tribes to use a fish intake level derived from local or regional data. Consideration of local data is important to ensure protection of the local populations, especially when that population includes subpopulations that eat larger quantities of fish and shellfish. A four preference hierarchy concerning the use of fish consumption rate data is set forth: (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 rate of 17.5 grams per day if no' state/site-specific information is available. ***(Jennings (EPA))***

Consistency with CERCA and MTCA Reasonable Maximum Exposure (RME) Concept

Cleanup standards under the state and federal superfund programs are based on a reasonable maximum exposure (RME). Several people stated that using information from high exposure population groups to establish a default fish consumption rate was consistent with the requirements and philosophies in the state and federal Superfund law. For example, one person[8] wrote:

…Agencies have recognized that, in order to protect public health, environmental standards would need to be set so as to protect even the most "vulnerable" members of the population (i.e., most exposed, most susceptible, or most sensitive due to the coincidence of lifestage and characteristics of particular contaminants, e.g., neurodevelopmental toxins such as mercury). In doing so, of course, those less vulnerable would also be protected. However, recognizing the multiplicative nature of quantitative exposure assessment, agencies sought to avoid setting standards that were protective of non-existent

[8] While pointing to the RME concept, Professor O'Neill also identified problems with how this approach might be implemented for a tribal exposure scenario.

individuals - phantom composites of maximum assumptions for the various parameters in the exposure equation. EPA, for example, uses the concept of "reasonable maximum exposure" (RME) in its guidance under CERCLA to capture this focus on actual high-end exposures rather than phantom exposures beyond the high end of a distribution of all those exposed… ***(O'Neill (Seattle Univ.))***

3.3 General population

A number of other people recommended that Ecology develop a default fish consumption rate that takes into account Washington's entire population. For example:

Simply because a segment of the population may consume fish or shellfish in relatively high amounts, that fact does not bequest a duty on society to assure that ALL fish and shellfish are safe to consume regardless of where or when they may be obtained. Common sense says that one would use good judgment in where and when individuals obtain their food. Even though I may ***like*** *to harvest clams during a period of red tide, common sense and public notices are sufficient to have me delay those activities or direct them elsewhere.* ***(Miller)***

****

Why has Ecology not included the fish consumption habits of the vast majority of the State's citizens when considering an appropriate value for a statewide FCR? Can Ecology quantify the benefit to the overall health of the state's population it expects to result from this decision? ***(McCabe (NWPPA))***

Those who recommended that Ecology establish a default fish consumption rate that takes into account the entire Washington population identified several reasons for their recommendations.

Consistency with MTCA Reasonable Maximum Exposure (RME) concept

Several people stated that it was appropriate to base the default fish consumption rate on the general population because this is consistent with how Ecology has implemented the RME policy under MTCA. For example:

This is the key issue that Ecology must decide. Ecology is proposing to use seafood consumption rates on a subset of the highest-end consumers in the State. This is contrary to the approach used to evaluate other exposure pathways (e.g., incidental soil ingestion, inhalation of air, and ingestion of groundwater) under MTCA. For those pathways, Ecology has made the risk management decision to be protective of the RME for the general population. ***(Waldron (PTC))***

****

Ecology has defined the fish consumption rates based on the RME of the high-fish consumer population (90 and 95 percentile of the Tribal and Asian Pacific Islander seafood consumption rate surveys) regardless of the source of the seafood being consumed, rather than the RME of the statewide fish consuming population that consumes seafood from Washington waters. For this reason, the selected consumption rates represent more of a worst-case scenario than a RME scenario (Chapter 5, Reasonable Maximum Exposure

defined under MTCA, page 7 5, Choice of the Reasonable Maximum Exposure, page 109). ***(Matsushita (Lockheed Martin))***

Consistency with Clean Water Act methods and policies

Several people stated Ecology should establish a new default fish consumption rate using information from the entire Washington population because this approach is consistent with the Clean Water Act methods and policies. Some people also noted that a default rate based on general population information could serve as a "floor" with the flexibility to use higher rates to establish site-specific requirements. For example:

Selecting a default FCR at the "ceiling" of fish consumers and basing statewide regulatory standards on that value, versus considering a "floor" FCR value, is a major issue. We note, for example, that the EPA has selected a default fish consumption rate for the general population of 17.5 grams/day, which represents an estimate of the 90th percentile consumption rate for the U.S. adult population. An appropriate default FCR range for Washington should certainly be expanded to include 17.5 grams/day. EPA guidance allowing for variable population-based risk protection levels and/or the possibility of site-specific water quality criteria, provide flexibility in deciding on compliant and protective regulatory standards ***(Johnson (Weyerhaeuser))***

Draft range overstates fish consumption for vast majority of population

Several people stated Ecology should establish a new default rate using information from the entire Washington population because a rate based on high exposure population groups overstates the rate of fish consumption by the vast majority of the people in Washington. For example:

The proposed range of default FCRs overstates the fish consumption rates for the vast majority of residents of the state. 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, 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, ultimately, an estimated 0.2-0.9% of the total population of the state. ***(Louch and Stratton (NCASI))***

Practical impacts on regulatory requirements

Several people questioned the value of increased fish consumption in terms of the practical impact on regulatory requirements and health benefits. In particular, a number of people noted that using a higher fish consumption rate to calculate risk-based concentrations will increase the number of situations where calculated values are below natural background concentrations. For example:

Ecology needs to avoid absurd regulatory outcomes in these upcoming regulation development activities. Selecting a FCR which ultimately yields human-health based water quality criteria of sediment management standards to levels below natural background concentrations is not good. ***(Johnson (Weyerhaeuser))***

3.4 Variability in fish consumption rates

No two people are exactly alike. Exposure to hazardous substances is influenced by multiple factors and may vary widely within a given population. Agencies may have some information on the variability for a particular parameter such as fish consumption rates. When estimating exposure levels, agencies have traditionally used a deterministic approach where one or more values from within the range of reported fish consumption rates are used in those assessments. Under this approach, agencies must decide which fish consumption rate should be used to characterize the range of individual rates (that is, whether to use an average value or a value from the high end of the exposure distribution). Alternatively, agencies can use a probabilistic approach that considers the distribution of values when performing exposure assessments.

Ecology presented information on the distribution of fish consumption rates among participants in the four primary studies in Technical Support Document, Version 1.0. That information was revised and presented in Version 2.0 in the table shown below

Summary of Fish Consumption Data, All Finfish and Shellfish (g/day)

Population	Source of Fish	Number of Adults Surveyed	Mean	Percentiles		
				50th	90th	95th
General population	All sources: EPA method	2,853	56	38	128	168
	All sources: NCI method	6,465	19	13	43	57
Columbia River Tribes	All sources	464	63	41	130	194
	Columbia River	–	56	36	114	171
Tulalip Tribes	All sources	73	82	45	193	268
	Puget Sound	71	60	30	139	237
Squaxin Island Tribe	All sources	117	84	45	206	280
	Puget Sound	–	56	30	139	189
Suquamish Tribe	All sources	92	214	132	489	797
	Puget Sound	91	165	58	397	767
Recreational Fishers (compilation of multiple studies)	Marine waters, WA State	–	11–53	1.0–21	13–246	
	Freshwater, WA State	–	6.0–22	–	42–67	

Sources: Adapted from Polissar et al., 2012, Table E-1. Data for recreational fishers is from Table 3, Technical Issue Paper: *Recreational Fish Consumption Rates* (Ecology, 2012).

This table highlights the range of options for choosing a summary measure to characterize population exposure. This choice reflects an explicit (or implicit) policy choice on the appropriate balance between over- or under-estimating exposure levels for particular individuals within the population group. For example, the Reasonable Maximum Exposure (RME) under MTCA and federal Superfund programs is typically set at 90 – 99 percent of the exposure

distribution. This reflects a policy that is based on protecting more highly exposed individuals. In the Technical Support Document, Ecology chose the 80th to 95th percentile of the combined local consumption surveys to define a range of proposed consumption rates (157g/day to 267 g/day).

Many people provided recommendations on how they thought Ecology should handle this issue. First, some people stated they found Ecology's proposal to be inconsistent with tribal treaty rights and Ecology's environmental mission. For example:

> *The fish consumption rate Washington currently uses does not reflect fish consumption rates for Yakama tribal members and therefore does not adequately protect the health of those who consume many times that amount. Ecology's proposed rate range of 157-267 grams of fish per day is based on percentiles (80^{th} – 95^{th} percentile) of a model that represents "high fish consumption" populations of the state. While certainly a more defensible proposal than the status quo, this protocol ensures that a significant portion of the tribal population most in need of protection will be exposed to health risk. It is unclear how WDOE reconciles its choice to knowingly allow a portion of a population to be subjected to risk with its stated mission "…to protect, preserve and enhance Washington's environment, and promote the wise management of our air, land and water for the benefit of current and future generations." Ecology needs to select a fish consumption rate that is protective of all Yakama tribal members, not just a portion of them.* ***(Smiskin (Yakama Tribal Council))***
>
> **********
>
> *…we are now aware that we are not debating probabilities; there are actual people who consume fish at (and who would consume above, but for the forces of suppression) the very highest rates, and we know who they are. A regulatory determination to set the FCR, say, at the 80th percentile of contemporary consumption surveys (as is the case for the lower end of the range proposed by the draft TSD) or some lower number, is thus a choice to deny protection to the actual people consuming at rates above this value, virtually all of whom will be tribal people or members of Asian/Pacific Islander or other higher-consuming groups.* ***(O'Neill (Seattle Univ.))***

Several people urged Ecology to consider the question of percentiles in light of the multiple parameters used to estimate exposure. For example:

> *Regulatory criteria and associated risk assessment methods typically rely on the use of reasonable maximum exposure (RME) assumptions in order to provide a high degree of public health protection. As noted in the TSD, "The RME is designed to represent a high end (but not worst case) estimate of individual exposures. It provides a conservative estimate that falls within a realistic range of exposures. The RME is defined as reasonable because it is a product of several factors that are an appropriate mix of average and upper-bound estimates. RME estimates typically fall between the 90th and 99.9th percentile of the exposure distribution." In other words, when all assumptions are taken together, the resulting exposure estimate should be in the range of the 90th and 99.9th percentile.* ***(Johns and Garry (Exponent))***

As discussed above, people expressed a wide range of opinions on what population groups should be considered when selecting a fish consumption rate for statewide or site-specific use.

However, many people recommended that Ecology select a fish consumption rate that corresponds to the 90th or 95th percentile of the rates for their recommended population group. For example:

> *In my view a single fish consumption rate should be established for the Water Quality Standards and MTCA/SMS as follows: 1.) The 90th/95th percentile of the general population of consumers in the State of Washington (this includes tribal and non-tribal members)….* ***(Waldron (PTC))***

****

> *The report recommends a fish consumption rate in the range of 157 to 267 grams per day. These results are consistent with the findings of CRITFC's comprehensive fish consumption study that was conducted in 1991-1992, which documented that a fish consumption rate of 176 grams per day would be protective of 95 percent of the adult population and 389 grams per day would be protective of 99 percent of the adult population. Based on the CRITFC study, the current fish consumption rate of must be increased in order to be protective of Washington fish consumers.* ***(Lumley (CRITFC))***

****

> *Consistent with this, if Ecology is driven to adopt a single default FCR it should accept the 90 percentile level consumption rate of freshwater/estuarine finfish and shellfish for the general US population recommended by EPA, which is 17.5 g/d. Using the flexibility afforded under different regulatory programs (MTCA, etc.), adjustments to this default FCR can then be made using site-specific information when circumstances warrant.* ***(Louch and Stratton (NCASI))***

****

> *…We support a rate that is at least this high. Fish consumption rates should seek to protect no less than the 90 percentile of any affected population.* ***(Trim (PFPS)/Bell (NWEA))***

Several people stated that they thought that is was inappropriate to use the 80th percentile to define a fish consumption rate. For example:

> ***Lower Limit of Recommended Rates:*** *Ecology chose the 80th to 95th percentile of the combined local consumption surveys to define a range of proposed consumption rates (157g/day to 267 g/day). The 95th percentile is commonly used in statistical applications to define an upper boundary (beyond the 95th percentile a "diminishing return" is assumed), but no reason is provided for choosing the 80th percentile as the lower boundary. Several reasons for choosing these rates are listed, including the recommendations of the Human Health Focus Report Oregon Fish and Shellfish Consumption Rate Project, 2008. However, this study from Oregon actually recommends using rates in the 90th to 95th percentile. The 90th percentile (210 g/day) should be used as the lower boundary of the range rather than the 80th percentile.* ***(Jefferies (Lummi NRD))***

Several people recommended that Ecology consider the relationship between the choice of percentile and the target cancer risk levels used to establish regulatory requirements.[9] For example:

> *The one in a million cancer risk goal is a significant factor in developing cleanup levels for RME populations. EPA uses a risk range of 1E-04 to 1E-06 to make risk management decisions. Ecology only uses the lower end of the cancer risk range to develop cleanup levels, which adds another level of conservatism to RME cleanup levels. Consequently, Ecology should not feel compelled to select fish consumption rates at the high end of the distribution (90th to 95th percentile) to be protective…* ***(Johns and Garry (Exponent))***

Other people expressed concerns about linking decisions on fish consumption rates with policy choices on "acceptable" risk. Many of these concerns appear to reflect concerns about applying different target risk levels for the general population and high exposure population groups. However, those concerns also appeared to encompass approaches that would link the choice of percentile to target cancer risk levels. For example:

> *…the target cancer risk should not be relaxed as a condition for a more protective fish consumption rate…****(Frank (NWIFC))***

****

> *Tribes' treaty-secured rights are guaranteed to all tribal members, not some. Notably, when environmental standards are keyed to lower percentile values, or when "acceptable" risk levels are manipulated to tolerate greater risks for the most highly exposed, it is the most traditional subset of the tribal population -those families whose practices are most consonant with the practices guaranteed by treaty- that are left unprotected. The consequences for tribes who have been working to reinvigorate such traditional practices are plain.* ***(O'Neill (Seattle Univ.))***

This issue is discussed further in Chapter 8.

[9] The Oregon DEQ has adopted this approach in their guidance on the use of probabilistic risk assessment (Oregon DEQ, 1999). Under the Oregon guidance, DEQ would use the 90th percentile of the exposure distribution to establish cleanup standards when the standard was based on a 10-6 cancer risk level, and the 95th percentile of the exposure distribution when the standard is based on a 10-5 cancer risk level.

Chapter 4: Comments on Salmon Issues and Considerations

4.1 Overview

Ecology summarized current information on salmon consumption and life cycles in the Technical Support Document. Three main points emerged from that analysis:

- Salmon are a primary fish species consumed by Washington fish consumers.
- In contrast to other species, a significant part of salmon body burden happens in waters and sources outside of individual MTCA sites, or in waters of the state that are regulated under the CWA-based criteria.
- There are significant variations in the life histories of different salmon species.

Ecology acknowledged that there are several important issues associated with deciding whether and how consumption of salmon should be taken into account when developing default fish consumption rates used in regulatory decisions. In the draft report, Ecology identified two key questions:

- How should the default rates take into account the consumption of fish species such as salmon that spend much of their life outside of Washington waters?
- How should the complex life cycle and biology of the different salmon species be considered when making regulatory decisions?

Ecology received numerous comments on these questions. For purposes of this Responses document, Ecology has organized those comments into the following categories:

- Support for including salmon when calculating statewide default rates.
- Opposition for including salmon when calculating statewide default rates.
- Regional or site-specific fish consumption rates.

In July 2012, Ecology decided not to propose a default fish consumption rate in the Sediment Management Standards (SMS) rule. Ecology also announced that the Water Quality Program was initiating the process to adopt human health criteria in the WQS rule.

Given Ecology's revised strategy, we decided not to provide broadly applicable responses to these comments. Instead, this chapter compiles and summarizes comments on this issue. Chapter 8 provides Ecology's evaluation and response to these comments within the context of defining reasonable maximum exposures under the Model Toxics Control Act.

Ecology will also consider these questions and comments when updating the human health criteria in the Water Quality Standards rule.

4.2 Support for including salmon when calculating statewide default rates

A large number of people recommended that Ecology include salmon when calculating an updated default fish consumption rate.

> ***Inclusion of Anadromous Species (Salmon) in Consumption Rates:*** *The Technical Background Document leaves open the question of whether or not salmon and other anadromous species should be included in the new Washington consumption rates. This should not be an open question- salmon should be included in the new Washington consumption rates.* ***(Jefferies (Lummi Nation))***

****

> ***Ecology Should Account for Salmon and Steelhead Consumption When Calculating the Default Fish Consumption Rate.*** *The Report currently includes salmon consumption in its recommended fish consumption rate. Ecology discusses this issue at length and requests input from stakeholders on this decision. The Washington Waterkeepers urge Ecology to retain salmon consumption in the final Report's recommendation because studies demonstrate that salmon are exposed to and impacted by bioaccumulative toxins during life stages spent in state-regulated waters.* ***(VandenHeuvel et al.(Waterkeepers))***

Those who recommended that Ecology include salmon when establishing a default fish consumption rate identified several reasons for their recommendations.

People in the Northwest eat large quantities of salmon

Several people stated that salmon must be included in the default fish consumption rate because numerous studies show that people in the Northwest eat large amounts of salmon. For example:

> *The Technical Support Document raises the question of whether salmon should be considered in fish consumption rates because they transit through contaminated and uncontaminated areas during their life cycle. Salmon must be included in fish consumption rates as they accumulate toxins within natal streams, local estuaries, and Puget Sound waters that are within the jurisdiction of Washington State. Salmon are the predominant seafood in tribal and non-tribal communities in the Pacific Northwest and exclusion of salmon from protective standards would create a substantial risk to public health and environmental quality.* ***(Frank (NWIFC))***

Salmon are essential to tribal cultures and the Northwest economy

Several people stated that salmon must be included in the default fish consumption rate because salmon are essential to tribal cultures, the Northwest economy. For example:

> *Simply put, any arguments that salmon should not be included in the fish consumption rate are unacceptable. Salmon are the finfish central to our cultural traditions. It is inconceivable to us that they not be included.* ***(Squaxin Island Tribal Council)***

****

I agree with the inclusion of consumption of salmon into the establishment of a FCR. Its inclusion makes good policy sense for a state that is dependent on the commercial salmon fishery. ***(Winters)***

****

*Salmon are a crucial part of Yakama tribal members' diet, culture and way of life….****(Smiskin (Yakama Tribal Council))***

****

Salmon are vital to the health of tribal people in the Pacific Northwest, just as tribal people are vital to the survival of the salmon: the two are inextricably linked. The significance of the salmon is difficult to overstate. They are what might be termed "cultural keystone species," at the center of physical, social, economic, spiritual, and political well-being for the tribes. ***(O'Neill (Seattle Univ.))***

Tribal treaty rights

Several people stated that excluding salmon when calculating a default fish consumption rate was inconsistent with tribal treaty rights and commitments on salmon recovery programs made by Washington State. For example:

Salmon are a crucial part of Yakama tribal members' diet, culture and way of life. The right to these fish was reserved in the Treaty of 1855 and has been upheld in numerous court decisions. Under the U.S. Constitution, Yakama's treaty is the supreme law of the land (O'Neill 2011). If salmon are excluded, Washington will be ignoring contaminant issues that affect Yakama Nation's way of life and our rights to clean healthy fish…Washington State has made a commitment to salmon recovery, as expressed and confirmed by Governor Gregoire. Excluding salmon as part of the fish consumption rate is in direct opposition to that commitment. Without setting appropriate water quality and cleanup standards, the salmon will not have the toxic free environment they require for recovery . ***(Smiskin (Yakama Tribal Council))***

Recent studies on chemical body burden in salmon

Several people cited recent studies on salmon uptake of toxic chemicals to support their recommendations that salmon be included in the default fish consumption rate. For example:

Recent studies demonstrate that salmon receive a significant percentage of their body contaminant burden from the freshwater portion of their life cycle through contact with contaminated sediments and ingestion of contaminated food sources. ***(Lumley (CRITFC))***

****

Ecology should also include salmon in the fish consumption rate based on studies demonstrating that juvenile salmon are exposed to toxic pollution in the Columbia River. The Washington Waterkeepers recommend that Ecology expand Appendix E to address Columbia River studies, rather than restricting "The Question of Salmon" to studies on Puget Sound. For example, the Columbia River Intertribal Fish Commission's comments state:

> *Recent studies demonstrate that salmon receive a significant percentage of their body contaminant burden from the freshwater portion of their life cycle through contact with contaminated sediments and ingestion of contaminated food sources. (NOAA, 2009, Data Report for Lower Columbia Juvenile Salmon Persistent Organic Pollutant Exposure Assessment, prepared by the Environmental Conservation Division, Northwest Fisheries Science Center, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, for the NOAA Damage Assessment Center and Portland Harbor Natural Resource Trustees; and Sloan, C.A., et. al, 2010, Polybrominated Diphenyl Ethers in Outmigrant Juvenile Chinook Salmon from the Lower Columbia River and Estuary and Puget Sound, Washington, Arch. Contam. Toxicol, (2010), 58:403-414.) Ecology should consider these findings when reviewing the discussion contained in Appendix E – The Question of Salmon. Letter from CRITFC to Ecology (Dec. 20, 2011).*
>
> *.....Aside from studies demonstrating that toxic pollution impacts salmon during life stages spent in Washington-regulated waterbodies, many Washington waterbodies, including the Columbia River and Puget Sound, influence marine toxic loading. In turn, Ecology should: (1) retain the draft Report's decision to include salmon consumption when calculating the recommended fish consumption rate, (2) expand Appendix E to address Columbia River studies, and (3) omit statements, such as the one identified above, which are not supported by scientific literature demonstrating that toxic pollution in Washington waterbodies impacts salmon.**(VandenHeuvel (Waterkeepers))***

Consistent with Oregon Department of Environmental Quality

Several people recommended that Ecology include salmon when calculating the default fish consumption rate, noting that this is consistent with the Oregon DEQ approach. For example:

> *…We also support the inclusion of salmon in the rate as was done by Oregon because contaminants in salmon contribute to the human health risks experienced by Washington fish consumers.* ***(Trim (PFPS)/Bell (NWEA))***

4.3 Oppose including salmon when calculating statewide default rates

Several people recommended that Ecology not include salmon when calculating an updated default fish consumption rate. One person who opposed including salmon stated that Ecology should answer the following question:

> *Why would Ecology not exclude anadromous fish from any default FCR meant for statewide use? Can Ecology quantify the benefit to the overall health of the state's population it expects to result from this decision? More specifically, can Ecology provide any data showing that anadromous fish accumulate a "significant" fraction of their ultimate pollutant body burden while in waters of the State of Washington?* ***(McCabe (February 24th e-mail)***

Those who recommended that Ecology not include salmon when establishing a default fish consumption rate identified several reasons for their recommendations:

Salmon life cycle

Several people stated that salmon should not be included in the default fish consumption rate because salmon spend the majority of their life cycle in the ocean where Washington standards do not apply. They concluded that Washington's regulatory efforts would have limited impacts on salmon body burdens of most chemicals. For example:

> ***Inclusion of Salmon in Default Seafood Consumption Rate.*** *From a sediment cleanup perspective, salmon are migratory and spend the vast majority of their lives in the open ocean where they are not exposed to localized site-related contaminants. Because the uptake of specific contaminants into biota from contaminated sediment is complex and the biota do not always reside through their complete lifecycle at a given site, the contaminated sediments at a particular site may not impact the seafood being consumed. Although the document states that salmon are recognized to not reside in most areas of the Sound, Ecology's recommended range of seafood consumption rates is based on total fish consumption including salmon. For a location with no resident salmon, that inclusion may result in a sediment cleanup action that does not result in any risk-reduction for people eating seafood harvested from the location. For these reasons, the default seafood consumption rate should not include salmon (Chapter 7, The Question of Whether to Include Salmon, pages 108-109****). (Matsushita (Lockheed Martin))***
>
> **********
>
> *The consumption of salmon should be excluded from any 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 and the Puget Sound food web is clearly impacted by loadings from the highly urbanized shoreline)….****(Louch and Stratton (NCASI))***
>
> **********
>
> *Salmon make up an overwhelming portion of the total amount of seafood consumed in Washington state. Numerous studies have shown that salmon accumulate a very large proportion of their total body burden of bioaccumulative toxins during the period of their life cycle when they are at sea, outside waters of our state. This includes their consumption of PCBs, dioxins and furans. As a result, any regulatory change in our state will only have a negligible impact on salmon, if it has any impact at all. Changing the state's regulations, therefore, seems very unlikely to improve the health of our salmon of those who regularly consume them. A more targeted approach, focused on consumption of shellfish and non-migratory finfish species, seems like an approach more likely to result in success. **(Hellman (WPPA))***
>
> **********

> ***Resident fish*** *vs.* ***anadromous fish:*** *Fish for which chemical concentrations are not affected by the water body or area being regulated should not be included in the fish consumption rate. Salmon and other anadromous fish that do not spend much of their adult life in freshwaters of the state should not be included in fish consumption rates for fresh waterbodies. Similarly, salmon that spend most of their life outside waters of the state should not be included in fish consumption rates for marine and estuarine waterbodies.* ***(Barrette (PCSGA)/Schoof (Environ))***

Consistent with EPA Region 10 framework

Several people stated during public workshops or meetings that salmon should not be included in the default fish consumption rate because EPA did not include salmon in the default rates included in the Region 10 framework (EPA 2007).

4.4 Consideration of salmon on a site- or chemical-specific basis

Several people concluded that it may be appropriate to consider the presence of salmon for some water bodies and not others. For example:

> *Ecology has specifically requested feedback on the inclusion of salmon consumption in the proposed consumption rates. Marine shellfish data and salmon have been included in the proposed rate to be applied to all waterbodies, even those where these species are not present. King County recommends that Ecology consider the presence of salmon and shellfish when selecting consumption rates for different waterbodies. To address the problem of including salmon and shellfish ingestion as part of the effort to protect, restore or remediate waters and sediments where habitat suitable for these organisms does not exist, King County proposes that Ecology develop three consumption rates:*
>
> *a. A rate for use in marine and coastal estuarine waters where anadromous adult salmon and the typical suite of crab and shellfish would be expected.*
>
> *b. A rate for the Columbia River and major tributaries, along with lakes where Kokanee are present.*
>
> *c. A rate for streams and lakes which only serve as migration corridors for migratory salmon or where salmon or shellfish are absent.* ***(True (King County DNRP))***

Several people also recommended that Ecology consider including salmon in the consumption rates applicable to particular sites or waterbodies. Under this approach, Ecology would consider whether local sources of contaminants contribute a significant portion of salmon body burden. For example:

> *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. 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 "locally harvested" 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).* ***(Louch and Stratton (NCASI))***

****

Recommendation. *Exclude salmon consumption from the default fish consumption rate, but evaluate whether it should be included on a site-specific basis.* ***(Johns and Garry (Exponent))***

****

The document discusses the issue that contaminants in salmon are in part derived from oceanic waters outside the influence of Ecology's regulatory programs or potential contaminant sources in Washington. King County agrees with that conclusion. However, the source of contaminants in any particular fish or shellfish tissue does not change the rate at which people consume those species, notwithstanding fish and shellfish advisories or other factors leading to consumption suppression. King County believes the most appropriate way to address the issue of contaminant sources is through site-specific study to understand contaminant sources and fish habitat usage. King County believes that distinguishing locally sourced contaminants from oceanic contaminants in particular fish or shellfish is best done at the waterbody, species, and contaminant specific level. ***(True (King County DNRP))***

These recommendations were consistent with the general approach recommended by another organization. They recommended that a decision on whether or not to include salmon in consumption rates for marine and estuarine waters should be based on an evaluation of what percentage of time a particular species spends outside waters of the state.

Resident fish *vs.* ***anadromous fish:*** *Fish for which chemical concentrations are not affected by the water body or area being regulated should not be included in the fish consumption rate. Salmon and other anadromous fish that do not spend much of their adult life in freshwaters of the state should not be included in fish consumption rates for freshwater bodies. Similarly, salmon that spend most of their life outside waters of the state should not be included in fish consumption rates for marine and estuarine waterbodies.* ***(Barrette (PCSGA)/Schoof (Environ))***

Two people stated that Ecology could also take into account exposure to salmon on a chemical-by-chemical basis. This could be done by using an approach similar to the relative source contribution (RSC) methodology for non-carcinogens. This approach is described in the EPA guidance on water quality standards.

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.* ***(Louch and Stratton (NCASI))***

Chapter 5: Comments on "Washington Fish Resources and Fish-Consuming Populations"

5.1 Overview

Chapter 2 was designed to provide information on Washington fish resources, as well as estimates on the number of Washington fish and shellfish consumers and consuming populations. The chapter was organized into the following sections:

- *Washington fish resources*. A summary of fish and shellfish resources in Washington.
- *Washington's population demographics.* A summary of current demographic information.
- *Estimated fish consumers in Washington* . This section provides rough estimates on the number of adults and children in Washington who regularly eat fish and/or shellfish.
- *High fish-consuming populations.* This section defines *high fish consumers* and identifies and describes subpopulations in Washington generally known to be high fish consumers.

Ecology received several comments on the information included in Chapter 2. The key issues raised in those comments are discussed in the following pages.

5.2 Information on fish and shellfish

Ecology compiled information on fish and shellfish resources from a wide range of sources. Several people suggested that Ecology clarify the different terms and groupings discussed in the report. For example:

> *You use different terms for fish & shellfish. You may need to clarify your groupings at some point by anatomy eg finfish & shellfish and groupings by habitat eg anadromous, marine, etc. You mention eggs here but I am not sure if you discuss them further in the document.* ***(Cirone (Univ. of Wash))***

Ecology's Evaluation and Response: Ecology has revised the Technical Support Document to include definitions for the following terms:

- **Estuarine:** from an estuary, i.e., a partly-enclosed water body, such as an inlet of the ocean or the mouth of a river where it meets the ocean that contains brackish water (a mixture of salty and freshwater) such as Elliott Bay in Seattle, Washington.
- **Finfish:** fish; a term that is usually applied to the consumption of fish as opposed to shellfish.

- **Fish:** any of various aquatic animals (belonging to the subphylum Vertebrata) having gills, commonly fins, and bodies usually but not always covered by scales, including those having bony skeletons (bony fishes) and more primitive forms with cartilaginous skeletons (lampreys; hagfishes; and sharks, skates, and rays).
- **Marine:** from, or living in, the ocean; saltwater, with a salinity of approximately 35 parts per trillion.
- **Pelagic fish:** fish that live near the surface or in the water column of coastal, oceanic, and lake waters.
- **Seafood:** aquatic organisms that are consumed, including mainly fish and shellfish, and less frequently, other invertebrate animals or plants or marine mammals.
- **Shellfish:** aquatic invertebrate animals having a shell or exoskeleton, the term usually used in the context of food, including species belonging to the following taxa (some of which have evolved such that the shell has become internal and/or reduced, or has disappeared entirely): (1) mollusks, including bivalves (e.g., clams, oysters, mussels, scallops), gastropods (e.g., snails, limpets, abalone), and cephalopods (e.g., squid, octopods); (2) crustaceans (e.g., crabs, shrimps, lobsters); and (3) echinoderms (e.g., sea urchins, sea cucumbers).

5.3 Number of fish consumers

Ecology developed estimates on the number of Washington fish consumers and presented that information in the Technical Support Document. This evaluation was modeled on work performed by the Oregon Human Health Focus Group.

One organization stated that it was inappropriate for Ecology to classify individuals as consumers or non-consumers. They recommended that Ecology viewed fish consumption rates as a continuum with very few true non-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).* ***(Louch and Stratton (NCASI))***

Other people expressed concerns about the limited information on the fish consumption habits of the majority of the general adult population. For example:

> 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. This number is equivalent to approximately 11% of the adult consumers of purchased fresh fish (as estimated by Washington's Department of Health, DOH), 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). **(McKrone)**

Ecology's Evaluation and Response: Ecology agrees that fish consumption rates should be viewed as a continuum with a lower number of true non-consumers than predicted using the results of the two-day national surveys.

Ecology reevaluated the NHANES fish dietary data using the National Cancer Institute's (NCI) statistical methodology that is summarized in the revised Technical Support Document. National dietary information (CSFII and NHANES) consists of two detailed 24-hour dietary recalls conducted for a large, randomly selected U.S. population. Although 24-hour dietary recall surveys capture detailed information on a person's food consumption, this dietary assessment method does not adequately measure the usual intake of foods that are not consumed nearly every day (i.e., episodically consumed foods such as fish).

The NCI method uses statistical modeling to combine food frequency questionnaire data with 24-hour dietary recall data to project long-term food consumption estimates. Ecology used this method to estimate the distribution of fish consumption rates in the general population. The results of this evaluation are shown below and described in Polissar et al. (2012).

Table 1. General Population: Adult Respondents, Consumers Only, Based on NHANES 2003–2006, Using NCI Statistical Survey Methodology

Population	Species Group	Descriptive Statistics (g/day)				
		50th Percentile	Mean	75th Percentile	90th Percentile	95th Percentile
National Estimates from NHANES 2003–2006	All Fish	12.7	18.8	24.8	43.3	56.6
	Finfish	9.0	14.0	18.1	31.8	43.3
	Shellfish	2.4	5.4	6.0	13.2	20.5

Sources: Adapted from Polissar et al., 2012, Table 4. Estimates based on NCI statistical methodology (Tooze et al., 2006) that models two days of fish consumption from 24-hour episodic dietary recall and fish dietary information from the food frequency questionnaire.

Ecology acknowledges the limited nature of information on fish consumption habits and patterns for the general population. Ecology is not aware of any Washington-specific studies that have examined the distribution of fish/shellfish consumption rates for the general population. Ecology agrees that it would be helpful to collect additional information on fish consumption rates for the general population. Research has shown that people living in coastal areas consume larger amounts of fish and shellfish than inland areas (Moya, 2004). Consequently, national data compiled from all 50 states may underestimate rates in coastal states such as Washington. However, Ecology does not currently have the resources needed to conduct such a study.

Ecology does not believe that the limited nature of information on the general Washington population should be considered a reason to further delay actions to revise regulatory values. Such an approach is inconsistent with how Ecology and other agencies have implemented laws designed to prevent adverse health impacts for both the general population and groups that are more highly exposed.

5.4 Defining and estimating high fish consumers

Ecology provided estimates on the number of "high fish consumers" in Washington. This work was modeled on a similar evaluation prepared by the Oregon Human Health Focus Group. Ecology used a fish consumption rate of 250 g/day to define a high fish consumer.

Several people provided comments on Ecology's definition of *high fish consumers.* For example:

> *Define "high fish consumers." This is a value statement that should either be defined by ecology or based on definitions in the surveys you reviewed.* ***(Cirone (Univ. of Wash))***

As noted above, several people expressed concerns about the limited information on the fish consumption habits of the majority of the general adult population. They expressed support for additional studies to obtain this information. For example:

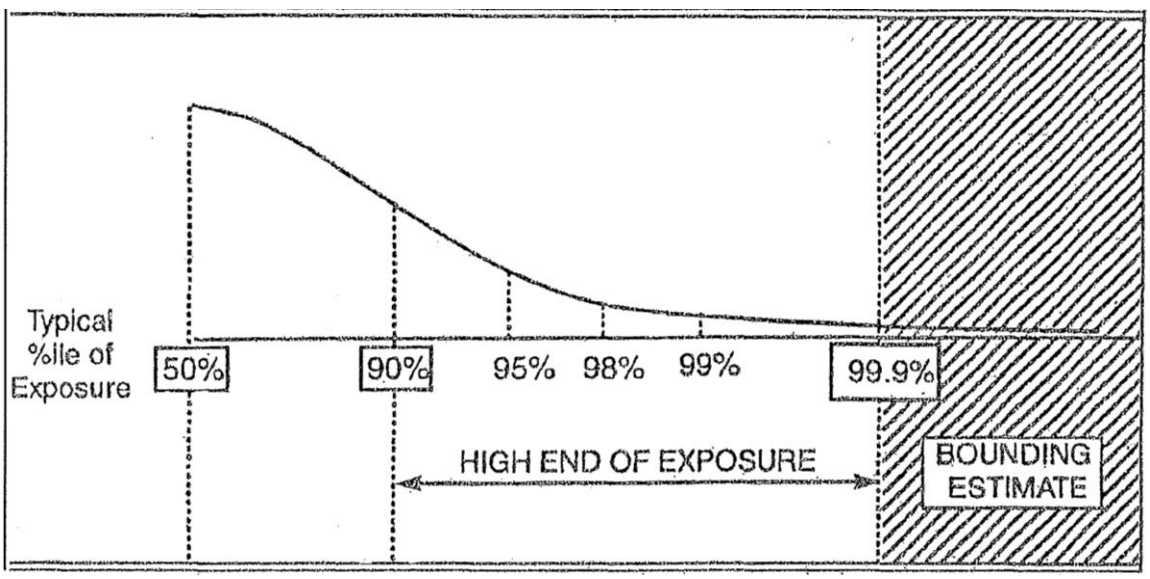
> *The statement is made on this site that "[i]n fact, we consume fish and shellfish in amounts that are much larger than the state's current rates reflect." While this statement is likely true, it is our hope that the Agency collects data to sufficiently determine the amount of fish and shellfish consumed in Washington that originate from Washington waters.* ***(Wendling (City of Bellingham))***
>
> **********
>
> ***Estimation of High-Fish Consumers.*** *The document estimates the number of high fish consumers (the most sensitive receptors) that would be protected by the change in fish consumption rates and lacks any comprehensive survey data to support this estimate. The estimate also includes fish consumers that do not obtain their fish from Washington waters and therefore is overly conservative. Based on review of the document, comprehensive state-wide survey data are needed to establish technically defensible seafood consumption rates that more realistically reflect the seafood consumption rate of the overall Washington population (Chapter 2, High-Fish Consuming Populations, pages 2 through 27).* ***(Matsushita (Lockheed Martin))***

Ecology's Evaluation and Response: Ecology estimated the number of high fish consumers to provide context for the discussion on fish consumption rates. The analysis was modeled on work performed by the Oregon DEQ Human Health Focus Group. The analysis combined information from national fish consumption surveys, demographic information from the Office

of Financial Management and the results from a Department of Health survey on fish consumption habits.

Ecology recognizes there are uncertainties associated with using the national data to estimate Washington fish consumption patterns. We also agree that defining "high fish consumers" is subjective and recognize that the definition has a large impact on the results and conclusions.

For purposes of this work, Ecology has defined *high fish consumers* as persons who consume fish at or above the 90th percentile of the exposure distribution based on information from national fish consumption surveys. This value is the fish consumption rate where 90 percent of people surveyed reported eating less than this amount of fish or shellfish and 10 percent reported eating more. The use of the term "above the 90th percentile" is one of several ways to define what is meant by high-end exposures and is shown diagrammatically in the figure below.



Source: Adapted from Figure 5-1, *EPA's Exposure Assessment Guidelines*,1992

The actual fish consumption rate that corresponds to the 90th percentile consumption rate depends on the dataset and statistical method used. The revised Technical Support Document includes two estimates:

- Estimate Method #1: Ecology used data from EPA's *Estimated Per Capita Fish Consumption in the United States* (EPA, 1992) when preparing the Technical Support Document Version 1.0. Using these data, the 90th percentile of the estimated national per

capita fish consumption rate for adult fish consumers corresponds to 250 g/day.[10] (250 grams is approximately 0.55 pound or 8.8 ounces.)

- Estimate Method #2: Ecology has also evaluated national fish dietary information using data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey (NHANES), 2003–2006. This analysis is discussed in Chapter 4 of the revised Technical Support Document. Based on this evaluation, the 90th percentile of the estimated national per capita fish consumption for adult consumers is in the range of 42.5 g/day to 128 g/day, depending on the statistical method used.

The revised Technical Support Document provides estimates on the number of fish consumers using several assumptions. However, the estimated number of people above the 90th percentile value does not vary depending on whether one uses Estimate Method #1 or #2 to define high fish consumers. For example, the Table below provides an estimated range of high fish consumers for 2010 (144,009 to 380,596 people). The estimated number of high fish consumers is independent of whether Method #1 or #2 has been used to define those consumers. However, the choice of method will influence the interpretation of the results. With Method #1, this range represents the estimated number of people eating more than 250 grams/day. With Method #2, this range represents the estimated number of people eating more than 42.5 g/day up to 128 g/day.

Estimated Number of Fish Consumers among the General Washington Adult Population

Year	Total Population (Adults)	Estimated Number of Washington Adult Fish Consumers		Estimated Number of Washington Adults Who Are High Fish Consumers (90th percentile or above)	
		Low Estimate	High Estimate	Low Estimate	High Estimate
2010	5,143,185	1,440,092	3,805,958	144,009	380,596
2030	6,590,283	1,845,279	4,876,809	184,528	487,680

[10] U.S. EPA, 2002a. Corresponds to the 90th percentile intake of finfish and shellfish for adult consumers only, based on uncooked fish weight.

Chapter 6: Comments on "Methodology for Assessing Fish Consumption Rate Information"

6.1 Overview

It is important to establish the scientific defensibility of survey data used in a regulatory context. Researchers use a variety of methods for estimating the amount of fish and shellfish consumed. Surveys are generally considered to be the best approach for collecting data; however, a number of design features determine whether a particular survey will provide a technically defensible basis for agency decision-making. *Technical defensibility* means that the survey stands up to technical and scientific scrutiny and provides a solid technical basis for regulatory decisions.

Ecology developed several *measures of technical defensibility* to help guide the evaluation of individual fish consumption surveys. Those measures are shown in the Table below.

6.2 Survey Method Development

The first measure was titled "Survey Method Development." Ecology identified several criteria for evaluating this measure:

- Was the survey design based on sound scientific survey methods recognized either in guidance or other technical publications?
- For surveys dealing with unique populations (for example, tribes or ethnic minorities), was the survey vehicle reviewed by tribal staff and tribal governments? Did it include review and collaboration with state and federal agencies?
- Was the survey tested and modified before it was conducted?

Two people submitted comments on this measure of technical defensibility. They noted that the two survey vehicles (food frequency and portion size survey and 24-hour recall) used in the Suquamish study produced significantly different fish consumption rate estimates. They questioned Ecology's decision to use the food frequency results.

They also recommended that Ecology evaluate which survey instrument provides estimates that are closer to the actual daily rates over a lifetime. They suggested asking a subset of participants to compile diet records that included weighed meals.

Ecology's Evaluation and Response: Ecology's review and evaluation of these comments and issues are provided in Sections 7.11 through 7.14 of this Responses document.

Measures of Technical Defensibility

Measure	Description
1. Survey Method Development	• Was the survey design based on sound scientific survey methods recognized either in guidance or other technical publications? • For surveys dealing with unique populations (for example, tribes or ethnic minorities), was the survey vehicle reviewed by tribal staff and tribal governments? Did it include review and collaboration with state and federal agencies? • Was the survey tested and modified before it was conducted?
2. Survey Execution	• Was the execution of the survey based on sound survey methods recognized either in guidance or other technical publications? • Were the personnel conducting interviews provided adequate training? • Were fish /shellfish models used as visual aids to help participants estimate approximate amounts and types of fish consumed?
3. Publication of Results	• Was the publication of survey results based on sound survey methods recognized either in guidance or other technical publications? • Was the study methodology clearly defined and reported? • Was the study methodology consistent with sound survey practices? • Were the survey results tabulated and reported clearly? • Were statistical approaches (including weighting and treatment of outliers) clearly explained? • Were the study conclusions clearly reported and supported by study findings? • Were variability and uncertainty recognized? • Were uncertainties identified and reported? • Did the survey design take into account and/or discuss factors that might contribute to bias in the study results?
4. Applicability and Utility for Regulatory Decision Making	• Is the sample population representative of the population of concern, and does the survey provide sufficient information about the population? • Is the information current? • Are exposure estimates sufficiently identified and are data sufficient for descriptive statistics to define statistical distributions?
5. Overall Technical Suitability to Support Regulatory Decision Making	• Are the results of the survey suitable and can they be used in a regulatory context? • What is the range of technical defensibility based on the above criterion? • Can the results be considered appropriate for establishing risk-based standards?

6.3 Execution of Survey Vehicle

The second measure was titled "Execution of Survey Vehicle." Ecology identified several criteria for evaluating this measure:

- Was the execution of the survey based on sound survey methods recognized either in guidance or other technical publications?

- Were the personnel conducting interviews provided adequate training?
- Were fish /shellfish models used to help participants estimate approximate amounts and types of fish consumed?

Ecology did not receive specific comments on this measure of technical defensibility.

6.4 Publication of Results

The third measure was titled "Publication of Results." Ecology identified several criteria for evaluating this measure. Many people expressed concerns that the tribal studies used to prepare the draft recommendations had not been published in peer-reviewed journals and that the underlying data were not available for independent scientific review. For example:

> *The Suquamish study has not received the benefit of a formal, external peer-review, nor has it been published in a peer-reviewed journal. Equally important, for data that will be used as the basis of public health policy applicable to the general public, a transparent public review process is critical. However, because it is a tribal study, data from the study are not available to the public. In addition, the study report itself has not had the benefit of a public review and comment process to evaluate study design, results, and applicability for use in public health decision making.* ***(Johns and Garry (Exponent))***
>
> **********
>
> *This should be one of the Mandatory Survey Elements for data to be included in the database for developing consumption rates. This needs to be a transparent process where all data are available for review. We (scientists) do not accept these limitation in other venues so why is this an acceptable practice with regard to fish consumption rates?* ***(Waldron(PTC))***
>
> **********
>
> *The technical support document goes into great depth describing the criteria that were applied to assess the scientific defensibility of the results of the various fish consumption surveys considered in the document. Ecology obviously recognizes the importance of making data available for scrutiny so that other researchers can verify results and test conclusions, and even refers on page 45 to a recent editorial in Science that makes that very point. However, the technical support document then states:*
>
> > "Many Pacific Northwest tribal organizations or tribal governments do not provide their raw seafood dietary data to researchers outside of their sovereign tribal government or organizations. They may consider survey data as confidential and not allow independent evaluations. Data evaluation typically occurs through government-to-government agreements or tribal technical personnel."
>
> *Despite all of the supposedly detailed assessment of the scientific defensibility of the fish consumption surveys that Ecology describes, I believe that the inability of anyone outside the tribes to independently evaluate the raw survey data seriously compromises the use of those data. For data that are to have such far-reaching and costly ramifications, I believe that a true assessment of the scientific defensibility of the surveys can only be conducted if*

*the raw survey data are available for a complete and independent assessment of their conclusions. If the tribes truly want the results of these surveys to be considered, they should make the raw survey data available, and Ecology should then enlist the services of independent experts in the field of fish consumption surveys to evaluate those data to ensure that the conclusions can be supported. This is no different than if the tribes had their own scientists conduct studies of the toxicity of contaminants, but then put forth conclusions without allowing other scientists to see their results. The evaluation of any data considered for use in such regulatory settings must be totally transparent and subject to independent verification. I believe that the results of any fish consumption surveys that have not been subject to such scrutiny should not be used. (**McKrone)***

Ecology's Evaluation and Response: Ecology has reviewed the public comments on this issue and agrees that it would be preferable to have access to the underlying data from all of the individual studies. However, Ecology believes that the published reports are sufficient for assessing the three Northwest tribal surveys. Ecology's rationale for this conclusion includes the following:

- These studies have received a high level of scientific review during the design, implementation and evaluation process. The peer-review processes for the four Pacific Northwest studies included technical advisory and oversight groups, as well as institutional review boards that provided critical reviews of each study design and methodology.
    - **A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes.** The Columbia River Inter-Tribal Fish Commission (CRITFC) published a detailed report and findings (CRITFC, 1994). The survey was funded through an EPA grant and subjected to rigorous review by a 16-member technical panel and 9 peer reviewers. Peer review was provided by university scientists, the Oregon and Washington State Departments of Health, and senior epidemiologists from the Indian Health Service (IHS). The scientific review process is described in the study report and a recent letter attached to the revised Technical Support Document.
    - **A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region.** The Tulalip Tribe published a detailed report and findings (Toy et al, 1996). The survey was funded through an EPA grant and subject to rigorous review by a 13-member technical panel. The scientific review process is described in the study report.
    - **A Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservations.** The Suquamish Tribe published a detailed report and findings (Suquamish Tribe, 2000). The survey was funded by the Agency for Toxic Substances and Disease Registry (ASTDR). The Washington State Department of Health served as the Co-Principal Investigator. A technical review panel consisted of representatives from EPA Region 10, Washington Department of Ecology, Washington Department of Health, and the University of Washington. A representative from the Fred Hutchinson Cancer Research Institute also served as a survey consultant. The scientific review process is described in the study report.

- These studies have undergone extensive review during regulatory reviews performed by EPA, Ecology and other states. The results from the regional fish dietary surveys are provided in published reports. The data included in the published reports provide a sufficient basis to evaluate these studies. These studies have been extensively reviewed and are widely accepted as technically sound. For example, EPA has reviewed these studies numerous times and concluded that they provide a sufficient basis for regulatory decisions. The studies are evaluated in the Environmental Protection Agency's *Exposure Factors Handbook* (EPA, 2011) which is the primary guidance for human health risk assessment at EPA and in the states. The Oregon Human Health Focus Group concluded that these four fish consumption studies were relevant and reliable in establishing Water Quality Standards in Oregon. The Washington State Department of Health (DOH) also relies on these and other studies to help determine when fish consumption advice is warranted to limit exposure to contaminants fish.
- Ecology and other agencies often do not have access to underlying study data. Ecology routinely uses published reports to support regulatory decisions. Peer review of academic publications is "almost always conducted solely on the basis of the submitted manuscript." (Daniell, 2012) The "raw data" itself (that is, the individual responses to survey questions) is not published. Individual survey results are often kept confidential per agreement with survey participants. When using peer-reviewed literature, it is not usual to obtain raw data, but rather to rely on the adequacy of the described methods, the provided analysis, and the integrity of the peer-review process. This was discussed by Dr. William Daniell (University of Washington professor) in a recent letter to Ecology. Dr. Daniell's letter is attached to the revised Technical Support Document.

6.5 Applicability and Utility for Regulatory Decision-Making

The fourth measure was titled "Applicability and Utility for Regulatory Decision-Making." Ecology identified several criteria for evaluating this measure:

- Is the sample population representative of the population of concern, and does the survey provide sufficient information about the population?
- Is the information current?
- Are exposure estimates sufficiently identified and is data sufficient for descriptive statistics to define statistical distributions?

Two people recommended that Ecology consider the regulatory goals and purposes when evaluating whether particular study results were applicable to broader populations. They recommended that issues such as survey duration, sample sizes, outliers, etc., be evaluated within the context of how the survey results are being used (for example, are the studies being used to estimate short-term exposure, annual exposures or both?). They also recommended evaluating

whether the sample population is representative of the broader population of concern. Additionally, they recommended that study results be considered in light of other parameters used to estimate exposure levels. For example:

> *Regulatory criteria and associated risk assessment methods typically rely on the use of reasonable maximum exposure (RME) assumptions in order to provide a high degree of public health protection. As noted in the TSD, "The RME is designed to represent a high end (but not worst case) estimate of individual exposures. It provides a conservative estimate that falls within a realistic range of exposures. The RME is defined as reasonable because it is a product of several factors that are an appropriate mix of average and upper-bound estimates. RME estimates typically fall between the 90th and 99.9th percentile of the exposure distribution." In other words, when all assumptions are taken together, the resulting exposure estimate should be in the range of the 90th and 99.9th percentile. Therefore, each individual input (e.g., fish consumption rate, fish diet fraction, exposure duration) need not be at the high end of the distribution for the overall exposure estimate to be at the high end of the distribution. Ecology applies a RME in the range of the 90th to 95th percentiles for deriving cleanup standards, and has historically recommended use of a fish consumption rate representative of the 90th percentile for a given population or study.9 The 90th percentile is consistent with the U.S. FDA's designation of high-end consumption rates as the 90th percentile from large national, 2 to 3 nonconsecutive day surveys of food intake by thousands of individuals. The specific percentile selected should be considered on a study-specific basis and will depend on such factors as the characteristics of the data distribution and the representativeness for the study population to which the fish consumption rate will be applied. In the case of the Suquamish study, the study population appears to be high-end consumers even compared with other high fish consuming populations included in the TSD. Even within the Suquamish study population, the data are highly skewed and the upper percentiles (90th and 95th) are greatly affected by a few individuals with very high reported intakes.* ***(Johns and Garry (Exponent))***

Ecology's Evaluation and Response: This comment raises several important issues. Most of those issues appear to trend toward using study data to support RME decisions at cleanup sites. Ecology's review and responses to RME issues are provided in Chapter 8 of this Responses document.

Johns and Garry's comment, however, does highlight one area of potential confusion associated with the criterion, "Is the sample population representative of the population of concern, and does the survey provide sufficient information about the population?" This question could be interpreted in two ways:

- Is the sample population was representative of the study population from which the sample was drawn?
- Is it appropriate to extrapolate the study results to other populations? (For example, is it appropriate to use the results from one tribal study to estimate the fish consumption rates for a second tribe?)

Ecology's application of this measure focused on the first question. The second question is equally important. However, the second question requires judgments on how to handle uncertainty and variability that may vary depending on the type of regulatory decision facing the agency.

6.6 Overall Technical Suitability to Support Regulatory Decision-Making

The fifth measure was titled "Overall Technical Suitability to Support Regulatory Decision-Making." Ecology identified several criteria for evaluating this measure.

- Are the results of the survey suitable and can they be used in a regulatory context?
- What is the range of technical defensibility based on the above criterion?
- Can the results be considered appropriate for establishing risk-based standards?

Two people submitted comments on this measure of technical defensibility. They identified two issues that they believe are particularly important when evaluating the technical suitability of the Suquamish tribal survey and other fish consumption surveys. First, they recommended that Ecology evaluate which survey instrument provides estimates that are closer to the actual daily rates over a lifetime.

Second, they and several others recommended that Ecology consider whether the estimated rates are consistent with information on metabolic energy needs over extended periods of time. For example:

> *… fish consumption rates should reflect the reality of metabolic energy needs over long time periods (i.e., how much food does a person need and how much can they reasonably consume to maintain weight, health, etc.). The amount of fish consumption must make sense in the context of the entire diet. Unfortunately, the Suquamish study, like the other available fish consumption studies, considers only fish and shellfish consumption and not total diet. Without understanding the usual intake of other foods, it is not possible to accurately assess the results, particularly with regard to factors that may shift the overall distribution of consumption rates because of systematic biases. The daily energy requirement of an active adult male of average size is approximately 2,900 kcal/day; more for a larger or more active person and less for a smaller or less active person. Ideally, a survey assessing usual intake of most/all foods would be administered to at least a subset of study participants in order to validate the fish consumption estimates. A similar analysis could be conducted regarding limits to the amount of protein intake that could be sustained over a longer time period. In the absence of such data, results should at least be evaluated using other means of estimating total diet intake (e.g., follow-up studies in the survey group, literature values for similar populations.* ***(Johns and Garry (Exponent))***

Ecology's Evaluation and Response: Ecology's review and evaluation of these comments and issues are provided in Sections 7.12 through 7.14 of this Responses document.

6.7 EPA information quality guidelines

Several people noted that other organizations have developed procedures and criteria to ensure the scientific integrity of data used to support regulatory decisions. One person pointed to the EPA Region 10 *Information Quality Guidelines Pre-Dissemination Checklist* that includes a series of questions that must be answered in situations where EPA relies on data that has not undergone external peer review. He concluded that neither EPA's nor Ecology's evaluation of the available tribal studies satisfied these criteria:

> *For documents such as the framework document, EPA Region 10 does require those preparing the document to complete a form titled "Region 10 Information Quality Guidelines Pre-dissemination Checklist." One of the questions to be answered is "Does the work product meet 'quality' objectives?" Normally, "formal, external peer review" is necessary to meet agency criteria for quality. In the absence of external peer review, the following questions must be answered:*
>
> 1. *Is the information accurate and reliable?*
> 2. *Is the information unbiased?*
> 3. *Is the information useful?*
> 4. *Is the information secure?*
>
> *EPA Region 10's guidelines regarding the first question indicate that if the data were developed or funded by EPA, the information may not be considered accurate and reliable unless the data were obtained under an approved quality assurance project plan (QAPP). If the data were not developed or funded by EPA, the data must be assessed against agency assessment factors to determine whether they are accurate and reliable. As indicated earlier, EPA Region 10's framework document is based on seafood consumption surveys of the Tulalip, Squaxin, and Suquamish tribes. The Tulalip/Squaxin surveys (Toy et al, 1996) were funded by EPA, but there is no evidence of a QAPP having been prepared. The Suquamish survey (The Suquamish Tribe 2000) was funded by the Agency for Toxic Substances and Disease Registry (ATSDR), and administered through the Washington State Department of Health. Again, there is no evidence of a QAPP having been prepared. The Suquamish survey results are reported only in summary form in a publicly available document (The Suquamish Tribe 2000), but the underlying data have never been released to anyone, including EPA. A consultant to the Suquamish tribe conducted all statistical analyses of the data. Given that neither EPA nor anyone other than the Suquamish Tribe and their statistical consultant has ever seen the data, there is no way to know whether the statistics are correct. Hence, it is not apparent how EPA could vouch for the accuracy and reliability of the Suquamish data.* ***(McKrone)***

One person stated that the fish consumption rate surveys should be considered "influential information" that requires additional scrutiny. He concluded that neither EPA's nor Ecology's review satisfied the *EPA Region 10 Information Quality Guidelines* for data transparency and

peer review. For example:

> *It also appears that EPA further failed to comply with EPA Region 10's Information Quality Guidelines, which state that "influential information" should be subjected to a higher degree of transparency about data and methods, than other disseminated information. Prior to dissemination of "influential information," all five of the following questions must be answered in the affirmative:*
>
> 1. *Is the source of the data presented?*
> 2. *Are the various assumptions employed fully described?*
> 3. *Are the analytical methods fully described?*
> 4. *Are the statistical methods fully described and discussed?*
> 5. *Do all the original and supporting data meet the above criteria, to the extent practicable, given ethical, feasibility, and confidentiality constraints?*
>
> *Because EPA has not seen the underlying data from the Suquamish survey, it cannot answer all of these questions affirmatively. The lack of opportunity to review the underlying data used in development of EPA Region 10's framework document compromises the transparency of the process, which, just as in the case of Ecology's technical support document, is necessary for any document with such far-reaching implications.**(McKrone)***

Ecology's Evaluation and Response: The EPA Region 10 Framework underwent extensive review and changes. Numerous reviews and changes were made by EPA senior technical staff and management over nearly four years between 2004 and 2007. EPA Region 10's information quality guidelines were finalized after the framework was released. Nonetheless, the report describing the Suquamish survey and subsequent analyses of Suquamish data requested by EPA satisfactorily answers the five questions identified in the above comment. Does the Suquamish survey have a quality assurance project plan (QAPP) or an equivalent document?

The Suquamish survey design includes quality assurance/quality control procedures that were used when conducting the survey (see page 19 of the study report). However, the project team did not develop a QAPP that meets current EPA information guidelines. The use of QAPPs is common when developing plans to collect environmental data in support of remediating toxic waste cleanup sites. However, Ecology believes that the lack of a document that is formally labeled a QAPP does not in any way reduce the credibility of the Suquamish survey. Again, the published report and survey development processes fully address the five questions identified in the comment above.

EPA did not have access to the underlying study data given the confidentiality agreements. However, EPA did conclude that, to the extent practicable, and given ethical, feasibility and confidentiality constraints, the original and supporting data meet the criteria for influential information. EPA contacted the Suquamish Tribe and determined that the original data have

been kept in a secured facility in locked boxes since transcription of the data into computer file format. Only two tribal representatives have access to the original survey forms.

EPA recognizes that tribes have concerns about others using tribal data to conduct analyses that result in actions that might be potentially detrimental to tribes. The Freedom of Information Act (FOIA) precludes EPA from withholding sensitive tribal data. For example, in 2007, the Boeing Corporation, a potentially responsible party (PRP) in the Lower Duwamish Waterway cleanup, obtained all materials related to the development of EPA's Framework under an FOIA request. In the process, the Boeing Corporation obtained tribal data from the Toy (et al) study that EPA and the tribes had hoped to keep confidential. In response to tribal sensitivities around release and interpretation of tribal data, EPA agreed to have the Suquamish Tribe provide summary data needed for seafood consumption risk assessment activities. These summary analyses have been prepared by qualified and respected statisticians retained by the Suquamish Tribe. These statisticians also have a long history of supporting quantitative analysis of Puget Sound seafood consumption.

As discussed in Section 6.4 above, the Suquamish survey received extensive internal and external review. The Suquamish Tribe published a detailed report and findings (Suquamish Tribe, 2000). The Washington State Department of Health served as the Co-Principal Investigator. A technical review panel consisted of representatives from EPA Region 10, Washington Department of Ecology, Washington Department of Health, and the University of Washington. A representative from the Fred Hutchinson Cancer Research Center also served as a survey consultant. The scientific review process is described in the study report.

Chapter 7: Comments on "Fish Consumption Survey Data Applicable to Washington Fish Consumers"

7.1 Overview

Ecology compiled the results of its evaluation of individual fish consumption surveys in Chapter 4 of the Technical Support Document Version 1.0. The purpose of Chapter 4 was to provide an initial determination as to which studies Ecology believes should be used in identifying an appropriate default fish consumption rate or rates. As discussed by the National Research Council, this is an important step at several stages in the risk assessment process:

> *….each stage of the risk-assessment process involves an initial survey of the scientific literature and relevant databases to identify and isolate studies pertinent to the pollutant or situation under review. The array includes information from many sources: reports in peer-reviewed journals, reports in the gray literature, personal communications about recent results not yet published, and the like. Some studies have been replicated or otherwise substantiated; others may have a questionable provenance. Judgments on those issues parallel judgments made in developing any scientific analysis. Continuing analysis involves reviewing each study for fundamental strengths and weaknesses, for example, quality assurance issues, replicability, consistency with comparable studies, and peer-review status* ***(NRC, 2009, p.60)***

Chapter 4 incorporated the results of evaluations conducted by Ecology, EPA and other agencies over the last several years. Ecology concluded there are four surveys that should be considered when establishing a statewide default fish consumption rate:

1. *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (Columbia River Inter-Tribal Fish Commission, 1994).
2. *A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region* (Toy et al., 1996).
3. *Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservations, Puget Sound Region* (Suquamish Tribe, 2000).
4. *Asian and Pacific Islander Seafood Consumption Study* (Sechena et al., 1999).

Ecology received numerous comments on the studies and statistical methods used to develop the recommended range of fish consumption rates. Ecology has compiled and evaluated those comments in this chapter. As discussed in Chapter 6, Ecology received several comments on

the measures of technical defensibility pertaining to certain aspects of the Suquamish tribal survey. Ecology decided to consolidate and address those issues in this chapter, as well.

7.2 Fish consumption rates for the general population

Several people stated that the studies used to develop the range in the Technical Support Document were not representative of the overall Washington population. They recommended that Ecology include information on fish consumption rates for the general population in a revised report. For example:

> *King County encourages inclusion of general population seafood consumption surveys for self-harvested and locally caught seafood purchased in local markets to describe the level of protectiveness provided by the proposed consumption rates to all Washington citizens.* ***(True (King County DNRP))***

Several people recommended that Ecology conduct additional studies before updating the current default fish consumption rates. For example:

> *….. A more comprehensive survey of seafood consumption patterns should be performed, before revised default fish consumption rates are selected for adoption (Chapter 4, Table 21, Summary of Fish Consumption Rate Surveys Considered by Ecology, page 71).* ***(Matsushita (Lockheed Martin))***
>
> **********
>
> *It is our hope that the Agency will conduct a comprehensive survey of the citizenry of our state to accurately assess not only fish consumption levels but also to assess the amount of seafood available and consumed in Washington that originate in Washington.*
> ***(Wendling(City of Bellingham))***

Ecology's Evaluation and Response: Ecology is not aware of any dietary recall surveys that have examined the distribution of fish/shellfish consumption rates for Washington's general population. Ecology agrees that it would be helpful to collect additional information on fish consumption rates for the general population. Research has shown that people living in coastal areas consume larger amounts of fish and shellfish than inland areas (Moya, 2004). Consequently, national data compiled from all 50 states may underestimate rates in coastal states such as Washington. Ecology does not currently have the resources needed to conduct such a study.

We have revised the Technical Support Document to include information from national fish consumption surveys. Ecology has worked with the University of Washington to review national dietary surveys that provide information on fish consumption rates for the general population, and has included the results of that review in the revised Technical Support Document Version

2.0. A separate document[11] details the statistical methodology applied to the national dataset (2003–2006 National Health and Nutrition Examination Survey).

7.3 Fish consumption rates for recreational anglers

Several people recommended that Ecology include information from various recreational studies in the Technical Support Document. For example:

> *Did WA DOE consider providing estimates for the general population as well as high-end consumers. Several relevant surveys have been conducted which should be incorporated into your assessment. In addition, EPA just released its revised Exposure Factors Handbook which should be cross-referenced here. Please see: Results of a human used survey for shoreline areas of lake union, lake Washington, and lake Sammamish Survey of fish consumption patterns of King County (Washington) recreational anglers (attached) Exposure Factors Handbook 2011 Edition (Final)* ***(Mayfield)***
>
> **********
>
> *Details of the 1991 Commencement Bay survey, which are the basis for the current MTCA default consumption rate of 54 grams/day, are not provided in the document. The data contained in this survey were also not included in the statistical analysis conducted to develop the proposed range of consumption rates. We recommend that Ecology provide more information about this general recreational consumption survey and describe why these data were not included alongside the cited tribal and API survey details.* ***(True (King County DNRP))***

One individual also recommended that Ecology conduct additional studies to gain a better understanding of the amount of fish caught and eaten by recreational anglers:

> *Washington's recreational fishers should also be surveyed to assess the amount of fish and shellfish that are consumed by these individuals and their families. Assumptions of 100% consumption of recreational catch by these fishers should not be made unless it is substantiated by good survey data.* ***(Wendling)***

Ecology's Evaluation and Response: Ecology assessed the recreational fish consumption studies conducted in Washington.[12] Ecology's assessment includes many of the same studies evaluated by EPA in Chapter 10 of the most recent update to the *Exposure Factors Handbook* (EPA, 2011). Ecology has summarized the results of that review in the revised Technical Support Document.

[11] Polissar et al., 2012.

[12] Technical Issue Papers are provided in Ecology, 2012 (*Supplemental Information to Support the Fish Consumption Rates Technical Support Document*).

7.4 Other studies

Several people identified ongoing studies that they recommended should be considered during this evaluation process. For example:

As you may know, the Lummi Nation is in the process of conducting a Lummi specific diet study to both inform the triennial review of the Lummi Nation Water Quality Standards and the Washington State water quality and sediment standards. To date, 40 out of our targeted 100 surveys have been completed and entered into the database. We have decided not to include individuals whose consumption rates are greater than the 95th percentile of responses out of concern that these outlying values would have undue leverage on the final estimate and adversely impact the precision goal for the survey. Out of the 40 respondents so far, two individuals were removed that exceeded the 95th percentile. Overall, the mean consumption rate for the remaining 38 respondents was 5.1g/kg/day or 390 g/day. The precision of these estimates is 26 percent and 24.5 percent respectively. We will provide our final report when it is completed during the second quarter of 2012. ***(Jefferies, Lummi Natural Resources Dept)***

****

There are other populations in Washington State that consume large amounts of seafood that are not reflected in the document. Once the following new studies are conducted, supportable consumption rates may even be higher.

- *Colville Tribe fish consumption study (results pending in 2012).*
- *The University of Washington School of Public Health, DRCC/TAG and Just Health Action will be conducting a survey of Duwamish River subsistence fishermen in 2012. Evidence collected from past surveys suggests that some Duwamish fisher people eat fish daily and give or sell their extra catch to family members and neighbors.*
- *Anna Schmidt's 2011 MS thesis: An Evaluation of Fish Consumption and Environmental Concern in Low Income and Food Insecure Populations in Seattle reports that people who obtain food from food banks in Seattle are also high fish consumers.*

The evidence from these and other pending studies should be evaluated and incorporated into the Washington State fish consumption rates as they become available. In the meantime, the proposed new fish consumption rates will provide a greater level of health protections for those who currently are disproportionately exposed to contaminant levels and associated health risks from local fish and seafood. Please do not delay on the new rates. Sooner is better in this case. ***(Rasmussen (DRCC/TAG))***

Several people recommended that additional studies be conducted to characterize the fish consumption rates for non-tribal subsistence fishers. For example:

We believe it is vital that the end-result of cleanups be the protection of high-rate seafood consumers.. ***To this end, we ask that a reassessment of subsistence fishers be conducted to ascertain a consumption rate protective of high-rate consumers.*** *In reviewing the literature and in speaking with members of subsistence and indigenous groups, we believe the seafood consumption rate should be set close to 300 g/day, if not higher. The setting of a subsistence*

*rate for non-tribal peoples should be in no way construed as a substitute for individual tribal consumption rates…**(Branch et al. (Environmental Coalition))***

Ecology's Evaluation and Response: Ecology plans to complete a revised Technical Support Document (Version 2.0) by the end of 2012. The Department will continue to evaluate new studies as they become available. Ecology will consider both the newer studies and the Technical Support Document when revising the Water Quality Standards rule and making site-specific decisions at MTCA cleanup sites.

- **Confederated Tribes of the Colville Reservation (CTCR)**. The CTCR and EPA have collaborated on the Upper Columbia River Resource Survey. As part of this effort, trained personnel administered a Food Questionnaire to 1139 people. The CTCR has distributed initial results on the percentage of residents consuming fish, the frequency of consumption, and the percentage of consumers harvesting from local areas. Percentages are provided for 17 fish types. This information is summarized in Appendix B of the revised Technical Support Document. However, as of August 2012, the CTCR has not distributed information on the amounts of fish consumed by people participating in the survey.
- **Lummi Natural Resources Department**. Ecology is aware of the study being conducted by the Lummi Natural Resources Department. However, as of August 2012, Ecology has not received a final study report.
- **Lower Duwamish River Subsistence Survey**. Ecology is aware that the University of Washington, Duwamish River Cleanup Coalition/Technical Advisory Group (DRCC/TAG) and Just Health Action will be conducting a survey of subsistence fishers on the Duwamish River. Ecology understands that the study has been funded and looks forward to receiving the final study results. Ecology also understands that results from Ms. Schmidt's thesis (2011) have been used to design this survey.

7.5 Suppression of fish consumption

Information indicates that tribal fish consumption rates are suppressed compared with both historical rates and presumable rates that would have existed given historical fishing stocks. Ecology briefly discussed that information in the Technical Support Document Version 1.0. The recommendations in the Technical Support Document, however, were developed using data from published studies that reflect current consumption rates.

Several people urged Ecology to take suppression effects into account when making regulatory decisions. For example:

Existing fish consumption rates have been suppressed. Historical tribal fish consumption rates cited in the Technical Support Document include estimates of approximately 1,000 grams per day prior to darns and other habitat alterations (p 87). The availability of

abundant and uncontaminated fish and shellfish is a major concern to tribes, since habitat loss and degradation and other factors have significantly reduced the amount and type of fish that is available for tribes to safely harvest and consume. As noted in the recent workshop on fish consumption rates [held in December 2011], tribal consumption has been suppressed by several factors including declining abundance of fish resources, lack of opportunity to go fishing and loss of access to fishing grounds, prohibition of fishing and gathering due to known contamination, and avoidance of seafood consumption due to perceived contamination and risk warnings. In the 1970s, tribes struggled with legal suppression of fishing opportunity, leading to the affirmation of treaty fishing rights in U.S. v. Washington 384 F. Supp. 213 (1974). In recent years, tribal harvest of Chinook and coho salmon has dropped below pre-Boldt levels, and the trend continues downward. The recent report by the Northwest Indian Fisheries Commission, "Treaty Rights at Risk," describes the loss and degradation of habitat throughout western Washington, and the resulting loss of tribal opportunity to fish for subsistence and livelihood. Historical habitat loss for salmon and the pollution of shellfish harvest areas in Puget Sound are further described in the Puget Sound Salmon Recovery Plan and the 2009 State of the Sound Report.

Tribes are constantly working to restore fish and shellfish populations above status quo levels and want to ensure that, once restoration is successful, they can safely consume these traditional and nutritious food sources. Contemporary tribal fish consumption rates of approximately 500 grams per day have been estimated by researchers who have investigated suppression effects. This research is acknowledged in the Technical Support Document (p 96). The state should align fish consumption rates with restoration objectives, and provide a clear path forward and commitment to re-address and adjust the default rate as habitat is restored and improvements to water quality are made. Individual tribal studies already indicate that fish consumption rates are likely to rise ·in the future as resource availability improves ***(Frank (NWIFC))***

****

In the FCR document, Ecology states that, consistent with EPA guidance (the Framework) and policy and precedence established by Ecology for the cleanup of contaminated site (Port Angeles – ITT Rayonier), fish and shellfish habitat quality and abundance must be evaluated and considered when establishing a site-specific fcr for clean up purposes.
The Suquamish Tribe disagreed with EPA when this policy decision was included in the Framework and does not support its inclusion as general practice in Ecology's regulatory decisions. ***(Taylor (Suquamish Tribe))***

****

Suppression effects. *Similarly, suppression effects are not being incorporated. Reduction of habitat, toxic contamination, loss of access, and other factors have artificially reduced consumption. We believe that suppression effects should be included.* ***(Trim (PFPS)/Bell (NWEA))***

****

In contrast to estimates of historical fish consumption rates, recent surveys of tribal populations produce estimates of contemporary fish consumption rates. It is important to recognize that these snapshots of contemporary practices will be distorted due to suppression. ***(O'Neill (Seattle Univ.))***

Other people recommended that Ecology not "correct" the results of fish consumption rates based on concerns about suppression of historical rates. They noted that many factors influence consumption rates and some changes may actually result in higher rates relative to historic practices. For example:

> ***Suppression** vs. **increased fish consumption:** Ecology raises concerns about consumption rates possibly being suppressed for a variety of reasons (page 96). Some of these reasons are associated with irreversible changes due to development, fluctuation in fish populations and changing cultural preferences. Such changes should not be "corrected" in estimated fish consumption rates. Suppression due to concerns about chemical contamination is unlikely in most marine and estuarine waterbodies of the state because most of them are not highly contaminated. Actions taken over the past 40 years have led to substantial improvements in water quality throughout the state. Remedial actions at many contaminated sites have also yielded cleaner sediments in urban areas. In contrast to concerns about suppression, Ecology should describe changing dietary preferences leading to increased fish consumption rates in the general population over the past decade or two.* ***(Barrette (PCSGA)/Schoof (Environ))***

Ecology's Evaluation and Response: Oregon DEQ (2008) discussed some of the factors that may result in depressed fish consumption rates compared to historic rates. Potential factors include (1) significant reductions in fish populations, (2) the belief that fish that reside in polluted waters will accumulate unhealthy levels of pollutants, (3) elevated contaminant levels in local fish and shellfish, 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.

Ecology continues to believe it is appropriate to use available fish consumption surveys to establish default and site-specific fish consumption rates. However, we also agree with EPA that this issue should be considered "…when deciding whether the use of a surrogate Tribal fish and shellfish consumption rate would better represent potential future consumption rates than would consumption rates that represent only current or near-term contamination and habitat conditions…" (EPA, 2007).

Habitat restoration is a primary goal of ongoing efforts to restore Puget Sound. Ecology hopes that over time, this restoration work will reduce suppression effects. Ecology believes this is vital and important work and continues to look for ways to partner with Tribes, other government agencies, businesses and citizens on restoration efforts.

7.6 Locally harvested fish

Several people stated that it was important to distinguish between locally harvested fish and fish from other areas (for example, Alaska) purchased in stores. They noted that this is particularly important because most regulations are applied to specific waterbodies. Several people

recommended that Ecology use an approach similar to EPA Region 10 to adjust the tribal study results to remove non-regionally harvested fish. For example:

> *It appears that the data from the Tulalip and Suquamish Island tribes also need to be adjusted to remove non-regionally harvested fish, as EPA Region 10 did in developing its guidance for site-specific cleanup levels.* ***(Louch and Stratton (NCASI))***
>
> **********
>
> ***Origin of fish:*** *Distinctions are frequently made between fish caught by anglers vs. fish purchased in stores, between locally sourced fish vs. fish from other areas, and between resident fish and anadromous fish such as salmon. Most regulations are applied to specific waterbodies or sites. logically, applicable fish consumption rates would be limited to fish harvested from the water body or site being regulated. Most regulated chemicals will be present in a variety of food items in addition to fish. Chemicals in fish from other areas are no different conceptually from chemicals in other food items. Thus, consumption of fish from other areas should not be included in the local fish consumption rates, just as consumption of other kinds of foods should not be included. The framework provided by U.S. Environmental Protection Agency (USEPA) Region 10 is a good resource for site-specific approaches (USEPA 2007b).****(Barrette (PCSGA)/Schoof (Environ))***
>
> **********
>
> ***Origin of Consumed Seafood.*** *The document does not adequately specify the amount of consumed seafood that comes from waters of Washington State versus other locations (e.g., Alaska), the amount from commercial aquaculture operations in Washington and elsewhere, and the amount of consumed seafood representing natural resources of Washington state (i.e., the amount of seafood living in an uncontrolled environment that may be exposed to environmental contaminants). The seafood consumption rate is most reasonably defined based on the seafood representing natural resources of Washington State. The recommended range of fish consumption rates is overly conservative because the rates were not adjusted to account for the percentage of seafood consumed that originates in other locations. Further surveys should be performed if adequate data are unavailable (Chapter 2, High-Fish Consuming Populations, pages 2 through 27). The text states that traditional fishing areas for tribes cover essentially all of Washington. While this may be true based on treaty rights, it appears that the majority of the fishing and seafood harvesting (particularly subsistence fishing and seafood harvesting) occurs in significantly less areas of the state. It does not appear technically justifiable to apply a high-fish consumer seafood consumption rate (that likely includes subsistence fishers) to all locations in Washington when not all locations are used or can be used (due to their ecologic productivity) for this purpose. (Chapter 2, Washington Native American Tribes, page 27).* ***(Matsushita (Lockheed Martin))***

Ecology's Evaluation and Response: Ecology has revised the Technical Support Document to more clearly distinguish locally harvested fish from fish obtained from other sources. This information is similar to information provided in Oregon DEQ (2008) and EPA (2011). However, the revised Technical Support Document incorporates additional evaluations (Polissar,

et al. 2012) prepared in response to public comments. A summary table from the revised report is shown below.

Summary of Fish Consumption Data, All Finfish and Shellfish (g/day)

Population	Source of Fish	Number of Adults Surveyed	Mean	Percentiles		
				50th	90th	95th
General population	All sources: EPA method	2,853	56	38	128	168
	All sources: NCI method	6,465	19	13	43	57
Columbia River Tribes	All sources	464	63	41	130	194
	Columbia River	–	56	36	114	171
Tulalip Tribes	All sources	73	82	45	193	268
	Puget Sound	71	60	30	139	237
Squaxin Island Tribe	All sources	117	84	45	206	280
	Puget Sound	–	56	30	139	189
Suquamish Tribe	All sources	92	214	132	489	797
	Puget Sound	91	165	58	397	767
Recreational Fishers (compilation of multiple studies)	Marine waters, WA State	–	11–53	1.0–21	13–246	
	Freshwater, WA State	–	6.0–22	–	42–67	

Sources: Adapted from Polissar et al., 2012, Table E-1. Data for recreational fishers is from Table 3, Technical Issue Paper: *Recreational Fish Consumption Rates* (Ecology, 2012)..

7.7 Use of "consumer only" or "per capita" data

The results from fish consumption surveys can be reported in terms of "consumer-only" rates and "per capita" rates. Consumer-only intake rates refer to the quantity of fish and shellfish consumed by individuals who report eating fish and/or shellfish during the survey period. These data are generated by averaging intake across only those survey participants who consumed fish and shellfish during the survey period. Per capita intake rates are generated by averaging intake rates over the entire survey population (including those individuals who reported no intake).

Ecology elected to use "consumer-only" rates when preparing the Technical Support Document. Several people expressed concerns about this approach and recommended that Ecology use per-capita information when updating default fish consumption rates. For example:

> ***Consumers** vs.**nonconsumers:** Use of long term average consumption rates also mitigates concerns regarding use of data for "consumers only" vs. data for "consumers and non-consumers" combined. Short term surveys will include many "nonconsumers" who may consume fish at other times, but didn't during the short period of the survey. Surveys that calculate long term averages will include few "nonconsumers" because most people consume some fish or shellfish**. (Barrette(PCSGA)/Schoof (Environ))***
>
> **********
>
> *In situations where subpopulations are believed to be subject to significantly greater risks than the general population, an appropriate, science-based response would be to conduct a*

population- or site-specific risk assessment to determine if actual risk (in this case due to a greater than average FCR) for that subpopulation exceeds target values consider in all aspects of exposure including, in this case, the health benefits of fish consumption. ***(Louch and Stratton (NCASI))***

Ecology's Evaluation and Response: Ecology recognizes that there can be large differences in study results reported on a consumer-only and per-capita basis when a large percentage of study participants report that they did not eat any fish or shellfish during the survey period.

This is particularly true for the general population where many people do not consume fish on a regular basis. EPA (2002) has evaluated the data from *Continuing Survey of Food Intakes by Individuals* (CSFII). This survey included more than 20,000 participants who provided dietary information during two consecutive 24-hour periods. Approximately 28 percent of the participants reported that they ate some amount fish or shellfish during the survey period. When expressed on a per-capita basis, the 90th percentile of the reported results was 17.5 g/day. When expressed on a consumer-only basis, the 90th percentile of the reported results was 250 g/day.

Fish and shellfish are primary sources of protein for several population groups in the Pacific Northwest and fish is consumed on a regular basis. One would expect to see much smaller differences between "consumer-only" and "per-capita" rates in studies where a high percentage of study participants reported they ate some amount of fish during the survey period. This is the case with the CRITFC (1994) study where the per-capita and consumer-only rates are virtually identical. The Oregon Human Health Focus Group (Oregon DEQ, 2008) reported that the fish consumption rates corresponding to the 90th percentile of survey results were 170 grams/day (reported on a per capita basis) and 176 grams/day (reported on a consumer-only basis).

The EPA 2011 *Exposure Factors Handbook* notes that: "[i]n general, per capita intake rates are appropriate for use in exposure assessments for which average dose estimates are of interest because they represent both individuals who ate the foods during the survey period and individuals who may eat fish at some time but did not consume it during the survey period. Per capita intake, therefore, represents an average across the entire population of interest but does so at the expense of underestimating consumption for the population of fish consumers."

Ecology currently establishes cleanup standards at individual cleanup sites that are based on consumer-only data. Ecology's rationale for this approach is discussed in Chapter 8. However, Ecology will be considering several approaches when developing human health criteria in the Water Quality Standards (WQS) rule.

Chapter 6 of the revised Technical Support Document provides examples of how federal and state environmental agencies have used both types of information to establish regulatory requirements. These include:

- *Per capita data.* Environmental agencies have used per capita fish consumption rates to establish regulatory requirements. For example, several states have adopted surface water quality standards that are based on 17.5 g/day.

- *Consumer-only data.* Environmental agencies have used consumer-only fish consumption rates to establish regulatory requirements. For example, the EPA Region 10 framework includes several default fish consumption rates that are based on consumer-only information.
- *Supplemental analyses.* Health statisticians at the National Cancer Institute (Tooze et al., 2006) have developed statistical methods to adjust study results to account for variations in daily patterns for foods that are not eaten nearly every day. Section 4.2.2 of the revised Technical Support Document and Polissar et al. (2012) provide an example of this approach. However, Ecology is not aware of situations where this approach has been used to establish environmental protection standards.

7.8 Salmon consumption

People expressed a wide range of opinions on whether and when salmon should be considered when calculating a statewide default fish consumption rate. Those comments are compiled and evaluated in Chapters 4 and 9 of this Responses document. Several people recommended that Ecology revise the report to provide rates calculated with and without salmon.

Ecology's Evaluation and Response: Ecology has revised the Technical Support Document to provide information on fish consumption rates broken down by species group and source. An example of this information is shown in the table below. Ecology also compiled additional information on salmon species and salmonid life cycles to help inform site-specific regulatory decisions. This information is provided in Ecology (2012) and Appendix C of the revised Technical Support Document.

CRITFC Adult Fish Consumption Rates by Species Group and Source, Consumers Only

Population Tribal	Species Group	Harvest Source of Fish	Descriptive Statistics (g/day)				
			50th Percentile	Mean	75th Percentile	90th Percentile	95th Percentile
The 4 Tribes Affiliated with the Columbia River Inter-Tribal Fish Commission	All finfish	all	40.5	63.2	64.8	130.0	194.0
	Non-anadromous	all	20.9	32.6	33.4	67.0	99.9
	Anadromous	all	19.6	30.6	31.4	63.1	94.1
	All finfish	Columbia River Basin	35.6	55.6	57.0	114	171
	Non-anadromous	Columbia River Basin	18.4	28.6	29.4	58.9	87.9
	Anadromous	Columbia River Basin	17.3	27.0	27.7	55.5	82.8

Source: Adapted from Polissar et al., 2012, Table E-1.

7.9 Asian and Pacific Islander (API) Study

Ecology concluded that the *Asian and Pacific Islander Seafood Consumption Study* (Sechena et al., 1999) should be considered when establishing a statewide default fish consumption rate. Ecology believes this survey was well-designed and conducted, and is directly applicable to Washington population groups.

Several people stated that the Asian and Pacific Islander (API) study results are not representative of the broader API population because of the high percentage of first generation residents. For example:

> *First, the API study is dominated by first-generation residents (89% of respondents), who are known to consume more fish than later generations. This known bias in the results casts some doubt on the representativeness of the results to describe the fish consumption rates of the broader API population.* ***(Louch and Stratton (NCASI))***

Several people also noted that the data presented for the API study included both locally-harvested and store-bought fish. They recommended that Ecology use EPA's reanalysis (Kissinger, 2005) because EPA had adjusted the data to correct for fish harvested in other areas and API population demographics. For example:

> *The selected API consumption survey appears to include fish and shellfish which were store-bought and not sourced locally (e.g., tuna). King County believes data for nonlocal store-bought fish like tuna, or tropical species, should be removed from the API dataset and the distribution of the remaining locally sourced fish and shellfish used instead. We recommend that this issue be addressed and clarified in the document and the statistical analysis is re-evaluated to develop consumption rates reflecting self-harvested and locally-sourced seafood purchased in local markets. Consumption rates forming the basis of Washington water quality and sediment management standards should not include non-local seafood.* ***(True (King County DNRP))***
>
> **********
>
> *Table 1 shows a median fish consumption rate of 78 g/day and a 95th percentile of 306 g/day for Asian & Pacific Islanders, and this is used by Ecology without adjustment in developing recommended fish consumption rates.*
>
> *Pages 60-62 show that EPA Region 10 reanalyzed the API data to correct for cooking weight loss, regional harvest and API population demographics and determined median fish, shellfish and crab consumption to be 5.9 g/day, and the 95th percentile to be 57 g/day (and these included salmon consumption). When salmon consumption was excluded the values dropped to 5.3 g/day and 51.1 g/day.*
>
> *The reanalysis was done to develop API fish consumption rates to establish cleanup levels in the Lower Duwamish Waterway. The reanalysis provides some important insights. The significant difference from the overall API study illustrates why Ecology should not adopt a default fish consumption rate for use across the sediment, water quality and MTCA programs.* ***(McClellan (EPW) Attachment)***

Ecology's Evaluation and Response: The Asian and Pacific Islanders community includes a broad range of ethnicities. The Kissinger (2005) analysis presents fish consumption estimates determined by aggregating fish consumption data for small numbers of individuals from these varied ethnic groups. Ecology believes that the Kissinger (2005) evaluation is a highly credible analysis that includes a demographic weighting approach applicable to King County.

Ecology has reviewed this analysis and believes it would be inappropriate to project the fish dietary patterns for the 10 API populations beyond King County. There is a high level of uncertainty associated with basing statewide API fish dietary patterns on the King County API fish dietary information because of the small number of respondents for each API ethnic group. API fish consumption rates for King County are tabulated and provided in Chapter 4 of the Technical Support Document (Version 2.0). Additional fish dietary information is available for Japanese and Korean populations from King County and is provided in Appendix B of the revised Technical Support Document.

7.10 Suquamish tribal survey – Summary tables

The Technical Support Document included as series of tables that summarized the results of the individual studies. Several people questioned whether Ecology had correctly summarized the Suquamish fish consumption data. For example:

> Tables 1 and A-1 and C-1 identify 284 adults surveyed for the Suquamish Tribe. The text on pages 55 and 56 indicates that there were only 92 respondents out of a total of 142 potentially eligible tribal adults in the Suquamish study. It is not at all clear how 92 respondents equals 284 adults surveyed. **(McClellan (EPW) Attachment)**

The Suquamish Tribe provided information in their written comments.

> *Please correct the summary survey results for Suquamish adult fish consumers presented in the tables throughout the FCR document and cite the Suquamish survey as the source:*
>
> *Number of adults surveyed = 92*
> *75^{th} percentile rate = 284 gpd*
> *95^{th} percentile rate = 797 gpd*
>
> *On page 65, Table 20, correct the description of the Suquamish survey to indicate that it pertains to Suquamish tribal members.* ***(Taylor (Suquamish Tribe))***

Ecology's Evaluation and Response: Ecology has revised the Technical Support Document to reflect the information from the Suquamish Tribe. All Suquamish fish consumption estimates have been changed to correspond to areas of harvest and species groups harvested and consumed. The revised report also states:

Consumption data were based on a random sample of adults (16 years and older) selected from the tribal enrollment roster. Of 425 tribal members of all ages living on or near the reservation, 284 adults were identified as eligible to participate in the survey. Of these 142 adults were randomly selected and 92 participated in the survey, for a 64.8 percent participation rate.

7.11 Suquamish tribal survey – Survey methods

Two people submitted comments on survey method development. While the concerns and recommendations were broadly applicable, they focused on the Suquamish tribal survey methods to illustrate those concerns. In particular, they observed that the two survey vehicles (food frequency and portion size survey and 24-hour recall survey) used in the Suquamish study produced significantly different fish consumption rate estimates. They questioned Ecology's decision to use the food frequency results to develop a default and/or site-specific fish consumption rates.

The primary survey instrument used in the Suquamish study to derive consumption rates was a food frequency and portion size survey. This type of survey asks participants to estimate the frequency at which they ate specific fish and shellfish species over the previous week (i.e., meals per day, week, or year) and the portion size of the typical meal. In addition, participants were also administered a 24-hour recall, in which participants are asked to recall what fish or shellfish they ate and how much during the last 24 hours only. The 24-hour recall results were not used to derive the final recommended consumption rates, but rather were provided for comparison and validation. There are strengths and weaknesses with each survey method. For example, the food frequency covers a longer period of time so may be able to reveal long-term patterns, but accuracy of recall suffers over the longer period of time. The 24-hour recall is likely to more accurately reflect intake during the survey period (i.e., 24 hours), but may miss out on daily variation on an individual level or seasonal variation on a population level. In the Suquamish study, 55% of participants reported no seafood consumption in the 24 hours prior to taking the survey. Correspondingly, the mean consumption rate measured in the 24-hour recall portion of the study (1.5 g/kg-day) was nearly half the consumption rate estimated in the food frequency survey (2.7 g/kg-day). The lack of seafood consumption during the 24-hour recall survey period does not, however, indicate those respondents are nonconsumers in general because the food frequency survey revealed that all participants were seafood consumers. Study authors concluded that the "lower mean consumption rate for dietary recall suggests that a brief set of questions does not uncover all forms of consumption."

However, this conclusion is not supported by scientific literature on dietary surveys. Although on an individual level the 24-hour recall does not capture day-to-day variability; on a population level it may provide a more accurate account of the consumption rate than the food frequency survey instrument. This type of dietary assessment (i.e., the 24-hour recall) has been shown to accurately reflect dietary patterns.6 Retrospective diet history surveys, such as the Suquamish food frequency questionnaire that looked back over a year, may be more likely to overestimate usual consumption.7 Results should be validated by summing reported consumption for individual food items, along with food groups not included in the survey, to determine if reported intake is consistent with energy requirements.

Ideally, multiple non-consecutive day 24-hour recall surveys would be administered to study participants over a longer period of time to capture seasonal and individual variability. For example, Nobmann et al. (1992) conducted a study on dietary intake in Native Alaskans from 10 communities throughout Alaska. Their methodology included the use of multiple 24-hour recall surveys, completed during five seasons over an 18-month period. Nobmann et al. (1992) reported the typical caloric intake for native Alaskans as approximately 2,750 kcal per day for men and 1,950 kcal per day for women (Table 5-12; Nobmann et al. 1992). Caloric intake in the general U.S. population during that time period was approximately 2,550 kcal per day for men and 1,550 kcal per day for women (NHANES II, as reported in Nobmann et al. 1992). Results would be validated with a small subset of participants completing diet records with weighed meals.(Johns and Garry (Exponent)

Ecology's Evaluation and Response: The regional fish dietary surveys have been performed using a combination of 24-hour dietary recall and food frequency questionnaire. This combination provides information on the amounts of food consumed for a short period of time (24-hour dietary recall) and food frequency and portion sizes over a longer period of time (food frequency questionnaire). The strengths and weaknesses of the two methods are discussed in Chapter 3 of the Technical Support Document.

The Suquamish fish dietary survey is an example where these two survey instruments were used in combination to provide estimates of fish consumption. While the 24-hour dietary recall survey provides information to estimate short-term consumption rates, this method does not account for the inherent dietary variability in fish consumption rates over longer periods of time. (Subar et al, 2006) The food frequency questionnaire better accounts for the variability of consumption by estimating portion sizes over a longer period of time.

The results from the two methods have been used to estimate fish consumption rates. As noted in the comments above the results from the food frequency questionnaire produced higher estimates than the 24 hour recall survey. There are several reasons why the estimates from the food frequency questionnaire have been used when preparing the Technical Support Document:

- The food frequency questionnaire results provide a reliable and representative estimate of usual fish consumption. The questionnaire was administered by trained Suquamish tribal representatives. The questionnaire was administered in conjunction with visual aids used to depict finfish and shellfish meals. It is also important to note that fish is a primary source of protein for the tribal populations in the Pacific Northwest. Unlike many population groups, members of the Suquamish Tribe consume fish on a regular basis. This would tend to minimize dietary recall issues relative to population groups where fish consumption is less frequent.
- The food frequency questionnaire accounts for the temporal variability in fish consumption rates. The use of the results from the food frequency questionnaire accounts for seasonal variations in fish harvests and other factors that affect fish consumption habits and patterns.

Dodd et al. (2006) reviewed the statistical methods used to estimate the usual intake of nutrients and foods. They concluded that "…[a]lthough 24-hour recalls are frequently used in dietary assessment, intake on a single day is a poor estimator of long-term usual intake.." (p. 1640).

- The results from the food frequency questionnaire are correlated with the results from the 24-hour recall survey. One of the data validation steps involved comparing the results from the two survey methods. The study'sauthors concluded:

  As an additional validation step, total seafood consumption rates reported for the day preceding the interview were compared with the rates reported for year-round consumption. A majority of the 92 participants reported no seafood consumption the day before (55%). Mean consumption was 1.5 g/kg/day in the preceding day, compared to 2.7 from the full survey. The two sets of rates were positively correlated (Spearman's rho = 0.41, p < 0.001). The positive and significant correlation indicates some consistency between the dietary recall and the body of the questionnaire for consumption rates. However, the lower mean consumption rate for the dietary recall suggests that a brief set of questions does not uncover all forms of consumption.

One other point made in the above comment is that, "…[r]etrospective diet history surveys, such as the Suquamish food frequency questionnaire that looked back over a year, may be more likely to overestimate usual consumption [than 24-hour recall surveys]..." This statement is somewhat inconsistent with conclusions reached by Tooze et al. (2006). They observed that both 24-hour recall surveys and food frequency questions are more likely to under-report than over-report energy intake.

"Most importantly, the model is based on the assumption that the 24-hour recall is an unbiased instrument for measuring usual food intake. Many recent studies with doubly labeled water have found misreporting of energy intake on both the 24-hour recall and FFQ, almost always in the direction of underreporting (11-14). This suggests that at least some foods are underreported as well." (Tooze et al. 2006, p. 1585)

7.12 Suquamish tribal survey – Metabolic energy needs

Several people also recommended that Ecology consider whether the estimated rates are consistent with information on metabolic energy needs over extended periods of time. For example:

...fish consumption rates should reflect the reality of metabolic energy needs over long time periods (i.e., how much food does a person need and how much can they reasonably consume to maintain weight, health, etc.). The amount of fish consumption must make sense in the context of the entire diet. Unfortunately, the Suquamish study, like the other available fish consumption studies, considers only fish and shellfish consumption and not total diet. Without understanding the usual intake of other foods, it is not possible to accurately assess

the results, particularly with regard to factors that may shift the overall distribution of consumption rates because of systematic biases. The daily energy requirement of an active adult male of average size is approximately 2,900 kcal/day; more for a larger or more active person and less for a smaller or less active person. Ideally, a survey assessing usual intake of most/all foods would be administered to at least a subset of study participants in order to validate the fish consumption estimates. A similar analysis could be conducted regarding limits to the amount of protein intake that could be sustained over a longer time period. In the absence of such data, results should at least be evaluated using other means of estimating total diet intake (e.g., follow-up studies in the survey group, literature values for similar populations. ***(Johns and Garry (Exponent))***

Ecology's Evaluation and Response: Ecology agrees that an important component of regional-specific fish dietary information is an assessment of tribal populations' dietary caloric intake requirements that are based on traditional and subsistence tribal lifeways. Several researchers have evaluated this issue. Based on those evaluations, Ecology believes that the fish consumption rates from the Suquamish survey are consistent with the metabolic energy requirements associated with subsistence and traditional lifestyles.

Harris and Harper (1997) evaluated the daily dietary caloric requirements of traditional Columbia River basin tribes. They noted the following regarding nutritional caloric intake requirement for subsistence tribal lifeways: (Harris and Harper, 1997)

…estimated that a tradition Columbia Basin diet is composed of 1300 g/day roots (or 1330 Kcal/day) plus 100 g/d of other vegetation (or 62 Kcal/d) plus 500 g/d salmon and other fish (or 850 Kcal/d) and 250 g/d venison and other game (or 310 Kcal/d) for a total of 2562 Kcal/d. The caloric content of fresh salmon is approximately 500 Kcal/275 g (Chinook) or 400 Kcal/275 g (Sockeye). The fish ingestion rate of 540 g/d therefore represents about 800-100 Kcal/d. The caloric requirement for moderately active adults is approximately 3000 Kcal/day for males and 2200 Kcal/d for females, with an additional 500 Kcal/d for pregnant or lactating females (or 80,000 Kcal per pregnancy). The daily protein requirement is about 75 g for a 75-kg male for a sedentary lifestyle and 25% more for a moderately active lifestyle. Salmon contains 17 g protein per 100 g wet weight, and thus would provide close to the required daily amount of protein and one-third to one-half of the caloric requirement.

A more detailed nutritional analysis for subsistence diets and caloric intake requirements was performed for the Confederated Tribes of the Umatilla Indian Reservation (CTUIR). (Harper et al, 2007) The caloric nutritional basis for subsistence diets is about 2000 to 2500 kcal/day. As a comparison, 2000 kcal/day is much less than required for an athlete in training, but reflects a mix of 2 hours of high physical activity, 6 hours of moderate physical activity, 8 hours of low and sedentary activity, and 8 hours of rest. The table below shows the food categories and Kcal/day intake for each of the food categories contributing to the Umatilla tribal diet. The tribal fish consumption rate of 620 grams/day is considered a tribal subsistence fish consumption rate. (Harper and Harris, 2008).

Columbia River Basin Tribal Diets and Nutritional Caloric Intake			
Food Category	Grams / Day Consumption	Kcal / Day	% of 2500 Kcal
Fish	620	1000	40
Game, Fowl, eggs	125	150	6
Roots	800	800	32
Berries, fruits	125	125	5
Green, medicinal leaves, tea, stems, etc	300	300	12
Other: mushrooms, sweeteners, etc	125	125	5

Adapted from Figure 31, CTUIR Diets, page 48, Traditional Tribal Subsistence Exposure Scenario and Risk Assessment Guidance Manual. August 2007

7.13 Suquamish tribal survey – Portion sizes

One person questioned whether the large portion sizes reported by some individuals in the Suquamish survey were plausible:

> *Review of the portion sizes (that is, serving sizes per meal) reported in the Suquamish survey raises questions about the validity of these high seafood consumption rates. In Table T-8 of the Suquamish report (The Suquamish Tribe 2000), the mean, median, minimum, maximum, and 90th percentile portion sizes for various seafood categories are reported. Most of the tabled values appear plausible, with the exception of the maximum portion sizes for the various shellfish species. For bivalves (i.e., clams, mussels, oysters), the maximum reported portion sizes range from 1,134 g (2.5 pounds) for mussels to an incredible 2,720 g (6 pounds) for geoduck clams. I have a hard time envisioning anyone eating 6 pounds of geoduck clams in one meal. Without access to the underlying data, it is impossible to say what effect such extreme portion sizes might have had on the 95th percentile rate used in the HHRA. However, these extreme portion sizes certainly raise the question of whether the responses given by the individual(s) reporting such portion sizes are believable.* ***(McKrone)***

Ecology's Evaluation and Response: Ecology believes that the reported rates are plausible and consistent with tribal cultures and traditions. The reported rates do not represent the amount of fish eaten every day and need to be evaluated along with information on consumption frequency. The high individual rates in the Suquamish survey are also consistent with the distribution of rates reported in other fish consumption surveys.

Table T-8 of the Suquamish survey reports a maximum serving size for geoducks was 2720 grams, which is approximately 6 pounds. The text describing this table is important; in

particular: "In cases where respondents reported different consumption rates for the periods considered 'in season' and the 'rest of the year' the larger value of the two was utilized in reporting typical portion sizes." Consequently, the reported amount may have been typical for only part of the year.

It is also important to consider the information regarding the frequency of eating geoduck. Table T-9 presents the number of servings per year of each species. Among the 82 consumers of geoduck (out of 92 in the survey), the median was eight servings per year (range 1-80), indicating that half of these 82 respondents ate geoduck eight or fewer times a yearDetails were not available regarding the individual whose typical serving was six pounds (the maximum, typical,in-season and out-of-season servings) , so the frequency of those large meals of geoduck is unknown. However, it is unlikely an individual sits down to a daily meal of this magnitude. Since half of the geoduck consumers ate it eight or fewer times per year, a more likely explanation is an infrequently high consumption, perhaps at social gatherings.

Comments were also made about the large values of maximum portion sizes for clams, mussels and oysters. There are other species with large maximum values, (such as shrimp—see Table T-8 of The Suquamish report), but the median number of servings per year is 12 or fewer for any species that has a maximum serving size of more than 1000 grams (Table T-9 of the report.) Therefore, a scenario of sustained, extremely high consumption is unlikely, though not impossible.

Fish consumption estimates are positively skewed toward high distributions. Estimates of maximum amounts of fish consumed, either as a rate or portion size, from a highly positively skewed dataset can be very large. These maximum fish consumption estimates reflect the maximum amount of fish eaten by a subset of fish consumers within a larger indigenous fish-consuming population. Several researchers have indicated that these very high fish consumers are true subsistence populations (fish consumption rate exceeding 454 g/day or 1 pound/day) within the larger indigenous fish-consuming populations (Harris and Harper, 1997; Harper and Harris, 2008; Donatuto and Harper, 2008).

The large portion sizes documented in regional-specific fish dietary surveys also need to be considered in the cultural context for tribal populations. Many of these fish meals may be part of a larger tribal gathering where large portion sizes are individually consumed or large quantities of fish are shared during a cultural event or religious ceremony. Also, these fish-consuming tribal populations have true subsistence sub-populations where large amounts of fish are harvested and shared by individuals and their family members.

Ecology has encountered high fish dietary estimates from other types of datasets. Estimates of fish consumption from national 2003-2006 NHANES data have estimates that are much higher and appear to differ from the population under study. The 2003-2006 NHANES fish dietary information for more than 6400 adult respondents, reported that the highest fish consumption rate was approximately 940 g/day, or more than 2 pounds of fish/day. (Polissar et al, 2012)

Although this fish consumption rate estimate is large, there is no reason to disregard or eliminate it as impossible. Similar to the regional-specific fish dietary information for the Pacific Northwest, there are subsets of fish consumers within the larger national population of fish consumers who consume very large amounts of fish.

7.14 Suquamish tribal survey – Statistical methods and data outliers

Several people raised questions about the statistical methods used in the various studies. In particular, people raised questions about the procedures used to deal with outliers. For example:

> *The Suquamish data also indicate some very high consumption rates compared to other Tribes. Have the data been made available for review? We understand that the data are not available to others who have requested, and that raises concerns about putting too much weight on the study.* ***(McClellan (EPW) Attachment)***

****

> *The issue of the credibility of survey respondents is a curious one. Although the same statistical consultants participated in the Tulalip, Squaxin, and Suquamish surveys, data "outliers" were treated differently. In the Tulalip/Squaxin survey report (Toy et al. 1996), the authors recognized that there were "a number of outliers representing unusually large consumption rates", and that "values such as these represent large but uncertain consumption rates". Rather than use these questionable values, the statisticians "recoded" these extreme values "to the largest reported consumption rate within three standard deviations of the arithmetic mean". That is, no reported consumption rate was allowed to be more than three standard deviations above the arithmetic mean of all respondents, regardless of what the individual tribal members reported.* ***(McKrone)***

Ecology's Evaluation and Response: The Suquamish survey does include several large consumption rates for individual or grouped species. This is consistent with the fact that the distribution of Suquamish fish consumption rates is positively skewed to the right. Estimates of maximum amounts of fish consumed, either as a rate or portion size, from a highly positively skewed dataset can be very large. This is a phenomenon rather than an aberration. This phenomenon is consistent with the results from other regional fish consumption surveys. Specifically, the fish consumption rate estimates reported by CRITFC (1994), Toy et al. (1996) and Sechena et al. (1999) are also highly positively skewed distributions.

Large fish meal portion sizes documented in regional-specific fish dietary surveys need to be considered in the context of tribal cultures. As discussed in Section 7.13, many of these fish meals may be part of a larger tribal gathering where large portion sizes are individually consumed or large quantities of fish are shared during a cultural event or religious ceremony. Consequently, none of the consumption rates that have been cited as "too high" can be dismissed as implausible.

The EPA's *Guidance for Conducting Fish and Wildlife Consumption* Surveys (EPA, 1998) states that "…[i]f variances are high, it is appropriate to examine the data for outliers and apply the appropriate nonparametric test." Given this guidance, Ecology recognizes that a wide range of statistical methods can be used to evaluate very high consumption rates. Regional-specific fish dietary surveys have employed several different statistical methods to account for potential outliers. These include:

- **CRITFC (1994).** This was the first of the tribal surveys conducted and the concept of subsistence populations was not fully considered during the data analysis. The published report states that "…[o]utliers, those data points that seemed unreasonably high due to discontinuity in distribution, were identified in responses to some survey questions. A total of five outliers were identified and these data points were ignored in all calculations." (p. 26)
- **Squaxin Island and Tulalip Tribes (Toy et al 1996)).** The published report states that "...outliers were handled by recoding them to the largest reported consumption rate within three standard deviations of the arithmetic mean. This recoding was done separately by tribe and separately within each fish group subtotal: anadromous, pelagic, bottom, shellfish, and other fish. These corrections were applied separately for adults and for children."
- **Asian and Pacific Islanders (Sechena et al. (1999)).** The published report states that "…[a]ll observed values greater than 3 standard deviations (SD) above the mean was substituted by a smaller value (mean plus 3SD) within each seafood group. After the treatment of outliers for each of the individual seafood categories, the "all seafood" consumption rate was computed as the sum of all individual seafood subcategories. Again, the outliers in the "all seafood" category were adjusted downward to a value of its mean + 3SD. Finally, a readjustment was carried out to reflect the fact that the overall "all seafood" rate was the sum of the individual seafood categories, proportionately allocated using the percentage of each subcategory in the "all seafood."
- **Suquamish Tribal Survey (Suquamish, 2000).** The authors of the Suquamish tribal survey considered high consumption rates as actual estimates of consumption of subsistence populations within the Suquamish Tribal population. The published report states that "…[a] number of high consumption rates were included in calculations of the mean, standard errors and percentiles, in contrast to some preceding survey (e.g., Toy et al.) where high values were considered as outliers and were truncated to a smaller value, such as the mean plus three standard deviations." (pp. 70-71).

In response to public comments, Ecology reevaluated the regional-specific fish dietary information. As part of that work, Ecology recalculated fish consumption rates using the results from all study participants (including large values that had been treated as statistical outliers in earlier analyses). In other words, the fish consumption estimates were not adjusted and were derived based on the estimates as reported. The non-adjusted estimates are presented in *2012 Statistical Analysis of National and Washington State Fish Consumption Data* (Polissar et al, 2012) and the revised Technical Support Document (Version 2.0).

The table below compares the results from the earlier analyses and the recent calculations. The *Technical Support Document Version 1.0* rows summarize the information provided in the Technical Support Document published in October 2011. These values were included in the

published report and reflect the different statistical methods described in those reports. The *Technical Support Document Version 2.0* rows summarize the results of Ecology's reevaluation.

Comparing the two sets of analyses indicates that the statistical methods used to deal with outliers in the earlier studies resulted in a 5 to 15% lowering of the upper percentile values. As expected, the decision to adjust or not adjust for high values appears to have had little impact on the mean and median values.

Comparison of Mean, Median and Percentile Values Using Alternate Approaches for Handling Statistical Outliers

Study	Report	Descriptive Statistics (g/day)			
		50th Percentile	Mean	90th Percentile	95th Percentile
CRITC (1994)	TSD Version 1.0	63	40	113	176
	TSD Version 2.0	63	40	130	193
Tulalip (Toy et al. 1996)	TSD Version 1.0	72	45	186	244
	TSD Version 2.0	82	45	193	268
Squaxin (Toy et al. 1996)	TSD Version 1.0	73	43	193	247
	TSD Version 2.0	84	45	206	280
Suquamish (Suquamish, 2000)	TSD Version 1.0	214	132	489	
	TSD Version 2.0	214	132	489	797

In the Suquamish Survey, the high values were judged to reflect the actual amount of fish consumed by survey participants and were not treated as outliers. The high values have no influence on the percentiles reported here for all seafood groupings (A-G) and for all larger groups (all finfish, all shellfish, all seafood). The single exception is "all finfish," where the 95th percentile would be slightly higher due to the inclusion of the high consumption rate reported by one respondent (4.570 g/kg/day), rather than the value that would have been used had it been truncated. Thus, percentiles are virtually unaffected by the use of these large consumption rates.

Although it is possible that the mean consumption rate estimated may have been affected by the high individual rates, the impacts would be small. For example, if the two highest consumption rates for all seafood reported by two individuals (18.4 and 14.8 g/kg/day) had been truncated to the mean plus three standard deviations (12.364), the revised consumption rate would have been 2.61 instead of 2.71, a minor difference. For Group G, if the one high rate reported (1.344 g/kg/day) had been truncated to the mean plus three standard deviations (0.78), the mean would have been revised to 0.45 g/kg/day rather than 0.52 g/kg/day, a 14% difference.

Ecology elected to present the non-adjusted estimates in the Technical Support Document (Version 2.0). There are two primary reasons for selecting this approach:

- The largest fish consumption estimates reported for the tribal populations are plausible estimates that may represent estimates for subsistence fish consumers within the larger fish consuming population. Although these estimates are large, there is no compelling reason to designate them as implausible for fish consuming populations who obtain much of their protein from fish.
- Additional bias may be introduced into fish consumption estimates when adjustments are made only for large consumption rates. It is impossible to determine whether an estimate is

too high, too low or correct/accurate because the true estimate is unknown. If only the highest rates are adjusted downward, then the mean and the high end percentiles calculated after such an adjustment will be biased downward.

7.15 Suquamish tribal survey – Relationship to other surveys

Several people observed that the Suquamish fish consumption rates were much higher than the rates reported by other tribes in the Pacific Northwest. They noted that the differences were more pronounced when comparing the 95th percentile rates and expressed concerns that the 95th percentile values could be heavily influenced by a small number of individuals. For example:

Although the raw survey data have not been made available for at least some of the tribal fish consumption surveys, there are enough incongruities and inconsistencies in some of the published results of those studies to raise serious questions. Although I have no reason to single out any one survey as causing concern, the results of the Suquamish tribal survey are sufficiently different from those of the other tribal surveys to warrant careful consideration. As shown in Table 1 of Appendix C of the technical support document, the Suquamish tribal fish consumption rates are substantially higher than those of the other four surveyed populations. For example, the mean Suquamish rate is 214 g/day, whereas the mean rates for the other surveys range from 63 to 117 g/day. The difference in the 95th percentile rates is even more pronounced: 796 g/day for the Suquamish vs. 176 to 306 g/day for the other four surveys. It is not readily apparent why the Suquamish rates should be so much higher. The very high 95th percentile rate is especially of concern because such high percentile values are often used to identify a "reasonable maximum exposure". When the number of people surveyed is relatively small, 95th percentile values are based on the responses of a very few individuals. In the case of the Suquamish, for example, there were 92 adults surveyed. For this number of respondents, the 95th percentile rate falls between the rates reported by the respondents with the 5th and 6th highest consumption rates among all of the respondents; the rates for all other respondents may be much lower but they have no bearing on the absolute value of the 95th percentile consumption rate. The fact that the 95th percentile rate for the Suquamish tribe is much higher than the reported rates for most of the tribal population surveyed is especially apparent in cumulative frequency plots in the Suquamish report; the top six or so respondents reported eating far more seafood than most of the other tribal members. Thus, the 95th percentile consumption rate for the Suquamish survey represents only a few individuals within the tribal population. ***(McKrone)***

Ecology's Evaluation and Response: There is a wide diversity in fish consumption patterns and rates among different tribes. EPA has acknowledged this diversity when preparing various versions of the *Exposure Factors Handbook* (EPA, 2011). For example:

The Suquamish Tribe's seafood consumption rates for adults and children under six years of age represent the highest seafood consumption rates reported in studies conducted among the CRITFC, Tulalip Tribes, Squaxin Island Tribe, and the Asian Pacific Island population of King County (Suquamish, 2000). This disparity illustrates the high degree of variability found between tribes even within a small geographic region (Puget Sound) and indicates that exposure and risk assessors should exercise care when imputing fish consumption rates to a population of interest using data from tribal studies.

> *It is important to note that the report indicates that increased levels of development as well as pollutants from residential, industrial, and commercial uses have resulted in degraded habitats and harvesting restrictions. Despite degraded water quality and habitat, tribal members continue to rely on fish and shellfish as a significant part of their diet. [EPA, 2009)*

Ecology believes that the diversity in habitats and fish consumption rates and patterns should be considered when extrapolating the results from one population group to a second population group. Ecology previously addressed this issue when evaluating whether it is appropriate to use the survey results from the Suquamish Tribe to estimate the consumption rates for the Lower Elwha Klallam Tribe (LEKT) at the Port Angeles Harbor site. At this site, Ecology decided that the Suquamish study provided an appropriate basis for establishing a site-specific rate. At other sites, Ecology has concluded that the results from the Suquamish Tribe do not provide an appropriate basis for selecting site-specific fish consumption rates.

Ecology consulted with the MTCA Science Advisory Board when making this site-specific decision for the Port Angeles Harbor site. Ecology posed a series of questions for the Board's consideration. The first four questions and the Board's responses are particularly relevant to this issue. [13]

- Question 1: Ecology has concluded that the MTCA exposure parameters do not provide a reasonable basis for estimating fish consumption exposures for members of the Lower Elwha Klallam Tribe (LEKT). Does the Board believe this conclusion is consistent with current scientific information?

  > *Board Recommendation The Board agreed with Ecology's conclusion that the MTCA exposure parameters do not provide a reasonable basis for estimating fish consumption exposures for members of the Lower Elwha Klallam Tribe (LEKT) and that this conclusion is consistent with current scientific information.*

- Question 2: Is it scientifically defensible to use consumption surveys from other tribes with similar dietary habits to estimate fish and shellfish consumption exposures for members of the LEKT?

[13] http://www.ecy.wa.gov/programs/tcp/SAB/SAB_mtg_info/mtg_info.htm See page 3 of the March 11, 2008 meeting summary.

Board Recommendation: The Board concluded that it is scientifically defensible to use consumption surveys from other tribes with similar dietary habits to estimate fish and shellfish consumption exposures for members of the LEKT.

- Question #3: What factors should Ecology consider when evaluating whether it is appropriate to use consumption surveys from other tribes to estimate exposures for members of the LEKT?[14]

  Board Recommendation: The Board concluded that the factors identified by Ecology are adequate and appropriate for answering the questions that Ecology has presented to the Board. However, the Board concluded that there may be other factors to consider when evaluating this question.

- Question 4: Does the SAB believe it is scientifically defensible to use the fish consumption survey completed by the Suquamish Tribe to estimate fish and shellfish consumption exposures for members of the LEKT?

  Board Recommendation: The Board concluded that it is scientifically defensible to use the fish consumption survey completed by the Suquamish Tribe to estimate fish and shellfish consumption exposures for members of the LEKT.

7.16 Temporal variations in fish consumption rates

Several people expressed concerns about using the results from 24-hour recall surveys to estimate long-term average fish consumption rates. For example:

> ***Long-term average consumption rates:*** *Fish consumption rates for high consumers should be derived from surveys that provide distributions of long-term average rates for each individual rather than from short term dietary surveys such as those presented in USEPA (2002). Upper percentile values from short term surveys can markedly overestimate upper percentiles of long term average rates within populations.* ***(Barrette (PCSGA)/Schoof (Environ))***
>
> **********
>
> *Limitations of the Use of Short-Term Dietary Data for the General Population. The USDA dietary data do not provide a strong basis for estimating a long-term fish consumption rate to be used in developing the AWQC because of the way that the data were collected. This is particularly problematic when one attempts to use them to estimate high-end consumption rates.* ***(Attachment to Perlwitz (Nippon Paper))***

[14] Ecology prepared a short issue paper to support the Board's review and discussion. In that paper, Ecology listed several factors to consider when evaluating this question. In that paper, Ecology cited data hierarchy, study design, similarities in tribal dietary habits and customs, similarities in harvesting techniques, and similarities in wetlands.

****

Risks of concern for seafood ingestion include those that might result from life-long exposure. Fish consumption intake rates that are used for calculating fish consumption criteria must therefore represent an average daily intake over a long time period up to a lifetime, rather than a short-term (e.g., 24 hour period). Accurate measurement of usual daily food intake over a long term period is a difficult undertaking. ***(Johns and Garry (Exponent))***

Ecology's Evaluation and Response: Current health risk models are designed to evaluate health risks associated with exposure over long periods of time. Risk assessors typically use the results from short-term dietary surveys to characterize the amounts of fish and shellfish eaten on a regular basis over longer periods of time (years).

This approach can work well when average values are used in the health risk model. However, regulatory concepts like *reasonable maximum exposure* are based on the use of upper percentile values (e.g., 90th percentile or above). In these cases, extrapolation from short-term to long-term exposures becomes a little more complicated. The complications arise because the distribution of estimated fish consumption rates over a short period of time will tend to be more spread out than the actual fish consumption rates over a longer period of time. This means that estimates of the 95th percentile of the fish consumption rates observed over a short period of time (one or two days) will be higher than the 95th percentile of the average daily fish consumption over the longer periods of time considered in health risk assessments (years). This narrowing of the distribution of estimates is called *regression to the mean*.[15]

Ecology agrees that this is an important issue – particularly when evaluating the results from national dietary studies that employed one or more 24 hour recall surveys. Ecology re-evaluated the National Health and Nutrition Examination Survey (NHANES) fish dietary data using the National Cancer Institute's (NCI) statistical methodology. This evaluation is summarized in Technical Support Document Version 2.0. The full evaluation and results are present in "*Supplemental Information to Support the Fish Consumption Rates Technical Support Document*".

Ecology has also considered this issue when evaluating the fish consumption rate surveys. However, this does not present the same challenges as the national studies because fish and shellfish are a regular part of most tribal diets. Regional fish consumption survey designs have also included both a 24-hour recall survey and a food frequency questionnaire.

[15] Regression to the mean is encountered in many areas of science and everyday life. For example, baseball batting averages have a much larger distribution early in the season compared to the end of the season. The following case study illustrates the implications of this situation. There were 177 major league players with at least 400 plate appearances during the 2011 season. Consider the players' batting averages after their first game and at the end of the 162 game season. The first day estimates for the median and average provide a reasonably good estimate of those values for the whole season. However, the first day estimates for the 90th and 95th percentiles of the distribution of batting averages are much higher than the end-of-the season values. As with many situations, players who did extremely well on the first day of the season also had days where they were hitless. Conversely, players who went hitless on opening day had games later in the season where they had one or more hits.

Chapter 8: Comments on Issues Related to "Regulatory Context for Using Fish Consumption Rates" and "Site-Specific Fish Consumption Rates"

8.1 Overview

Chapter 5 of the Technical Support Document Version 1.0 summarized the Ecology regulatory requirements designed to prevent human exposure to contaminants in fish and shellfish. Ecology presented information on the Surface Water Quality Standards for the State of Washington (Chapter 173-201A WAC), the Sediment Management Standards (SMS) rule (Chapter 173-204 WAC) and the Model Toxics Control Act (MTCA) Cleanup Regulation (Chapter 173-340 WAC).

Chapter 6 of the Technical Support Document Version 1.0 described some of the factors that should be considered when establishing site-specific fish consumption rates. The chapter was oriented toward site-specific determinations to support MTCA cleanup decisions. The chapter discussed the reasonable maximum exposure (RME) concept, fish consumption rates, and other parameters (e.g., body weight, exposure duration, fish diet fraction) that are considered when preparing RME estimates.

Concurrent with the release of *Fish Consumption Rates Technical Support Document Version 1.0*, Ecology distributed draft SMS rule revisions for public and advisory committee review in October 2011. Many of the comments on Chapters 5 and 6 reflected concerns and questions surrounding how the information in the Technical Support Document would be used to support decisions under the SMS rule and other Ecology regulations. For example:

> *….many of the concerns raised in these comments stem from the lack of any indication on the part of Ecology about how these fish consumption rates will be used. The fish consumption rates cannot be fairly evaluated in a vacuum. It will only be possible to consider the full implications of the adoption of these fish consumption rates once Ecology has explained how they intend to use them.* ***(McKrone)***

In order to respond to the range of comments received regarding how fish consumption rates would be used by Ecology, comments related to the SMS rule revisions are consolidated in this chapter. The responses are organized in a way that recognizes the connections with related issues. The SMS rule was first adopted in 1991 and provides the primary regulatory foundation for sediment cleanup in Puget Sound and throughout Washington. The SMS rule works well when making decisions based on acute and chronic ecological risks to the benthic community

(sediment toxicity). However, Ecology has found that the existing SMS rule does not work as well where bioaccumulatives are chemicals of concern.

Ecology proposed revisions to the SMS rule on August 15, 2012.[16] The proposed SMS rule revisions address the challenges associated with cleaning up sediments that contain elevated levels of persistent bioaccumulative toxic chemicals. Key concepts that shaped the proposed SMS rule revisions include:

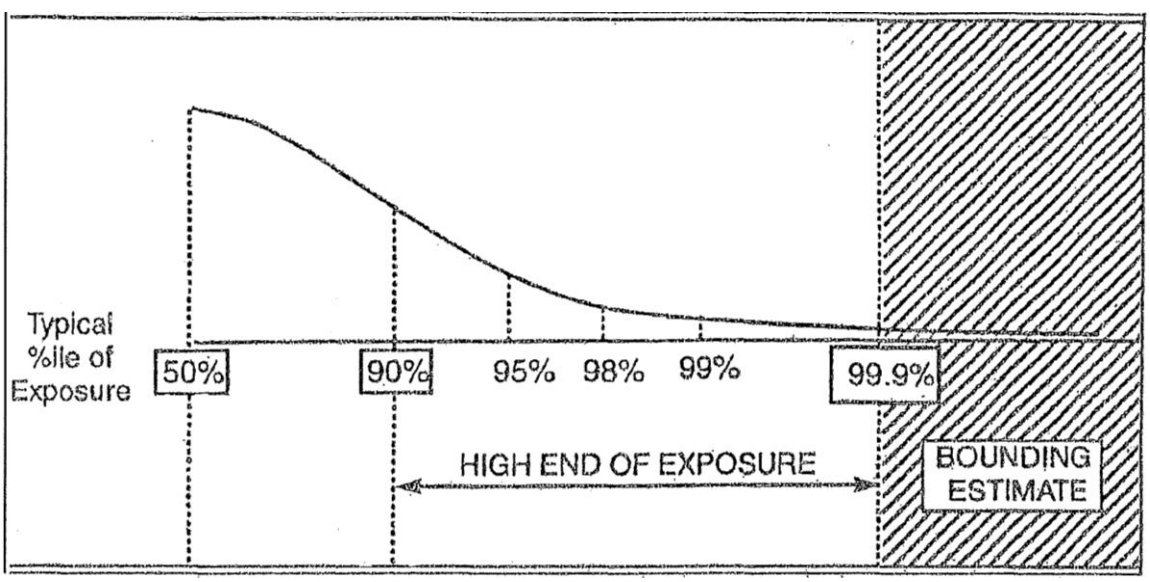
- Sediment cleanup actions are one part of a broader strategy needed to reduce bioaccumulative chemicals in the environment. The proposed SMS rule revisions reflect an understanding that sediment cleanup actions need to be integrated with (1) source control measures, (2) reducing the amounts of toxic chemicals used in various consumer products and manufacturing processes, (3) monitoring, and (4) researching how these chemical behave in the environment and affect living systems. Experience has shown that preventing exposure is the smartest, cheapest, and healthiest way to protect people and the environment.
- Significant progress on reducing exposure and health risks can best be served by a solutions-based decision framework for addressing existing cleanup sites. Current decision processes are focused on initially answering, "How large are the health risks?" or "How bad is the problem?" While these are important questions, an over-emphasis on problem definition can lead to extended cycles of analysis and re-analysis. Finkel (2011) has proposed a framework for fusing analysis and action that builds upon recommendations from the National Research Council (2009). The proposed SMS rule is intended to facilitate more timely cleanup solutions that fit within a broader strategy of reducing exposure to unhealthy levels of hazardous substances.
- Methods for establishing sediment cleanup standards based on human health protection need to be predictable, protective, and able to account for the diversity of cleanup sites in Washington. The proposed SMS rule includes a new section that integrates current SMS and MTCA requirements for establishing cleanup standards based on human health protection. Sections 8.2 through 8.10 of this chapter summarize and respond to comments that relate to how information on fish consumption rates would be used when making decisions around protecting human health at sediment cleanup sites.
- Requirements for establishing sediment cleanup standards need to take into account current analytical methods. The proposed SMS rule includes language for addressing situations where risk-based concentrations are below levels that can be detected or quantified using current analytical methods. Specifically, the proposed SMS rule revisions specify that the practical quantitation limit should be used as the cleanup standard when risk-based concentrations are below detection limits. Section 8.11 addresses comments related to this issue.

[16] Information on the proposed SMS rule revisions can be obtained at http://www.ecy.wa.gov/programs/tcp/regs/2011-SMS/2011-SMS-hp.html.

- Requirements for establishing sediment cleanup standards and selecting sediment cleanup actions need to take into account background levels of ubiquitous hazardous substances. The proposed SMS rule includes language that explains how background concentrations fit into the decision framework for establishing cleanup standards and selecting cleanup actions. Sections 8.12 through 8.14 summarize and respond to comments related to background concentrations and exposures.

8.2 Reasonable maximum exposure – Tribal exposure scenario

Cleanup standards under the state and federal cleanup programs are typically based on a reasonable maximum exposure (RME) scenario. The RME is designed to represent a high end (but not worst case) estimate of individual exposures. It provides a conservative estimate that falls within a realistic range of exposures. The RME is defined as reasonable because it is a product of several factors that are an appropriate mix of average and upper-bound estimates. RME estimates typically fall between the 90th and 99.9th percentile of the exposure distribution. This concept is illustrated in the figure below.



Adapted from Figure 5-1, EPA's Exposure Assessment Guidelines, 1992

The RME approach was discussed in Chapters 5–7 of the Technical Support Document Version 1.0 and concisely summarized by two people who provided comments on the document:

> *Regulatory criteria and associated risk assessment methods typically rely on the use of reasonable maximum exposure (RME) assumptions in order to provide a high degree of public health protection…[W]hen all assumptions are taken together, the resulting exposure*

estimate should be in the range of the 90th and 99.9th percentile. ***(Johns and Garry (Exponent))***

The key aspects of this issue are reflected in the following two questions posed by another person who provided comments on the Technical Support Document Version 1.0:

Should the default fish consumption rate be based on the 90th/95th percentile of the entire population of Washington State fish consumers? Or: [s]hould the default fish consumption rate be based on the 90th/95th percentile of high-end consumers? ***(Waldron (PTC))***

Ecology received numerous comments related to this issue. Chapter 3 of this Responses document organizes and summarizes those comments into the following categories:

- Establishing fish consumption rates based on high exposure population groups,
- Establishing fish consumption rates based on the general population,
- Selecting values from the distribution of individual rates in the chosen population group.

The following section provides responses to comments related to using an RME for establishing cleanup requirements under the MTCA and SMS rules.

Ecology's Evaluation and Response: Ecology announced and distributed proposed revisions to the SMS rule in August 2012. The proposed revisions include language stating that sediment cleanup standards should continue to be based on a RME scenario. The proposed rule revisions state that, except where Ecology approves an alternative exposure scenario, the RME should be based on tribal exposure. Ecology's rationale for this approach includes the following:

- This approach complies with the statutory requirements in the Model Toxics Control Act (MTCA). RCW 70.105D.030(2) directs Ecology to adopt rules under Chapter 34.05 RCW (the Administrative Procedures Act) to "...[p]ublish and periodically update minimum cleanup standards for remedial actions..." The cleanup standards must be at least as stringent as the cleanup standards established under the federal Superfund law. Federal cleanup standards are based on the RME concept.[17] EPA Region 10 uses a tribal exposure scenario to establish cleanup standards at Superfund sites in Puget Sound (EPA 2007).
- The vast majority of sediment cleanup sites are located in the Usual and Accustomed (U&A) or traditional fishing areas for one or more tribes. Ecology has identified over 150 sediment cleanup sites in Washington. Based on information compiled by the Washington State Department of Transportation (WSDOT 2008), the vast majority of these cleanup sites are

[17] The federal rule defines RME as "…the highest exposure that is reasonably expected to occur at a Superfund site..." The preamble to the federal rule (the National Oil and Hazardous Substances Pollution Contingency Plan) includes the following guidance:

"EPA defines reasonable maximum such that only potential exposures that are likely to occur will be included the in the assessment of exposures. The Superfund program has always designed its remedies to be protective of all individuals and environmental receptors that may be exposed at a site; consequently, EPA believes it is important to include all reasonably expected exposures in its risk assessments…"

located in the Usual and Accustomed (U&A) or traditional fishing areas for one or more tribes.

- This approach is consistent with advice from the MTCA Science Advisory Board. In 2008, Ecology asked the MTCA Science Advisory Board for advice on a site-specific fish consumption rate applicable to a cleanup action being conducted in the Port Angeles Harbor. The harbor is located within the U&A fishing area for the Lower Elwha Klallam Tribe (LEKT). The Board agreed with Ecology's conclusion that the recreational default fish consumption rate used in the MTCA Cleanup Regulation does not represent a RME scenario for Native American populations who often eat higher amounts of fish and shellfish than recreational anglers. [18]
- This approach is consistent with current site-specific decisions at MTCA sediment cleanup sites. The general MTCA requirements for cleanup standards (including the RME requirements) apply to soil, water, air and sediments.[19] Ecology currently establishes site-specific sediment cleanup requirements using a RME approach that reflects a tribal exposure scenario.[20]

8.3 Reasonable maximum exposure – General response

Ecology distributed draft SMS rule revisions for public and advisory committee review in October 2011. The October 2011 draft rule revisions include the following language:

> "Sediment concentrations that correspond to no significant human health risk shall be based on estimates of the reasonable maximum exposures expected to occur under both current and future site use conditions. For sites located within a tribal usual and accustomed fishing area, the reasonable maximum exposure scenario shall be based on tribal fish consumption rates. The department has developed a statewide default fish consumption rate of XXX g/day. The department may approve a site specific fish consumption rate."

(The draft distributed did not specify a default fish consumption rate; the draft included "XXX" to indicate this was still subject to ongoing analysis and dialog.)

[18] MTCA Science Advisory Board (SAB), Meeting Notes for SAB Meetings held December 14, 2007 and March 11 and June 2, 2008, http://www.ecy.wa.gov/programs/tcp/SAB/SAB_mtg_info/mtg_info.htm.

[19] See WAC 173-340-700 through WAC 173-340-710.

[20] Ecology has established (or is in the process of establishing) sediment cleanup requirements for a wide range of sites located in usual and accustomed fishing areas of one or more tribes. In these situations, Ecology has used a tribal exposure scenario to establish cleanup standards. Sites include, for example, Bellingham Bay (Whatcom Waterway), Port Gamble Bay, Lower Duwamish Waterway, and the former Rayonier mill site in Port Angeles.

Ecology received many comments on the need for site-specific evaluations and how such evaluations would be considered in relation to a default fish consumption rate. Those comments are compiled and summarized in Chapters 3 and 4 of this Responses document.

Ecology's Evaluation and Response: In July 2012, Ecology decided not to adopt a default fish consumption rate in the Sediment Management Standards (SMS) rule. Consequently, Ecology will continue to make site-specific decisions on fish consumption rates and other parameters associated with defining the reasonable maximum exposure scenario.

Ecology is preparing draft guidance materials to support site-specific evaluations and sediment cleanup standard determinations. The draft guidance (*Sediment Cleanup Users Manual II*) will provide direction on many of the issues summarized in Chapters 3, 4 and 7 of this Responses document. The guidance (once finalized) will not establish legally-binding requirements. Ecology and PLPs will have the option of proposing alternate ways to comply with the SMS rule requirements.

Data used to establish exposure scenario:

- Consumer Only vs Per Capita Data. To protect human health, Ecology currently establishes cleanup standards at individual cleanup sites based on exposure. That is, exposure scenarios take into account who is being exposed and how. Currently, this is based on exposure to people who consume fish and shellfish from the site. Ecology's rationale for continuing to use this "consumer only" approach includes the following:

  - This approach is consistent with MTCA statutory and regulatory policies and requirements. Using "consumer-only" rates to establish sediment cleanup standards is consistent with the MTCA policy statement that "…"[e]ach person has a fundamental and unalienable right to a healthful environment…"[21] This approach is also consistent with the MTCA directive that Ecology "…[p]ublish and periodically update minimum cleanup standards that are at least as stringent as the cleanup standards under section 121 of the federal cleanup law…"

  - This approach is consistent with the approach used to develop the EPA Region 10 Decision Framework. EPA used "consumer-only" data to establish the default fish consumption rates in the framework document. EPA uses this document to support cleanup decisions at federal sites in Puget Sound.

  - This approach is consistent with the Oregon Human Health Focus Group recommendations. The Oregon Human Health Focus Group reviewed this issue and recommended that the Oregon Department of Environmental Quality use "consumer-only" data to calculate fish consumption rates used to update the state's water quality standards.

[21] RCW 70.105D.010(1).

- This approach is consistent with recommendations from the National Environmental Justice Advisory Council (NEJAC). The NEJAC is a federal advisory committee that provides independent advice, consultation, and recommendations to the EPA administrator on matters related to environmental justice. NEJAC has criticized EPA for using "per capita" data when calculating fish consumption rates.

Ecology currently establishes cleanup standards at individual sites using "consumer-only" data from the four Pacific Northwest studies evaluated in the Technical Support Document. From a practical standpoint, there is generally not a large difference between the "per capita" and "consumer-only" fish consumption rates in those surveys because a high percentage of study participants reported they ate some amount of fish during the survey period. For example, the Columbia River Inter-Tribal Fish Commission (CRITFC) reported that ninety-three percent (93%) of the respondents were fish consumers. Consequently, the "per-capita" and "consumer-only" rates from the CRITFC study are virtually identical. The Oregon Human Health Focus Group reported that the fish consumption rates corresponding to the 90^{th} percentile of survey results were 170 grams/day (reported on a per capita basis) and 176 grams/day (reported on a consumer-only basis) (Oregon DEQ, 2008).

- Salmon. This is a complex issue. On the one hand, Ecology has information that people in the Northwest eat large amounts of salmon. On the other hand, Ecology also has information that shows that salmon spend a significant portion of their life in the open ocean outside Washington waters. Ecology's Toxics Cleanup Program believes that site-specific decisions must take into account both sets of information. The draft guidance, *Sediment Cleanup Users Manual II*, includes three main components relevant to this issue:

  - **Fish consumption rates**. Ecology's Toxics Cleanup Program believes that salmon should be considered when calculating site-specific fish consumption rates. The rationale for this approach includes the following:

    - People in the Pacific Northwest eat large amounts of salmon. The regional fish dietary surveys document that salmon are the most frequently consumed finfish and are consumed in the largest amounts of all finfish. This information was summarized in the Technical Support Document.

    - Salmon obtain some of their body burden from their river of origin. Research and agency evaluations indicate that salmon do obtain some of their body burden from their natal streams and estuaries during migration. (O'Neill et al, 1998)

    - Resident salmon ("blackmount") have higher contaminant levels than salmon that migrate to the open ocean. Salmon from Puget Sound that migrate to the open ocean and then return to Puget Sound streams to spawn have higher contaminant levels than salmon from elsewhere along the Pacific coast (California, Oregon, British Columbia or Alaska.)

  - Salmon have great cultural and economic importance for people living in Washington. Several people provided comments emphasizing the significant importance of salmon in the Pacific Northwest (See Chapter 4 of this Responses document).
  - This approach is consistent with the approach used by the State of Oregon. The Oregon Department of Environmental Quality adopted a revised fish consumption rate in 2011. The revised fish consumption rate includes salmon. EPA has reviewed and approved the Oregon rule under the federal Clean Water Act.

- **Site use factor.** Ecology also recognizes that some species of salmon and other anadromous species spend considerable portions of their lives in the open ocean and can obtain much of their body burden of bioaccumulative chemicals outside of Washington waters. Hope (2012) recently evaluated the implications of including salmon in the fish consumption rate used to establish Oregon's water quality standards. Ecology's Toxics Cleanup Program will evaluate using a separate factor (called the "site use factor") in the equation used to calculate risk based concentrations. The Toxics Cleanup Program believes this approach will provide a flexible way to take into account the complex life cycle of anadromous fish (salmon) while accounting for the diversity of aquatic habitats and the large range of possible chemical contaminants in sediments.
- **Locally or regionally harvested fish and shellfish.** Ecology's Toxics Cleanup Program believes that risk-based cleanup standards should be based on preventing site-related exposures. With this approach, the fish consumption rate used to establish risk-based cleanup standards should reflect locally or regionally harvested fish and shellfish. The Toxics Cleanup Program believes this approach is appropriate for making decisions on site-specific cleanup standards.
  - This approach is consistent with the approach in the EPA Region 10 framework document. EPA (2007) adjusted the total fish consumption rates to account for fish harvested and consumed from Puget Sound.
  - This approach is consistent with current scientific information. Available regional studies indicate that most (but not all) fish reported by the survey participants was from local sources.
  - This approach acknowledges that Washington has abundant fish resources, and that those resources are enjoyed by the people of Washington.
  - This approach is consistent with the current MTCA rule. The MTCA rule currently considers the fish diet fraction (FDF) when calculating site-specific surface water cleanup standards. The FDF is defined in the MTCA rule as "….the percentage of the total fish

and/or shellfish in an individual's diet that is obtained or has the potential to be obtained from the site."[22]

8.4 Reasonable maximum exposure – Level of conservatism

The MTCA Cleanup Regulation defines Reasonable Maximum Exposure (RME)as "the highest exposure that is reasonably expected to occur at a site under current and potential future site use." The RME is designed to represent a high-end (but not worst-case) estimate of individual exposures.[23] It provides a health-protective estimate that falls within a realistic range of exposures. The RME is defined as reasonable because it is a product of several factors that are an appropriate mix of average and upper-bound estimates. RME estimates typically fall between the 90th and 99.9th percentile of the exposure distribution.

Several people expressed concerns that Ecology would adopt a higher fish consumption rate and then reduce the protectiveness of other factors used to establish risk-based cleanup standards. For example:

> ***Tribes assume that an increase in the fish consumption rate that is protective of human health will not coincide with a reduction of other protective factors affecting the standards.*** *For example, the target cancer risk level should not be relaxed as a condition of a more protective fish consumption rate. Fish consumption rates are part of a complex formula to address the potential risk from toxic chemicals that is used for toxic cleanup and water quality standards. A statement of assumptions about other relevant risk factors should be included in the document along with the basis for these assumptions.* ***(Frank (NWIFC))***
>
> **********
>
> *Finally, the previously mentioned health risk equation includes several other variables like dietary fraction, exposure duration, body weight, and inclusion/exclusion of nonconsumers. They are included in the calculation to ultimately determine the acceptable level of toxic constituents in the environment.*
>
> *None of the additional variables should be changed in any way to dilute the increased health safety provided by a higher fish consumption rate. In particular, our strong preference is that there be no risk of cancer from eating our finfish and shellfish. However, when approached*

[22] WAC 173-340-708(10)(b).

[23] The worst-case exposure represents an extreme set of exposure conditions, usually not observed in an actual population, which is the maximum possible exposure where everything that can plausibly happen to maximize exposure does happen. This is discussed in EPA's *Guidelines for Exposure Assessment*, Federal Register Vol. 57, No. 104, May 1992, pages 22888-22938.

from a regulatory standpoint, we insist that the cancer risk rate used in the equation remain at the lowest rate allowed. ***(Squaxin Island Tribal Council)***

Conversely, a number of other people expressed concerns that Ecology was evaluating revisions to the default fish consumption rate in isolation from other exposure factors, toxicity parameters, and agency risk policy determinations. In their opinion, this approach will produce overly conservative exposure scenarios and regulatory requirements. For example:

*Inherent conservatism applied throughout risk models and methods used to determine sediment cleanup requirements and water quality standards make use of a high FCR unnecessary. See the report titled "Evaluation of the Fish Consumption Rate....." dated May 2003 by AMEC which is attached. The conservatism applied throughout the fish ingestion survey process and the ultimate human health risk analysis make selection of a FCR in the range of 157 to 267 grams per day (g/day) an excessive value for use in state wide cleanup decisions or water quality.****(Perlwitz (Nippon Paper))***

****

As it currently exists, the risk assessment methodology used to develop environmental standards utilizes conservative assumptions. For example, the methodology for calculating risks due to carcinogenicity assumes that fish are consumed at the default rate every day for 70 years. Likewise, the dose of each chemical that is considered to be protective at a given risk level is chosen in a manner that ensures a high margin of safety. Finally, for general populations the chosen level of risk is typically one in one million. This is an exceedingly small risk, especially in light of a current lifetime cancer incident rate due to all causes of about 40% (400,000 in one million). ***(Louch and Stratton (NCASI))***

****

Risk Assessment Issues Identified During Ongoing Sediment Cleanups. *In addition to providing a framework for the selection of seafood consumption rates, the EPA Region 10 Tribal Framework also includes assumptions and guidance on how the consumption rates will be applied in human health risk assessments (a key technical and regulatory issue). Concerns regarding whether sediment cleanup level may represent more of a worst-case scenario as opposed to a RME are highlighted by ongoing Puget Sound EPA-led cleanups as well as recent EPA presentations in which EPA has specified that site specific risk assessments under the Region 10 Tribal Framework include the following assumptions: 1) harvested fish and shellfish represented by consumption rate are assumed to have originated at the site and could be impacted by site-related contaminants; the same consumption rate is used regardless of the site size and its proximity to actual seafood harvest areas, 3) use of the same overall consumption rate regardless of species actually present at the site (a secondary related assumption is that Tribes will harvest alternate species if desired species are not present), and 4) an adopted exposure duration of 70 years, rather than EPA typical default value of 30 years to account for Tribal lifestyles. Routine application of the EPA Region 10*

Tribal Framework risk assessment approach will result in overly conservative sediment cleanup levels that represent more of a worst-case scenario than a RME developed under MTCA (Chapter 5, EPA Region 10 Framework, pages 78 through 79, Chapter 6, Fish Diet Fraction, page 98, first bullet). ***(Matsushita (Lockheed Martin))***

Ecology's Evaluation and Response: These comments raise several important issues related to the level of "conservatism" associated with the methods used to establish site-specific cleanup standards under the MTCA and SMS rules. Ecology uses a risk assessment approach to establish cleanup standards based on human health protection. Risk-based concentrations can be calculated for both cancer and non-cancer health effects using standard risk assessment equations Human health risk assessment is complicated by scientific uncertainties and variability in exposure and susceptibility. There are often several plausible scientific options for resolving specific issues. Given the uncertainty and variability in current risk assessments, it is not surprising that there is a range of opinion on the appropriate level of conservatism. As noted in the above comments, some people believe Ecology is being too conservative and some people believe Ecology is not being conservative enough.

Ecology thinks the advice from John Calipari (University of Kentucky basketball coach) is particularly relevant to the question of conservatism. Mr. Calipari has noted that "…things are never as good as they seem, things are never as bad as they seem – reality is somewhere in between…" In particular:

- Things are never as good as they seem and conservatism or precaution in the face of scientific uncertainty is consistent with the MTCA statutory directives. MTCA states that "[e]ach person has a fundamental and unalienable right to a healthful environment…" To fulfill this mandate, Ecology's Toxics Cleanup Program has established methods and procedures that will result in cleanup levels that protect the whole population – including susceptible or high exposure population groups such as children, pregnant women, etc. Ecology believes that the use of conservative assumptions is consistent with this statutory directive. Indeed, the statutorily mandated MTCA Policy Advisory Committee recommended 2that Ecology "…err on behalf of protection of human health and the environment" (MTCA PAC, 1996).
- Things are never as bad as they seem and choices on individual exposure parameters need to take into account the cumulative impact of those individual choices. Selection of upper percentile values for all exposure parameters can produce a risk estimate that does not represent a reasonable maximum exposure scenario. The importance of this issue has been discussed in several evaluations of risk assessment methods prepared by the National Research Council (NRC, 1994; NRC, 2009) and the Environmental Protection Agency (EPA, 2004). With this in mind, it is important that agencies select fish consumption rates that are consistent with choices on other exposure parameters.

Ecology plans to seek further advice on this topic as the Toxics Cleanup Program revises the SMS rule, develops implementation guidance, and performs evaluations to support site-specific cleanup decisions.

8.5 Reasonable maximum exposure – Fish diet fraction

Many people submitted comments on the importance of distinguishing between locally harvested and store-bought fish when making regulatory decisions. There are several approaches used by regulatory agencies to address this issue. For cleanups conducted under the Model Toxics Control Act, Ecology uses a fish diet fraction (FDF) when calculating surface water cleanup standards. The fish diet fraction (FDF) is defined in the MTCA Cleanup Regulation as "….the percentage of the total fish and/or shellfish in an individual's diet that is obtained or has the potential to be obtained from the site..." The MTCA Cleanup Regulation establishes a default fish diet fraction of 50%. This value was selected based on a recreational fisher exposure scenario. However, the rule provides the flexibility to modify the fish diet fraction when necessary to establish a more stringent cleanup level to protect human health.[24]

Several people provided comments on the definition and use of this factor when establishing sediment cleanup standards. Some people recommended that the default fish diet fraction for a tribal scenario should be 100%. For example:

> *The diet fraction from the site should be based upon how much fish could be acquired from the restored site or 100% as default.* ***(Dunn (LEKT))***

Several other people recommended that Ecology continue to use the MTCA default value (50 percent) as the default fish diet fraction when implementing the SMS rule revisions. For example:

> *In my view the only other parameter that should be considered as a "default" is the default Fish Diet Fraction (i.e., the amount of shellfish + finfish consumed from a contaminated source). I would recommend that this value remain at 0.5 -- and be modified based on the regulatory program. For example, the Fish Diet Fraction for MTCA/SMS sites should be based on the relative size of the site.* ***(Waldron (PTC))***
>
> **********
>
> *We also ask that Ecology maintain the current fish diet fraction of .5. Given the wide range of sources (including supermarkets and imported fish) that we all use to obtain fish and shellfish for consumption, we think it is not accurate to assume that an individual would obtain 100 percent of his or her diet of these species from a single, small geographic area, except for the most vulnerable populations who rely on subsistence fishing in a specific area.*

[24] WAC 173-340-708(10)(b).

> *However, given that the number Ecology will be adopting is a default number applicable to all Washington citizens in all situations, we ask that Ecology not adopt a fish diet fraction that only represents one part of Washington's diverse fish eating population.* ***(Smith (Port of Olympia))***

Several people recommended that Ecology provide the flexibility to consider site-specific and species-specific differences in fish diet fraction. For example:

> *Regarding diet fraction and other modifying assumptions, we would suggest that any use of fish consumption rates must also consider context. In most cases, it is not realistic to assume that an individual would obtain 100 percent of their diet from one small geographic area. Many of the sites addressed under SMS simply could not support the types and quantities of fish and shellfish suggested by the high consumption rates proposed in the new default range. Therefore, the recommendations section should explicitly emphasize modifying assumptions (including diet fraction) in any application of fish consumption rates. This is especially important given the very high rates recommended by Ecology in the draft document.* ***….*** *If higher consumption rates are directly incorporated into the regulations, then sufficient detail will be required to clarify the various types of seafood associated with each consumption rate, potential receptor population and site condition. Also, site-specific adjustments of the consumption rates and diet fractions may be required.* ***(Hellman (WPPA))***

Ecology's Evaluation and Response: Ecology is currently preparing draft guidance for sediment cleanup (*Sediment Cleanup Users Manual II*). Ecology plans to post an initial draft of the guidance in September, 2012. Although it is a work in progress, Ecology decided to post the draft guidance to help people reviewing the proposed SMS rule revisions understand how the proposed revisions would be implemented.

The draft guidance provides flexibility for adjusting the fish consumption rate to reflect locally or regionally harvested fish and shellfish. The range of approaches includes the use of the FDF concept and an initial FDF of 100%, consistent with a tribal use scenario. However, this value is not a legally-binding requirement and can be reduced based on site-specific considerations.

It is important to keep in mind that the fish diet fraction focuses on people. (That is, where do people get the fish they are eating?). Several factors should be considered when deciding whether to use a FDF of less than 100%, including whether the site-specific fish consumption rate is based on the total amount of fish consumed or on locally- or regionally-harvested amounts. In the latter situation, use of a fish diet fraction of less than 100% would not be appropriate because the source of fish and shellfish has already been taken into account when selecting the fish consumption rate.

8.6 Reasonable maximum exposure – Exposure duration

Under the MTCA Cleanup Regulation, Ecology assumes an exposure duration of 30 years when calculating ground water, surface water, and air cleanup standards based on carcinogenic risks. The default exposure duration was established in 1991 and was based on the 90th percentile of the distribution of residential occupancy time (how long people live in the same house).

Several people provided comments expressing opinions on the appropriate exposure duration to be used when establishing cleanup standards. For example:

> *Exposure duration should be 70 years tribal members don't leave their U&A and most don't move far from the reservation due to service availability. Many Northwest people stay in the northwest most of their lives, even expatriates tend to return eventually.* ***(Dunn (LEKT))***

****

> *As it currently exists, the risk assessment methodology used to develop environmental standards utilizes conservative assumptions. For example, the methodology for calculating risks due to carcinogenicity assumes that fish are consumed at the default rate every day for 70 years….* ***(Louch and Stratton (NCASI))***

Ecology's Evaluation and Response: The 30-year exposure duration in the MTCA Cleanup Regulation is consistent with more recent information on population mobility. EPA has evaluated that information and published new estimates for current residence time[25] in the updated *Exposure Factors Handbook* (EPA, 2011). EPA concluded:

> *The 50th and 90th percentiles for current residence time from the U.S. Census Bureau (2008a) are 8 years and 32 years, respectively.* ***(EPA, 2011)***

Ecology recognizes that an exposure duration of 30 years may not accurately represent the length of residency for population groups (such as tribal members) who remain in communities for longer periods of time. It is also important to recognize that EPA values do not distinguish between people who moved to a different residence in the same county from those who moved to other areas, states or countries. Table 16-117 in EPA (2011) indicates that 65% of people who moved during the year 2006-2007 moved to a residence located within the same county.

Ecology is currently preparing draft guidance for sediment cleanup (*Sediment Cleanup Users Manual II*). Consistent with a tribal use scenario, the draft guidance assumes an exposure duration of 70 years when calculating cleanup standards based on carcinogenic risks. This is consistent with EPA guidance and the approach used by the Oregon Department of Environmental Quality. However, Ecology also recognizes that the use of a 70-year exposure

[25] Note: Risk assessors generally use current residence time (time since moving into current residence) as a substitute for the average total residence time (time between moving into and out of a residence).

duration may lead to exposure estimates that exceed the reasonable maximum exposure when one considers the full range of parameters used to prepare exposure estimates.

8.7 Reasonable maximum exposure – Body weight

One person commented on the body weight assumptions used to calculate risk-based cleanup standards.

> *Body weight is another problematic issue since the average body weight of an adult in the US has gone up considerably in recent years. According to the reports published by the Centers for Disease Control and Prevention (CDC), average body mass index BMI, has increased among American adults from approximately 25 in 1960 to 28 in 2002. BMI is a weight-for-height formula used to measure obesity. Study reports show that the average American man's (20-74 years old) height has increased from 5'8" to 5'9½", while the average height of an American woman of the same age has increased from 5'3" to 5'4". But in the meantime, average American male weight (aged 20-74 years) has increased dramatically from 166.3 pounds to 191 pounds and the average American female weight (of the same age) has increased from 140.2 pounds to 164.3 pounds.* ***(Dunn (LEKT))***

Ecology's Evaluation and Response: Ecology agrees that average body weights in the United States are increasing. EPA has compiled and evaluated more recent information on body weights collected as part of the National Health and Nutrition Examination Survey (NHANES) 1999−2006. Based on more recent data, EPA concluded:

> *[Table 8-1 shows] the mean body weight for all adults (male and female, all age groups) combined is 80 kg. Section 8.3 presents percentile data.* ***(EPA, 2011)***

Ecology also believes that it is important that the body weight assumptions used to calculate risk-based cleanup standards are consistent with the information used to establish fish consumption rates and information and trends in body weight. EPA also emphasized this point:

> *The mean recommended value for adults (80 kg) is different from the 70 kg commonly assumed in U.S. EPA risk assessments. Assessors are encouraged to use values that most accurately reflect the exposed population. When using values other than 70 kg, however, the assessors should consider if the dose estimate will be used to estimate risk by combining it with a dose-response relationship that was derived assuming a body weight of 70 kg. If such an inconsistency exists, the assessor may need to adjust the dose-response relationship as described in the appendix to Chapter 1.*
>
> *Use of upper percentile body-weight values are not routinely recommended for calculating ADDs [average daily doses] because inclusion of an upper percentile value in the denominator of the ADD equation would be a non-conservative approach. However, Section 8.3 provides distributions of body-weight data. These distributions may be useful if probabilistic methods are used to assess exposure. Also, if sex-specific data are needed, or if*

data for finer age bins are needed, the reader should refer to the tables in Section 8.3. ***(EPA, 2011)***

8.8 Default rate as a minimum rate

Ecology distributed preliminary draft SMS rule revisions for public and advisory committee review in October 2011. The October 2011 preliminary draft rule revisions include the following language:

> "Sediment concentrations that correspond to no significant human health risk shall be based on estimates of the reasonable maximum exposures expected to occur under both current and future site use conditions. For sites located within a tribal usual and accustomed fishing area, the reasonable maximum exposure scenario shall be based on tribal fish consumption rates. The department has developed a statewide default fish consumption rate of XXX g/day. The department may approve a site specific fish consumption rate."

Several people recommended that, when addressing cleanup of contaminated sediments, Ecology only approve site-specific fish consumption rates that are more protective than the default value. For example:

> *The Report states that "[a] site-specific fish consumption rate may be needed when default exposure parameters do not adequately protect the fish-consuming population in question." Report at 92. The Washington Waterkeepers agree that this is an appropriate circumstance for adopting a site specific rate. The Report does not, however, address the question of whether a site specific rate could be used when a third-party asks Ecology to evaluate whether the default rate is too protective of a specific area (i.e., a survey or other information indicates a lower fish consumption rate than the state-wide default rate). Due to the inherent challenges of accounting for suppression effects, the Washington Waterkeepers urge Ecology to revise the Report to clarify that site specific rates are only appropriate for the purposes of protecting populations where the default rate is under protective.* ***(VandenHeuvel (Waterkeepers))***
>
> **********
>
> *Tribal usual and accustomed fishing and harvesting areas were established by treaty; degradation of these areas prevents the full exercise of treaty and trust protected rights. Tribes are unable to adjust the location of fish and shellfish harvest if areas are contaminated or otherwise degraded. The Technical Support Document contains a section about the possibility of site-specific fish consumption rates (p 92) but does not specify criteria or how this option would be applied. Tribes assume that site-specific rates would be more protective than default rates throughout tribal usual and accustomed areas.* ***(Frank (NWIFC))***

Other people expressed that the use of a single default fish consumption would lead to situations where the default rate exceeded the sustainable harvest levels. They recommended that Ecology provide the flexibility to address these situations. For example:

King County is concerned that the proposed consumption rates may exceed sustainable harvest levels in some cases. In particular, small streams and lakes are unlikely to sustain harvest rates of 157-267 grams/day. King County encourages Ecology to work with fisheries managers and consider sustainable harvest rates in setting criteria for a specific waterbody. ***(True (King County DNRP))***

Ecology's Evaluation and Response: In July 2012, Ecology decided not to propose adding a default fish consumption rate to the Sediment Management Standards (SMS) rule. Consequently, Ecology will continue to make site-specific decisions on fish consumption rates and other parameters associated with defining the reasonable maximum exposure scenario.

Ecology believes that many of the comments remain relevant to site-specific decisions since there are many default assumptions embedded in standard risk assessment methods. The National Research Council (NRC, 2009) discussed the use of default assumptions in their recent report *Science and Decisions: Advancing Risk Assessment*. The NRC provided several recommendations to EPA on this issue that are relevant to how Ecology's Toxics Cleanup Program implements the MTCA and SMS rules.

- *EPA should continue and expand use of the best, most current science to support or revise its default assumptions.*
- *EPA should work toward the development of explicitly stated defaults to take the place of implicit or missing defaults.*
- *In the next 2-5 years, EPA should develop clear criteria for the level of evidence needed to justify use of alternative assumptions in place of defaults.*
- *When none of the alternative risk estimates achieve a level of plausibility sufficient to justify use in place of a default, EPA should characterize the uncertainty associated with the use of default assumptions.*
- *When EPA elects to depart from a default assumption, it should quantify the implications of using an alternative assumption, including describing how use of a default and the selected alternative influences the risk estimate for risk management options under consideration.*
- *EPA needs to more clearly elucidate a policy on defaults and provide guidance on its implementation and on evaluation of its impact on risk decisions and on efforts to protect the environment and public health.* ***(NRC, 2009)***

Ecology plans to issue guidance for establishing sediment cleanup standards based on human health protection. Ecology believes that a certain amount of flexibility is needed to address site-specific issues at MTCA sediment cleanup sites. Flexibility is important for considering questions around the size of a water body, current and future habitat, resource abundance and the variability of fish species present at individual sites.

8.9 Chemical uptake in fish and shellfish

Several people recommended that Ecology describe how chemicals are taken up by fish and shellfish and the process that agencies use to estimate human exposure. For example:

> ***….****chemical uptake into fish is a variable function of combined exposures to chemicals in diet, sediment and water. Because Ecology intends to apply fish consumption rates in the context of regulations of chemicals in water and sediment, we recommend that Ecology add a section to the fish consumption TSD describing how the bioaccumulation of chemicals in fish varies by the concentration of the contaminant in water, the type of organism, and the trophic level of the fish species. Historically, water quality criteria have been derived using overly simplistic assumptions that chemical concentrations in surface water can be related to fish concentrations by applying a bioconcentration factor (BCF) with fish consumption rates. As described in USEPA (2007a), bioaccumulation should be represented by a regression equation or some other algorithm rather than a simple constant. Ideally this discussion would come early in the document to provide perspective for the regulatory discussion. Ecology's discussion of exposure parameters (page 96) should also include some mention of how chemical concentrations in fish are predicted. An understanding of factors controlling chemical uptake into fish is crucial to identification of fish consumption rates that are relevant for the various regulatory contexts in which Ecology will apply them.* ***(Barrette (PCSGA)/ Schoof (Environ))***

Ecology's Evaluation and Response: Ecology agrees that this is an important issue and flexibility is needed to address the variability in chemical uptake across species and contaminants. The topic of bioaccumulation is touched on in the revised Technical Support Document (Version 2.0); Ecology has developed initial guidance on this topic and plans to work with the MTCA Science Panel to expand the guidance to support site-specific cleanup decisions.

8.10 Relationship to risk policies

Several people noted that regulatory requirements based on human health protection require several technical and policy choices. Some of these people stated that is not reasonable to decouple consideration of the fish consumption rate questions from decisions on target risk levels. They recommended that Ecology evaluate the appropriate risk level concurrently with the evaluation of fish consumption rates. For example:

> *I am writing to provide limited comments on the seafood consumption rate issues that Ecology is currently evaluating. My primary comment relates to the linkage between consumption rates and risk range. In the past, Ecology has recognized that a consumption*

rate that is more representative of what the general population consumes may be appropriately used when it is paired with a 10-6 risk level. This is because higher consumers are likely protected within the risk range recognized as protective (e.g., 10-5 to 10-6 in the Clean Water Act, and 10-4 to 10-6 in CERCLA). Ecology has opted to use the more protective end of those risk ranges in MTCA and in its water quality standard-setting efforts, but has in the past recognized that a consumption rate representative of the general population can then be used because sub-populations that consume at higher rates will still be protected within the risk range generally accepted as "safe" nationally. ***(Newlon, (Stoel Rives))***

****

The City is concerned that Ecology is moving towards a very significant change in the way human health based surface water quality criteria are established. Specifically, Ecology is keeping the risk range constant at one in a million, but changing from applying it to average consumers to applying it to high end consumers in high consuming groups. [end paragraph]

The fish consumption data presented provides a basis to compare our existing criteria with EPA's Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). EPA's methodology says that average consumers should be protected at the 10-6 or 10-5 level and high end consumers should be protected at least to the 10-4 level. Our existing human health based water quality criteria meet the intent of EPA's methodology. Because people have a range of fish consumption rates, it is not possible or practical to establish one risk level applicable to all consumption rates. Consequently, regardless of the fish consumption rate basis for a criteria, those who consume less will be protected at a higher rate and those who consume more will be protected at a lesser rate. EPA recognizes this and sets certain boundaries where criteria are protective and where criteria may need to be tightened. Our current criteria appear to be protective and to not require tightening. ***(McClellan (Everett Public Works))***

****

We have a similar concern in what appears to be the de-coupling of the fish consumption rate from the applicable risk range. In the past, EPA and Ecology have chosen a consumption rate that the general public as a whole would not often exceed, but then used a very protective risk level (10-6). The risk level protects high consumers, despite the fact that the consumption rate reflects the more general population. It appears Ecology has de-coupled the risk range from the consumption rate, and instead decided to adopt both a risk range and a fish consumption rate geared to protect the highest fish consumers. The original 10-6 decision on water quality standards was made with more of a general population level consumption rate, and a recognition that the smaller percentage of the

population that consumes at much higher levels will be protected by the more stringent risk range. If Ecology independently changes the consumption rate without also re-visiting the risk level/risk range, we could well end up with the very stringent and ultimately unattainable standards that some fear could come out of this process. In the context of the water quality program, it is particularly concerning if unachievable standards are adopted, as the Clean Water Act's citizen suit provisions expose parties who are doing all they can to meet the unachievable standards to potentially costly law suits. ***(Smith (Port of Olympia))***

Others opposed or expressed concerns about modifying the target cancer risk levels used to guide regulatory decisions. For example:

Relatedly, it is not appropriate for Ecology to increase its default FCR but then redefine the level of risk it would find "acceptable," thereby tolerating an order or two of magnitude greater risk for those most exposed. This end-run around the more protective environmental standards that would result from an increased FCR has been suggested in public comments. Such an argument might be entertained, again, if we thought everyone were equally likely to be exposed to this greater risk. But here in Washington we know that this is not the case. We know precisely who it is that consumes greater quantities of fish. In this case, an argument for redefining the acceptable level of risk becomes unconscionable. ***(O'Neill (Seattle Univ.))***

****

None of the additional variables should be changed in any way to dilute the increased health safety provided by a higher fish consumption rate. In particular, our strong preference is that there be no risk of cancer from eating our finfish and shellfish. However, when approached from a regulatory standpoint, we insist that the cancer risk rate used in the equation remain at the lowest rate allowed. ***(Squaxin Island Tribal Council)***

Ecology's Evaluation and Response: Ecology agrees that decisions on fish consumption rates should be made in the context of other regulatory policy choices (including target cancer risk levels). Comments on the Technical Support Document reflect a wide range of ideas on the relationship between choices on fish consumption rates and target cancer risk levels.

Several people have suggested that Ecology could establish different target risk levels for the general population and high exposure groups. EPA guidance under the Clean Water Act provides the flexibility to adopt this type of approach. However, for decisions related to establishing cleanup standards, the Toxics Cleanup Program believes this approach is inconsistent with the MTCA statute which states that "[e]ach person has a fundamental and unalienable right to a healthful environment…" [26]

[26] Several people also suggested that Ecology consider (1) establishing different target cancer risk levels for different chemicals and/or (2) providing the flexibility to establish cleanup standards using a target cancer risk level of one in ten thousand (10-4).

Ecology described an option in Technical Support Document Version 1.0 where RME determinations would be linked to the target cancer risk level. Under this option, the policy choice on how to handle exposure variability (for example, the choice of a 90th percentile fish consumption rate vs a 95th percentile value) would consider the target cancer risk level being used to establish cleanup standards. This approach has been adopted by the Oregon Department of Environmental Quality. The Oregon DEQ guidance document on probabilistic risk assessment (Oregon DEQ, 1999) established a policy that used different statistical metrics (percentiles) for different target risk levels. For example, DEQ states "…[f]or individual carcinogens, a lifetime excess cancer risk for each carcinogen of less than or equal to one per one million at the 90th percentile, and less than or equal to one per one hundred thousand at the 95th percentile, each based upon the same distribution of lifetime excess cancer risks for an exposed individual…" (OAR 340-122-115(2)(b)).

The Toxics Cleanup Program believes the Oregon DEQ approach has merit and plans to explore this further as the program develops guidance for implementing the SMS rule revisions.

8.11 Polychlorinated bi-phenyls (PCBs)

Several people provided general comments and opinions on the relationship between risk-based concentrations calculated using a revised fish consumption rate and background concentrations. One person provided recommendations on the appropriate methodology for characterizing PCB levels in fish tissue.

> *Have any studies been performed that focus on particular PCB congeners found in fish tissue that cause cancer risk in humans? It is our understanding that not all PCB congeners are hazardous to human health. Fish tissue should be analyzed for presence of the same PCB congeners that pose a human cancer risk.* ***(Arnold (City of Spokane))***

Ecology's Evaluation and Response: This comment highlights the importance of using up-to-date analytical methods to measure contaminants such as polychlorinated biphenyls (PCBs) in environmental samples. In some situations, risk-based concentrations are below levels that can be reliably measured with current analytical methods. In these situations, the practical quantitation limit (PQL) is used to evaluate compliance with cleanup standards established under the MTCA and SMS rules.

Polychlorinated biphenyls (PCBs) are a group of synthetic organic chemicals that include 209 individual chlorinated biphenyl compounds (known as congeners). Commercial mixtures of PCBs were manufactured in the United States from about 1930 to 1977 under the trademark

"**Aroclor**" followed by a four digit number.[27] PCBs were used as coolants and lubricants in electrical equipment, such as capacitors and transformers, because of their inflammability, chemical stability, and insulating properties. There are no known natural sources of PCBs.

There are two general approaches for evaluating health risks associated with environmental concentrations of PCBs:

- **Aroclor analyses:** PCB toxicity can be assessed by measuring total PCBs in a sample and calculating risk-based concentrations using the cancer slope factor for PCBs published in EPA's Integrated Risk Information System (IRIS) database. Compliance is evaluated using standard methods (e.g., EPA Methods 8080 and 8081) that involve the use of gas chromatography/electron capture detection systems (GC/ECD). Total PCB concentrations are estimated by comparing the chromatographic pattern of peaks in the environmental sample with the pattern or number of peaks in a commercial Aroclor sample.
- **Congener-specific analyses:** PCB toxicity can also be evaluated using a toxic equivalency factor (TEF) approach similar to the approach used for dioxin/furan mixtures. Ahlborg et al (1994)[28] concluded that TEFs are applicable to certain PCBs that display dioxin-like properties because they share a common mode of action with TCDD.[29] In 1998, the World Health Organization's (WHO) European Centre for Environmental Health (ECEH) and International Programme on Chemical Safety (IPCS), developed TEF values for dioxin-like PCB congeners. Those values were updated in 2005 (Van den Berg et al, 2006)[30]. PCB congeners are analyzed using high resolution gas chromatography/mass spectrometry (GC/MS) methods. These methods are more sensitive (provide lower detection limits) than the GC/ECD method typically used for Aroclor mixtures.

There are two reasons why the more sensitive analytical methods are needed to adequately evaluate health risks. First, congener-specific information is needed to assess dioxin-like toxicity. Second, the lower detection achieved with the GC/MS methods are needed to determine whether PCBs are present at concentrations above risk-based standards.

In many cases, the PCB detection limits associated with GC/ECD can be one or more orders of magnitude above risk-based concentrations. However, the more sensitive GC/MS method (@ $900/sample) is more expensive than the GC/ECD method (@$200/sample).

---

[27] The first two digits usually indicate the parent biphenyl molecule and the last two digits indicate the percent chlorine by weight For example, Aroclor 1260 contains 12 carbon atoms (parent biphenyl molecule) and approximately 60 percent chlorine by weight. Aroclor 1016 is an exception to this nomenclature scheme, as it contains 12 carbon atoms and contains over 41 percent chlorine by weight.

[28] The results of the 1991 EPA workshop were published in this peer-reviewed technical publication.

[29] Dioxin-like toxicity (as evaluated with TEF methodology) is an important component of PCB toxicity that should be considered when evaluating these mixtures. However, the TEF approach only evaluates the toxicity of the dioxin-like PCB portion of the PCB mixtures. Available research indicates that there are multiple modes of action involved in PCB toxicity. Consequently, risk assessments need to consider dioxin-like and non-dioxin-like toxicity.

[30] This peer-reviewed publication is the technical standard for using WHO-recommended TEFs for polychlorinated dibenzo-*p*-dioxins and dibenzofurans and dioxin-like PCBs.

Over the last 30 years, most of the surface water, sediment, and fish tissue collected in Washington have been analyzed using the GC/ECD method. Detection limits often exceed health-based standards. However, there is increasing use of the more sensitive GC/MS method in more recent studies. Ecology's Environmental Assessment Program has analyzed fish tissue and surface water in freshwater environments using the GC/MS method.

8.12 Background concentrations and exposures

Several people noted that the risk-based concentrations calculated for many hazardous substances are below natural background concentrations even when calculations are based on the current default fish consumption rates. Given those results, they questioned why Ecology is evaluating the use of higher fish consumption rates when such changes could have large economic consequences with limited health benefits. For example:

> *Ecology needs to avoid absurd regulatory outcomes in these upcoming regulation development activities. Selecting an FCR that ultimately yields HHWQ criteria or SMS to levels below natural background concentrations is not good.* ***(McCabe (NWPPA) (Agenda for February 10th meeting)***
>
> **********
>
> *At many, if not all cleanup sites in Puget Sound, sediment PCB and dioxin concentrations would exceed cleanup criteria derived based on the current Model Toxics Control Act (MTCA) default fish consumption rate of 54 g/day. In fact, as noted by Jim West of Washington Department of Fish and Wildlife in his presentation at Ecology's Technical Workshop on Fish Consumption [December 2011], most Puget Sound fish included in the State monitoring program have PCB concentrations above a fish tissue PCB criterion based on even the 1980 AWQC fish consumption rate of 6.5 g/day (70% of English sole, 90% of coho, and 100% of Chinook and herring). More than 50% of freshwater fish in the state would exceed such a criterion. Virtually all fish in State waters would exceed a PCB fish tissue criterion based on the current MTCA default fish consumption rate of 54 g/day and, by extension, virtually all sediments in State waters would exceed a PCB criterion based on the MTCA default fish consumption rate. Therefore, cleanup levels at these sites would default to background.* ***(Johns and Garry (Exponent))***
>
> **********
>
> ***Sediment Cleanup Levels Below Background Concentrations.*** *Recent risk assessments for sediment sites in Puget Sound urban areas also show that the range of background concentrations of bioaccumulative contaminants in sediment in urban areas (e.g., PCBs) exceed acceptable levels based on risk as calculated using a similar proposed range of seafood consumption rates and the EPA Region 10 Tribal Framework risk assessment approach. For this reason, MTCA risk-reduction goals for these chemicals cannot be attained through remediation. This problem greatly complicates remedy selection and increases the timeframe and expense for completing a sediment cleanup and evaluating its*

effectiveness (Chapter 5, Sediment Management Standards, page 76) ***(Matsushita (Lockheed Martin))***

Ecology's Evaluation and Response: Ecology's Toxics Cleanup Program acknowledges that risk-based cleanup standards for several frequently-found hazardous substances (dioxins, PCBs, etc.) are below background concentrations when calculated using the current default fish consumption rate in the MTCA regulation (54 grams/day).

Currently site-specific sediment cleanup standards are based on a reasonable maximum exposure (RME) scenario. Over the last five years, the Toxics Cleanup Program has used a tribal exposure scenario at sediment cleanup sites located in tribal Usual and Accustomed and/or traditional fishing areas. Establishing risk-based cleanup standards is often a time-intensive and expensive process.

As noted by several people, risk-based sediment cleanup standards are sometimes below background concentrations. In these situations, the sediment cleanup standard is based on background concentrations.

Ecology's original plan to adopt a default fish consumption rate in the SMS rule was part of a larger set of changes intended to streamline the sediment cleanup process. The changes were designed to reduce the transaction costs and reduce project delays caused by site-specific evaluations and negotiations.

As contaminated sediments are cleaned up, risk reduction will continue to be limited by background concentrations. However, Ecology believes the proposed revisions to the SMS rule will produce environmental and human health benefits relative to the status quo.

Ecology's Toxics Cleanup Program is aware that these two statements – actual risk reduction but limitation by background concentrations – appear to be contradictory. People have asked how exactly will the proposed SMS rule revisions produce additional risk reductions if cleanup actions continue to be limited by background concentrations?

To reconcile those two statements, it is important to recognize that lifetime cancer risks are a function of both concentration and time. In other words, the incremental lifetime cancer risk associated with a particular site is proportional to the area under the curve when concentrations are plotted over time.

Given this relationship, there are two approaches for reducing site-related cancer risks. First, risk reductions can be achieved by lowering the environmental concentrations through sediment cleanup measures. People have correctly pointed out that this approach will continue to be limited by background concentrations.

However, risk reductions can also be achieved by implementing earlier cleanup actions to reduce especially high environmental concentrations. In this case, the area under the concentration-time curve is reduced and risk is lowered. The Toxics Cleanup Program worked with an

advisory committee when developing a proposal that would facilitate earlier cleanup decisions that would translate into reductions in site-related lifetime cancer risks.

8.13 Background health risks – Cumulative impacts

Several people recommended that Ecology consider the total or cumulative risks posed by all chemicals when evaluating the risks of consuming fish and shellfish. One person noted that it was possible that the use of a higher fish consumption rate might translate into lower regulatory limits for some chemicals. However, he questioned the practical utility of lower cleanup levels for selected substances when cleanup levels for more potent chemicals would continue to be based on background levels that exceed MTCA risk levels.

> *Regulatory agency staff appear to be well aware that at high rates of fish consumption, allowable tissue concentrations of some of the most potent bioaccumulative contaminants will be below background concentrations. Nevertheless, some have voiced the opinion that these high consumption rates must still be considered in order to regulate other contaminants that may be less potent, and therefore have allowable tissue concentrations above background concentrations. This is a spurious argument, however. Fish everywhere have sufficiently high concentrations of potent bioaccumulative contaminants such as PCBs and dioxins as a result of worldwide atmospheric transport that they would represent unacceptable excess cancer risks if consumed at relatively high rates, even the MTCA default consumption rate of 54 g/day. Given that fact, it would be pointless to try to regulate the concentrations of much less potent contaminants in fish tissue because the overall magnitude of risk cannot be reduced below that associated with background concentrations of ubiquitous contaminants such as PCBs and dioxins. The risks of consuming fish and other seafood can only be meaningfully evaluated on the basis of the total risks associated with all contaminants they contain. Attempts to reduce risks by focusing on individual contaminants, while ignoring the risks associated with more potent and ubiquitous contaminants, would be futile. Ecology should recognize this fact, and not pretend otherwise.* ***(McKrone)***

Ecology's Evaluation and Response: Ecology agrees that cleanup decisions evaluating the risks of consuming fish and other seafood should not focus solely on individual chemicals. Such evaluations should also consider the cumulative effect of multiple chemicals. The proposed SMS rule revision includes requirements for individual chemicals and total site risk. For example, the sediment cleanup objective is based on a target cancer risk of one-in-one million (10^{-6}). Sediment cleanup objectives established using this target cancer risk level would be adjusted downward if the total site risk exceeds one-in-one hundred thousand (10^{-5}). This provision is designed to prevent unacceptable residual risks associated with a large number of chemicals and/or exposure pathways.

Experience has shown the importance of considering background concentrations when establishing sediment cleanup requirements. The above comment suggests that Ecology more

explicitly acknowledge background risks and the limitations that background concentrations impose on overall risk reductions.

Ecology agrees that clearer information should be provided on cleanup-related background risks in order to place site-related risks into proper context. However, the presence of background risks does not eliminate the need to consider reductions in less potent chemicals present in chemical mixtures. When addressing the cleanup of contaminated sites, Ecology believes it is important to take all reasonable steps to reduce exposure to hazardous substances, given the uncertainties in estimating health risks and the large variability in population responses to chemical mixtures.

Ecology's Toxics Cleanup Program has two main concerns with the suggestion that it is futile to address less potent chemicals when establishing cleanup requirements. First, it ignores scientific evidence that most diseases are complex and progress through several stages of development. A variety of factors can act to initiate or accelerate the disease process. This creates the potential for synergistic and antagonistic interactions between different chemicals and other risk factors. Chemical potency is also influenced by individual susceptibility which varies across population groups, across individuals within population groups and across time for any particular individual.

Second, the comment implies that site-related exposures act independently of background exposures. In some cases, it is the combination of background and site-related exposures that produce exceedances of health effects thresholds for non-cancer endpoints. In other cases, background exposures may alter the dose-response relationships. This was discussed in the recent NRC report on risk assessment methods:

A critical aspect of the new approach is the determination that, whether addressing cancer or noncancer end points, dose-response models should fully address both intersubject variability and background disease processes and exposures. How those factors may "linearize" dose-response relationships, which would otherwise be low-dose nonlinear relationships on the basis of MOA [modes of action], should be considered explicitly. The committee recommends that two systematic reviews be included as components of EPA dose-response assessments. The first is an assessment of background exposures to xenobiotics (for example, in pharmaceuticals, food, and environmental media) and endogenous chemicals that may affect the processes by which the chemical produces toxicity and may result in low-dose linearity. The second is an assessment of human vulnerability that identifies underlying disease processes in the population to which the chemical in question may be adding and that suggests groups of sensitive individuals and their characteristics. ***(NRC, 2009)***

8.14 Health benefits of eating fish and shellfish

Several people noted that fish and shellfish are an important part of a healthy diet. For example:

> *Because I also direct the Institute for Risk Analysis and Risk Communication, my comments support the Department of Ecology's use of established and well recognized risk assessment approaches. The increase in fish consumption is well documented with Pacific*

Northwest relevant references. In addition to the points that I covered in my presentation titled "What's the Public Health Issue, and Why Is It Important?" at the Department of Ecology's Fish Consumption Rate Workshop held December 12, 2011 at the University of Washington, there are even more recent recommendations by the Dietary Guidelines for Americans, 2010 that further promote increased levels of fish into healthy diets. For example, they recommend Americans "Increase the amount and variety of seafood consumed by choosing seafood in place of some meat and poultry." The dietary guidelines further recommend for women who are pregnant or breastfeeding to consume seafood each week from a variety of seafood types. These recommendations emphasize the importance of fish consumption, and, taken together with actual fish ingestion levels in the Pacific Northwest, point to the need for the scientifically-based documentation provided by the Department of Ecology's Fish Consumption Rates Technical Support Document. ***(Faustman (Univ. of Wash.))***

However, several people also observed that Ecology's plan to increase the default fish consumption rate poses several risk communication challenges. In particular, they noted that a higher default fish consumption rate would mean that background levels of contamination would be associated with higher health risk estimates.

They expressed concerns that this could cause people to stop eating fish and shellfish which could actually increase health risks. First, they noted that fish and shellfish are important sources of omega-3 fatty acids that have been shown to reduce risks of heart disease and improve neurological development. Second, they noted that other sources of protein (beef, poultry, and dairy products) have equal or greater amounts of chemical contaminants. For example:

If Ecology were to adopt the fish consumption rates proposed in the technical support document, we would be trying to regulate the contaminant concentrations in fish to much lower levels that allowable in other foodstuffs. Other protein sources such as beef, chicken, pork, and dairy products, not to mention fish from even relatively uncontaminated areas such as Alaska, all contain PCBs and dioxins at concentrations that would represent unacceptable risks if these foods were consumed at the rates put forth in the technical support document. Discouraging the public from eating fish because of contaminant concentrations that result in relatively low risks (i.e., any excess cancer risk greater than l x 10-6 , while ignoring the health benefits of eating fish, is not wise public policy, especially when alternative protein sources contain the same contaminants. ***(McKrone)***

****

Recommendations: The TSD should include a risk-benefit analysis addressing: 1) how the recommended fish consumption rate(s) will be implemented in regulatory framework (SMS, SWQS, MTCA), 2) the level of public benefit expected, and 3) the potential public health risk if people eat less fish. ***(Johns and Garry (Exponent))***

****

Ecology asserts at the bottom of page 102 that regulatory decisions should ultimately lead toward eliminating - or minimizing- risk to human health. This sounds initially like a reasonable goal, but when selectively administered in the confines of health risks from

eating fish and shellfish, while ignoring other very substantial dietary risks, could have the opposite effect. An understanding of comparative risks would be good.
*Human health criteria based on 10-6 risk applied to high end consumers could result in conclusions by Ecology in the 303(d) listing of impaired waters program, and other programs as well, that criteria are exceeded. Publicity could divert people away from consuming fish or shellfish. They would consume something else for which we have no similar evaluations of risk level, and for which the risks (including cardiovascular) could be much greater. As such, it could result in increasing risk to human health. Regulatory decisions such as are considered here should be made and put in context of relevant relative risks.**(McCellan (EPW) Attachment)***

Ecology's Evaluation and Response: Ecology has reviewed the public comments and agrees that the discussions on fish consumption rates raise important risk communication and public policy issues. The National Research Council discussed this issue in *Science and Decisions: Advancing Risk Assessment*:

*Risk estimates developed with defaults focus on a portion of the scientifically plausible risk estimate range. However, because some defaults may lead to the overstatement of risk posed by a chemical and others to an understatement of risk, EPA needs to be mindful of the influence of defaults on risk estimates when the estimates will influence risk-management decisions. Intervention options often involve tradeoffs, and the tradeoffs being considered (such as replacement of one chemical with another in a production process) might result in risk estimates whose health protectiveness depends on the defaults used in estimation. An example is the tradeoff between the risks resulting from exposure to mercury and PCBs in fish and the nutritional benefit of fish consumption **(NRC, 2009)***

Ecology will consider these issues when making final decisions on the SMS rule revisions and cleanup decisions at individual sites. For example, net environmental protection is considered when establishing cleanup standards. It might be appropriate to consider these types of risk-risk or risk-benefit tradeoffs within that context.

To support further evaluation of this issue, Ecology has prepared two issue papers that provide additional information on these issues.

- **Health Benefits and Risks of Consuming Fish and Shellfish.** Ecology compiled and evaluated available information on the known health benefits of eating fish and shellfish. Key findings include:
  - Fish is a good source of protein and, unlike fatty meat products, it is not high in saturated fat. Fish is also a good source of omega-3 fatty acids. Omega-3 fatty acids benefit the heart of healthy people, and those at high risk of, or who have, cardiovascular disease. The American Heart Association recommends eating fish (particularly fatty fish) at least two times (two servings) per week.
  - For those who consume meats, replacing meats with vegetable alternatives (e.g., beans) or fish is one strategy to replace saturated fats with monounsaturated fats and reduce

cholesterol. Increasing consumption of most seafood species will lead to increased n-3 PFA intake and reduced risk for major health conditions such as cardiovascular and coronary heart disease. Health benefits associated with consumption of fish, particularly fatty fish such as salmon, are well documented.

- While exposures to methylmercury and persistent organic pollutants may have negative human health impacts, there are considerable uncertainties about estimates of these health risks to the general population at levels present in commercially-obtained seafood.
- High rate fish consumers such as certain ethnic groups (Japanese, American Indian) can accumulate mercury levels that approach or exceed reference doses.
- Data on methylmercury and n-3 PFA concentrations in seafood might be used to guide the selection of individual fish and shellfish species that are higher in n-3 PFA and low in methylmercury content, thereby reducing mercury exposure. Further, the risks from lipophilic compounds can be reduced by trimming fat, using cooking methods that reduce fat such as broiling, and by eating a variety of species.
- A recurrent theme in recent reviews and analyses is that reducing fish consumption can negatively impact the health status of vulnerable populations**.** The evidence suggests that fetuses and infants may be among the principal beneficiaries from certain nutrients in seafood. Few data are available about the extent to which beneficial components of seafood, such as selenium and omega-3 fatty acids, might mitigate risks associated with contaminants in seafood.
- Where there are local instances of excessively high levels of contaminants such as PCBs in recreationally-caught fish, it is important that consumers, especially those in sensitive populations, consult with their local health department before consuming locally-caught fish.

- **Chemical Contaminants in Dietary Protein Sources.** Ecology compiled and evaluated available information on chemical contaminants in dietary protein sources (e.g., meat,fish, dairy products and poultry). Key findings include:
  - Contaminants occur in many food sources and for some, food is the major contributor to intake in the general population (i.e., those not exposed occupationally). Mercury, arsenic, PAHs, dioxins, and PCBs all have food as the major source of intake.
  - Over the past three decades, per capita chicken consumption has increased, beef consumption has decreased, and pork and seafood consumption have remained fairly stable.
  - In the United States, fish and shellfish are the primary dietary source of mercury and arsenic (organic forms). Shellfish may contribute significantly (about 20 percent) to the PAH intake for shellfish consumers.

- Inorganic arsenic (generally considered to be the more toxic form) is present in low concentrations in most animal-based protein sources, but dietary intake is largely from cereals, vegetables, fruits, fruit juices, and water used in cooking.
- Nearly all of the dietary intake of mercury in the United States comes from animal-based protein sources, with fish and shellfish being the principal sources. PAH concentrations in foods are largely influenced by cooking methods.
- Dietary intake studies show dioxin TEQs (Toxicity Equivalence) come largely from animal-based protein sources, with fish contributing roughly one-third of total TEQs.
- If fish and shellfish consumption increases in the future, exposure to methylmercury could increase. Actual increases would depend on the species consumed, as some contain higher average concentrations of mercury. (For more on this topic, see *Technical Issue Paper: Health Benefits and Risks of Consuming Fish and Shellfish.*)
- Direct comparison of contaminant concentrations in dietary protein sources is difficult due to variations in the way these data are presented in the literature. Concentrations are presented as wet weight or dry weight, cooked or uncooked, lipid-normalized or total, and using a variety of units. Data were collected during different time periods, in different locations, and using different analysis methods.

8.15 Impacts on upland cleanup sites

Several people expressed concerns about how a revised fish consumption rate would impact soil and ground water cleanup actions at properties adjacent to surface waterbodies. For example:

> *I am also aware of what I consider to be totally inappropriate use of fish consumption rates, such as attempts by both Ecology and EPA to back calculate upland groundwater and soil cleanup levels that would be protective of human health based on the tribal seafood consumption rates, assuming chemicals in soil would migrate to groundwater, and the groundwater would be discharged to surface waterbodies without dilution. It is important that implications of the application of fish consumption rates be understood in the context of all regulatory programs in which they are to be used. In some cases, as described below, I believe that the application of these rates will lead to untenable regulatory gridlock.* ***(McKrone)***

Ecology's Evaluation and Response: Under the Model Toxics Control Act (MTCA) Cleanup Regulation, cleanup levels must be established at concentrations that prevent violations of cleanup levels for other media (such as surface water and sediments). For example:

- WAC 173-340-720(c) states that "…[g]round water cleanup levels shall be established at concentrations that do not directly or indirectly cause violations of surface water, sediments, soil or air cleanup standards established under this chapter or applicable state and federal laws…"

- WAC 173-340-740(d) states that "…[s]oil cleanup levels shall be established at concentrations that do not directly or indirectly cause violations of ground water, surface water, sediment, or air cleanup standards established under this chapter or applicable state and federal laws…"

Ecology has analyzed the impacts of the proposed SMS rule revisions on soil and ground water cleanup standards. In general, Ecology does not anticipate that the proposed revisions will significantly impact requirements for soil and ground water cleanup standards at MTCA sites that are adjacent to a river, lake, stream or bay. The rationale for this conclusion includes:

- The proposed sediment cleanup objective requirements are virtually identical to current MTCA requirements which define baseline requirements. Site-specific sediment cleanup standards must currently comply with the general MTCA risk policies and methods. Site-specific sediment cleanup standards are based on a reasonable maximum exposure (RME) scenario and calculated using EPA toxicity values and MTCA risk policies. Ecology typically uses a tribal exposure scenario to define the RME at sites located in tribal Usual and Accustomed Areas (UAAs) or traditional fishing areas. Under the current rules, risk-based cleanup standards may be adjusted based on natural background concentrations or analytical limits.
- The proposed SMS rule revisions provide additional flexibility to establish site-specific cleanup standards for some chemicals that are higher than the maximum level allowed under the current SMS and MTCA rules. Specifically, Ecology is proposing that the maximum allowable level can be based on regional background levels in certain situations. Regional background levels may exceed natural background levels (the current rule requirement) for some chemicals at some sites.

Earlier in the rulemaking process, Ecology evaluated the impacts of establishing a default fish consumption rate in the SMS rule. We concluded that using a default fish consumption rate similar to the rate adopted by the Oregon Department of Environmental Quality (175 g/day) could alter the risk-based concentrations for some chemicals at some sites. However, we also concluded that those impacts would be minimal because of other rule provisions (consideration of natural background, regional background and analytical limits).

8.16 Sediment cleanup site boundaries

Several people expressed concerns about how a revised fish consumption rate would impact sediment cleanup actions. They said it was very important for Ecology to clarify how background concentrations would be taken into account when defining site boundaries and establishing site-specific cleanup standards. For example:

Recommendations: *A discussion should be provided in Chapter 7 regarding the impact that fish consumption rates have on the establishment of site cleanup criteria to background levels and the impact this has on developing site boundaries.* ***(Johns and Garry (Exponent))***

Ecology's Evaluation and Response: Ecology decided not to include a default fish consumption rate in the SMS rule. Under the proposed rule, site-specific sediment cleanup standards will continue to be based on a reasonable maximum exposure. In general, Ecology does not anticipate that the use of a site-specific fish consumption rate based on a tribal RME scenario will significantly increase or decrease the average size of sediment cleanup sites. However, the size of individual sites may increase or decrease depending on site location and the contaminants of concern. This conclusion is based on several considerations:

- The proposed revisions to the sediment cleanup objective are similar to the MTCA human health policies that are currently applicable to sediment cleanup actions. Consequently, the areal extent of cleanup sites will not significantly change.
- PLPs may elect to investigate and remediate cleanup units located within larger cleanup sites. Cleanup units may be defined by regional background levels. This may occur more frequently under the proposed rule revisions.
- The proposed rule revisions provide the flexibility to establish cleanup standards that exceed the sediment cleanup objective. Site-specific cleanup standards can be established at levels equal to regional background. The cleanup standards define areas of active remediation, but do not change the size of the site (as defined by the sediment cleanup objective).
- The ability to detect risk-based sediment cleanup standards that are based on a tribal RME scenario will continue to be limited by available analytical methods for detecting low levels of hazardous substances.

8.17 EPA Region 10 Framework

EPA Region 10 published the *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* in 2007. Ecology summarized the framework in the Technical Support Document (Version 1.0) and noted similarities and differences between the two documents. (See also related discussion in Chapter 6.)

Several people questioned whether it was appropriate for Ecology to cite the EPA Region 10 framework to support the evaluations and conclusions in the Technical Support Document. First, they expressed concerns that the EPA document had received insufficient technical and public review. Second, they stated that their concerns about tribal data accessibility applied to both documents. Third, they stated that EPA has a trust responsibility that is not shared by the Department of Ecology. For example:

Ecology's technical support document cites the earlier "framework document" prepared by EPA Region 10 (i.e., 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; EPA 2007) as lending credence to some of the analyses in Ecology's document. Unfortunately, EPA's framework document suffers from the same lack of transparency associated with not having access to the raw survey data. EPA's framework document was prepared by staff from EPA Region 10, without the benefit of review by any other state or federal agencies (e.g., Washington State Department of Health, Ecology, any offices of EPA outside Region 10 [including EPA headquarters]) or any experts in the development and application of seafood consumption surveys. ***(McKrone)***

****

The EPA Region 10 Framework for Selecting and Using Tribal Fish and Consumption Rates is cited repeatedly in Ecology's fish consumption rates technical support document, and was used to help develop the range of fish consumption rates. The EPA Framework title states that it is a "working document to be applied in consultation with Tribal Governments on a Site-Specific Basis." The EPA Region 10 Tribal Framework does not state that it represents final EPA guidance or policy or that it has been subject to internal or public review and approval. EPA has a federal government trust responsibility to assure that tribal concerns and interests are considered whenever EPA's actions and /or decisions may affect Tribes (particularly on tribal lands). Washington State Department of Ecology does not have this same trust responsibility. For these reasons, it appears inappropriate for the framework to serve as a primary basis for selection of state fish consumption rates and related rulemaking in Washington State (Chapter 5, EPA Region 10 Framework, pages 78 through 79). ***(Matsushita (Lockheed Martin))***

Ecology's Evaluation and Response: Ecology believes that the EPA document provides a technically sound decision framework. Ecology agrees that EPA has a federal government trust responsibility to assure that tribal concerns and interests are considered whenever EPA's actions and /or decisions may affect Tribes. While it does not have the same trust responsibilities, the State of Washington is party to several treaties that create responsibilities for protecting fish and shellfish resources. Consequently, the EPA document addresses many issues that are integral to fulfilling state and federal responsibilities.

Appendices A and B of the EPA document provide information regarding the extensive internal and external reviews of the draft Framework, public involvement, and consistency with national guidance and risk management policies to evaluate and assess the risks from hazardous waste sites. (EPA, 2007) The EPA Region 10 Framework was developed in accordance with applicable agency guidelines including the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*.

The EPA document is based on the fish dietary information from the Tulalip and Suquamish tribes. Appendix A details the acquisition of two tribal fish dietary surveys to assess seafood consumption in Puget Sound and the Strait of Georgia. Acquisition of the individual response tribal data was required in order to evaluate the fraction of seafood affected by site-specific contaminations defined as the fraction of seafood harvested from Puget Sound. Dr. Shiquan Liao (a statistician involved in the data analysis for the Suquamish, Squaxin Island and Tulalip Tribal fish dietary surveys) reanalyzed the tribal data to provide EPA with estimates of fish consumption harvested from Puget Sound.

The EPA Region 10 Framework underwent extensive review and evaluation between late-2004 and mid-2007. Numerous reviews and changes were made by EPA senior technical staff and management over that period. EPA sent the draft framework to all federally-recognized tribes in Puget Sound and the Strait of Georgia for review and comment. Reviews were conducted by senior tribal technical and policy staff.

Chapter 9: Comments on "Recommendations"

9.1 Overview

Over the past 20 years, many scientific and regulatory developments have occurred regarding statewide default fish consumption rates. The Technical Support Document was designed to compile and evaluate this information.

Ecology posed several questions for people to consider when reviewing the Technical Support Document. This list included the following question:

- What is a technically defensible default fish consumption rate (or rates) appropriate for use in regulatory decision making?

Ecology considered multiple ways of approaching the data obtained from the Pacific Northwest regional fish consumption rate surveys. Ecology chose a method that involved fitting the individual studies to lognormal probability distributions, combining the distributions, and developing a composite lognormal distribution based on the combined data. Ecology used the results of this evaluation to define a recommended range of fish consumption rates (157 g/day to 267 g/day).

Ecology received numerous comments in response to this question. Ecology has compiled and summarized the range of viewpoints reflected in those comments, which have been grouped into following categories:

- Support for revising the default fish consumption rates.
- Opposition to or concerns about revising the default fish consumption rates.
- Single vs multiple default fish consumption rates.
- Specific recommendations on default fish consumption rates.
- Method for developing recommended range.

In July 2012, Ecology decided not to adopt a default fish consumption rate in the Sediment Management Standards (SMS) rule. Ecology also announced that the agency was initiating the process for adopting human health criteria in the Water Quality Standards rule.

Given Ecology's revised strategy, we decided it was premature to provide responses to these comments. However, Ecology will consider these comments during future programmatic and site-specific discussions.

9.2 Support revising default fish consumption rates

Many organizations and individuals expressed support for Ecology's work and recommended that the Department continue efforts to update the current default fish consumption rates. Those who supported Ecology's efforts on this issue identified several reasons for their recommendations.

Current regulatory values are outdated

Several people noted that the current Ecology default rates are based on data collected in the 1980's. They stated that results from more recent surveys conducted in Washington support the need for updating the current default fish consumption rates. For example:

> *To reiterate, EPA believes the approach for developing a revised fish consumption rate should be based on current scientific information and local/regional data. The initial approach put forth in the draft report is aligned with this thinking. While we understand the need for continued coordination with your stakeholders and the Tribes, we encourage you to quickly incorporate this information into your rulemaking process and move forward with adopting revised criteria.* ***(Jennings (EPA))***
>
> **********
>
> *Just a comment on the current EPA water quality rates, they are based on data from the 1990's and are not consistent with the current knowledge of tribal consumption.* ***(Dunn (LEKT))***
>
> **********
>
> *…King County shares Ecology's long-term interest in protecting human health and believes Washington State's existing default fish consumption rates are inconsistent and outdated….* ***(True*** **(King County DNRP))**

People are eating more fish than in the past

Several people supported Ecology's efforts to update the default fish consumption rates because they had observed that they and others were now eating more fish and shellfish than in the past. For example:

> *As more and more people try to cut back on red meat and eat more fish, it's obvious from several sources that consumption rates are higher.*
>
> 1. *Check the ads for grocery stores, including the "box" stores. Not only are the number of seafood ads triple what they used to be, all are showing at least a few local choices.*
> 2. *Restaurants have more local seafood on their menus.*
> 3. *Even hospitals and other venues (fairs and sporting events too) that didn't try to provide a range of choices now have seafood entrees.*
> 4. *People who are transitioning from meat to vegetarian quite frequently still eat a little fish to provide the nutrients they lack.*

Using myself and friends and family as examples, we went from 2 times a week 10 years ago, to 5-7 times a week currently. Some of it in the form of canned tuna at lunch, or tuna noodle casserole at dinner. Mostly we choose halibut and wild salmon, and some shrimp. We want to choose locally caught seafood whenever possible for lots of reasons. It's critically important that we improve and sustain clean, safe waters to keep our food safe as well. ***(Furlong)***

Social, cultural and economic importance of Washington fisheries

Several people stated that Ecology needs to update the current default fish consumption rates because fish and shellfish are extremely important to people in Washington. For example:

Eating seafood in the Pacific Northwest is a lifestyle choice for most people, but for tribes the consumption of fish and shellfish is their life and legacy. Fish is a first food for tribal children and the foundation for the healthy hearts of the elders. Tribal communities are asking how to reduce the input of toxic chemicals into the environment in order to keep these essential food sources safe. A fish consumption rate that is more realistic and hence more protective of Washington residents will be an important step in protecting this healthy choice in the future. ***(Frank (NWIFC))***

****

Increasing the current Washington fish consumption rate will ultimately lead to decreasing the levels of toxic pollution that are considered "allowable" in our rivers, lakes, and streams. The importance of fish to the tribes cannot be overstated for the fishery resource is not only a major food source for tribal members; it is also an integral part of our cultural, economic, and spiritual well-being. As ceremonial and subsistence fishers, we rely on the protection and enhancement of water quality to a level that is sufficient to protect our water and fish from harmful exposure to waterborne pollutants. ***(Lumley (CRITFC))***

****

PCSGA commends Ecology for its decision to revise fish consumption rates for Washington residents. Accurate fish consumption rates help protect Washington's shellfish resources. Shellfish and fish caught in the State's waters play a vital role in our environment, culture, and economy, and are important parts of a healthy diet. ***(Barrette (PCSGA)/Schoof (Environ))***

Compliance with state and federal laws

Several people stated that the current default rates do not reflect current exposure patterns and consequently, may not comply with state and federal requirements for protecting human health. For example:

An update must occur. *Currently, the default rates in place do not protect either the general population or the high user groups. This is contrary to both state and federal law that standards must adequately protect human health. For this reason, we urge a speedy process to update the default fish consumption rates for both sediment and water quality standards.* ***(Trim (PFPS)/Bell (NWEA))***

****

The Spokane Tribe of Indians adopted an 86.3 g/day fish consumption rate in our first EPA approved standards. Although this rate was much less than the actual fish consumption level, EPA had designated that amount for subsistence populations at that time. The Tribe has since adopted 865 g/day which is reflective of the historic fish consumption level and is awaiting EPA approval. Oregon recently adopted a higher fish consumption rate to better reflect the amount consumed. Many tribal members live outside of the Reservation but still consume much more that 6.5 g/day of fish. The Tribal standards do not directly apply to the waters outside of the Reservation therefore they may not be protected under such a low fish consumption value. The State standards should consider the tribal community when developing a new fish consumption level. The Clean Water Act clearly identifies the most stringent standards apply between states/tribes and therefore the standards should be conservative enough to protect the higher fish consumers. ***(Crossley (Spokane Tribe of Indians))***

Environmental justice

Several people expressed support for Ecology efforts to update the fish consumption rate because it promotes greater environmental equity. For example:

DRCC/TAG agrees that the current default fish consumption rates do not reflect levels that the average population in WA State eats and certainly does not protect high fish consumers, such as Tribes, Asian/Pacific Islander and subsistence fishing families.

- *Tribal and subsistence fishing communities are Environmental Justice populations that must be protected by the revised fish consumption rates.*
- *We endorse the decision by Department of Ecology to raise the Washington State fish consumption rates.* ***(Rasmussen (DRCC/TAG))***

Consistency with Oregon DEQ and tribal standards

Several people stated that recent regulatory updates by the Oregon Department of Environmental Quality indicate that Ecology needs to update the current default fish consumption rates. For example:

Adopt the new Oregon rules, 175 grams. ***(Shaw)***

9.3 Opposition to or concern about revising default fish consumption rates

There were several organizations and individuals who recommended that Ecology not proceed with plans to update the current statewide default fish consumption rates. They also identified several reasons to support their position.

No demonstrated public health benefits

Several people stated that Ecology had not adequately explained and/or justified why updating the current default rates was necessary in terms of benefits to public health. For example:

Any decision to change the current default FCRs should be justified in terms of benefits to public health. The underlying premise of the report is that use of the current default FCRs results in water quality standards that are not sufficiently protective of high-end consumers of fish. Data cited in the report indicate that some residents of the state consume much larger quantities of fish than the default values currently used for assessing risks. However, these data provide no perspective on the degree to which public health is protected under the existing FCRs. More importantly, they do not indicate to what degree such risks would be reduced by changing the FCRs. ***(Stratton and Louch (NCASI))***

****

IEP urges Ecology to suspend development of default statewide fish consumption rates (FCRs) until a more thorough scientific evaluation can be performed to assess any public health benefits. The TSD document provides a superficial analysis of complex scientific issues and a number of policy determinations that are not appropriate for a technical guidance document. ***(Tupper (on behalf of IEP))***

Adverse economic impacts

Several people expressed concerns about adverse economic consequences associated with revising the default fish consumption rate. They stated that it was inappropriate to establish a default rate without first considering the costs and benefits of any proposed revision. They urged Ecology to fully evaluate potential economic impacts before making a final decision on an updated value. For example:

Our industrial waterfront areas are critically important to the economic viability and sustainability of our region. Reasonable approaches to cleanup of genuine hazards to human health and the environment are appropriate and necessary for these areas. But removing sediment and/or shoreline soil to "background" levels is irrational from a balanced public policy perspective. I believe that implementation of higher fish consumption standards will inevitably result in more important industries leaving our state, the creation or unwanted shoreline brownfield sites that the public cannot afford to remediate, more lawsuits and disputes over cleanup regulations, and fewer (not more) site cleanup efforts. Shoreline site remediation to current standards is largely infeasible from a cost and practical perspective; higher fish consumption standards will only make matters worse.

I urge Ecology to consider the economic consequences of increasing the fish consumption rate for Washington, in addition to environmental and political pressures. From a policy perspective, I urge Ecology to use default fish consumption standards that are consistent with those used by the federal government. We don't need Washington to set unattainable goals that go beyond federal requirements and penalize the weakened economy of our state. ***(Miller)***

****

As previously stated, the proposals regarding fish consumption rates could have a significant negative impact on economic activity and ecological progress in Washington State, so we suggest that further consideration is needed on the overall policy approach. If the Department chooses to proceed with this approach, then we believe additional technical

issues must be addressed and the port community stands ready to assist future discussions. ***(Hellman (WPPA))***

Cost-effective strategies for environmental improvement

Several people expressed concerns that Ecology's efforts to update the default fish consumption rate would lead to high costs and few benefits as scarce resources were diverted from higher priorities. For example:

*If current regulations are difficult to achieve will superimposing additional requirements result in any real improvement to water quality The questions begs an answer that deals with much broader efforts towards pollution reduction that involves infrastructure (stormwater control) and product toxics (pollutant input) requiring huge financial resources to achieve.****(Perlwitz (Nippon Paper))***

****

Clearly, Washington is one of the most environmentally aware and progressive states in the country. We have stringent federal, state and local (particularly in Seattle) regulation to minimize discharges to our waterbodies and to make sure they are cleaned up. At the same time, few people would argue that we must not maintain an economic base to fund cleanups and environmental responsibility, and to pay taxes for education and all other aspects of modern society. If our sole goal as a society were to return our environment to a pristine state, we would shut down all waterfront industry; however, most people recognize that a balancing is required. We are deeply concerned that the proposed changes to assumed fish consumption rates will create an imbalance, intended or unintended, that will result in a real and tangible reduction in water-dependent businesses and adversely affect Washington's economic vitality. In other words, the true cost of the changes to fish consumption rates may be much higher than most people expect. Meanwhile, the resultant environmental gain is likely to be theoretical and intangible, given that very few, if any, people actually consume fish at the assumed rates.

Through various complex formulas, the fish consumption rates drive clean up levels. Ecology has acknowledged that its risk-based calculations are very conservative and may already result in driving some clean up levels lower than natural background levels. The clean up levels will be reduced further under the proposed new rules. Cleaning up below natural background defies common sense. At the very least the regulations should establish a floor for sediment cleanup levels that provide a reasonably attainable cushion above natural background level for a given chemical constituent.

That we are currently experiencing a time of economic difficulty is no excuse to turn our back on the environment. However, it is an impetus to reassess the conservative and unrealistic assumptions on which the fish consumption rates are based, sharpen our pencils and spend our limited environmental restoration money where it is most effective. The proposed changes to the fish consumption rates are not an efficient use of limited resources and, more so, will be detrimental to economic vitality

By way of precedent and example we point out the current issue with the City of Seattle/King County sewer overflow. There, we are looking at a $1.2 billion cost to capture the "last drops" of overflow. Yet many studies have shown that the same money could do much more environmental good elsewhere. Even some prominent clean water advocates have

recognized the law of diminishing returns – that we can no longer do it all and must make choices. http://seattletimes.nwsource.com/html/localnews/2017147361_cso03m.html It is not too late to make the right choice in this case and leave the fish consumption rates unchanged, add a reasonable floor to sediment cleanup levels, and allow funding to be used better elsewhere. ***(Billingsley, ALASKA MARINE LINES))***

Questionable need for requirements that are more stringent than federal criteria

Several people stated that Ecology had not adequately explained and/or justified why it was necessary to establish a default fish consumption rate that is more stringent than federal standards. For example:

*Human-health based ambient water quality criteria used in The National Toxics Rule are based on a fish consumption rate of 6.5 grams per day. The EPA currently recommends a fish consumption rate of 17.5 grams per day. The Washington State Department of Ecology, however, proposes to use 150 to 275 grams per day which is 10 times more stringent than the federal standard. Ecology needs to develop and articulate both the public health need and a regulatory basis for setting a statewide standard that is far more stringent than the standards EPA recommends.****(Arnold (City of Spokane))***

Current authority to establish site-specific limits

Several people questioned the need to include an updated fish consumption rate in the SMS rule because the MTCA rule already provides the authority to establish site-specific requirements that protect high exposure population groups. For example:

The value of a "default" FCR for SMS is not apparent. Sites will have unique features. Skilled government environmental personnel and environmental consultants seem very capable to work in the RI/FS and CAP development process to derive a customized FCR for the specific contaminated site.

MTCA already provides sufficient flexibility to address the protection of high-consuming populations, so rule changes are not necessary. If the Department's goal is to clarify agency expectations and streamline cleanup decisions, then this can be addressed with an updated narrative standard accompanied by development of appropriate regulatory guidance. ***(Hellman (WPPA))***

Water and sediments should not contain any level of contamination

One person was strongly opposed to Ecology's efforts to revise the current default fish consumption rates because he concluded that approaches based on human health risk were a bad idea.

The amount of fish and shellfish we eat (our fish consumption rate) is used to determine how "clean is clean" for water quality standards and sediment cleanups. The more fish we are assumed to eat, the cleaner our sediment and water will be – because higher standards will have to be met. This is unbelievably stupid. Whoever dreamed this up is an ass. The water and sediment should be clean and devoid of contaminants even if humans never ate ANY water dwellers! Humans are NOT the only inhabitants of Washington.

9.4 Single vs multiple default fish consumption rates

Ecology has established two default fish consumption rates to support regulatory decisions. The Water Quality Standards (WQS) establish statewide standards that are based on a fish consumption rate of 6.5 grams/day. The MTCA rule establishes a statewide default rate of 54 grams/day, but provides the flexibility to establish site-specific rates.

Many people provided opinions on whether it was appropriate for Ecology to establish a single default fish consumption rate that would be applied throughout the state. Some people supported the use of a single statewide value. For example:

> ***Range versus single number.*** *We are concerned that Ecology will seek to promulgate a range of rates rather than a single minimum default rate. A range of rates will end up with legal challenges and extended fights for each cleanup or permit. We support a single minimum default rate, not a range of rates.* ***(Trim (PFPS)/Bell (NWEA))***

However, many of the people supporting the use of a single default fish consumption rate stated that Ecology must provide the flexibility to establish higher rates for individual sites. For example:

> *Finally, TCP should promulgate a single* ***minimum*** *default FCR, rather than a range of rates. From a pragmatic standpoint a single FCR will reduce the amount of legal haggling over cleanup levels. A minimum standard will allow for higher FCRs to be negotiated where specific populations would receive higher exposure based on higher population specific consumption rates.* ***(Winters)***

On the other hand, many people stated that it is inappropriate to establish a single statewide fish consumption rate. They identified several reasons for their opposition to a single statewide fish consumption rate:

Wide range of waterbody characteristics

Several people expressed the opinion that a single default fish consumption rate would not be useful because of the wide variability in fish consumption patterns and factors affecting the accumulation of substances in fish and shellfish tissue. For example:

> *No. Statewide or default FCRs should not be adopted even within one program. The primary reason for this is that each site cleanup has a very specific scope, with potentially unique food webs, fish consumption patterns, and affected population sizes. A single default rate seems unlikely to be of much utility for such projects….* ***(Louch and Stratton (NCASI))***
>
> **********
>
> *….We do not believe that a single default fish consumption rate can adequately support the varied regulatory needs of the State. Rather, we recommend that Ecology develop a series of rates for, at a minimum, resident marine and estuarine fish, marine and estuarine shellfish, and resident freshwater fish for various high consumer groups.* ***(Barrette (PCSGA)/Schoof (Environ))***
>
> **********

In addition to the risk level issue, it is very important that Ecology not set one default state-wide consumption rate. The circumstances involved across the state are so varied that a default consumption rate will necessarily be far off the mark for what one could reasonably expect to occur at most sites. ***(Newlon (Stoel Rives))***

Multiple regulatory programs

Several people expressed the opinion that a single default fish consumption rate would not be appropriate given the differences between the regulatory frameworks used to make decisions under the Model Toxics Control Act (MTCA) Cleanup Regulation, the Sediment Management Standards (SMS) and the Water Quality Standards for Surface Waters (WQS). For example:

….On the other hand, water quality standards developed under the Clean Water Act apply statewide, and so should be derived using an FCR representative of the total population of the State. As a consequence, a default rate appropriate for use in developing these water quality standards would be unlikely to be appropriate for the MTCA or SMS programs. ***(Louch and Stratton (NCASI))***

****

There is no explanation, however, why the assumptions in MTCA cleanup standards and Water Quality Standards have to be the same. The standards regulate different media and presumably different risk exposures. ***(Tupper (on behalf of IEP))***

Sustainable fish consumption rates

Several people questioned whether all waterbodies would be able to support the amount of fish and shellfish needed to sustain consumption of 157-267 grams/day. For example:

King County is concerned that the proposed consumption rates may exceed sustainable harvest levels in some cases. In particular, small streams and lakes are unlikely to sustain harvest rates of 157-267 grams/day. King County encourages Ecology to work with fisheries managers and consider sustainable harvest rates in setting criteria for a specific waterbody. ***(True (King County DNRP))***

****

In most cases, it is not realistic to assume that an individual would obtain 100 percent of their diet from one small geographic area. Many of the sites addressed under SMS simply could not support the types and quantities of fish and shellfish suggested by the high consumption rates proposed in the new default range. ***(Hellman (WPPA))***

Several people noted that there is substantial variation in the amount of fish and shellfish consumed in different parts of Washington. One person recommended that Ecology establish several default rates that would take into account differences between waterbodies (freshwater vs. marine) and fish species (shellfish vs. finfish vs. salmon). Specifically:

Ecology has specifically requested feedback on the inclusion of salmon consumption in the proposed consumption rates. Marine shellfish data and salmon have been included in the proposed rate to be applied to all waterbodies, even those where these species are not

present. King County recommends that Ecology consider the presence of salmon and shellfish when selecting consumption rates for different waterbodies. To address the problem of including salmon and shellfish ingestion as part of the effort to protect, restore or remediate waters and sediments where habitat suitable for these organisms does not exist, King County proposes that Ecology develop three consumption rates:

a. A rate for use in marine and coastal estuarine waters where anadromous adult salmon and the typical suite of crab and shellfish would be expected.

b. A rate for the Columbia River and major tributaries, along with lakes where Kokanee are present.

c. A rate for streams and lakes which only serve as migration corridors for migratory salmon or where salmon or shellfish are absent. ***(True (King County DNRP))***

Other people suggested that Ecology consider adopting multiple rates that allow consideration of chemical, species and water body characteristics. For example:

Chemicals in fish and shellfish are the result of exposures via diet, water and sediment, with the relative contribution from the various pathways being a function of the kind of fish, individual chemical and type of water body. For example, polycyclic aromatic hydrocarbons (PAHs) may be metabolized in fish, but not in shellfish, resulting in different rates of accumulation in fish vs. shellfish. Biomagnification of mercury results in higher concentrations in higher trophic level fish. Concentrations of arsenic are higher in marine species than in freshwater species, although most of the arsenic is present in nontoxic, organic forms. These examples illustrate the point that simplistically derived water quality criteria and sediment standards may not yield the expected reductions in chemicals in fish.

Strategies to reduce chemical concentrations might be better focused on relevant fish and shellfish species groups and habitat for each chemical. We recognize that existing regulatory frameworks may not support such an approach, but identification of multiple, carefully defined fish consumption estimates would provide greater flexibility in responding to limits of existing regulations. Some critical issues related to fish consumption definitions are described in the remainder of these comments. ***(Barrette (PCSGA)/Schoof (Environ))***

9.5 Specific recommendations on default fish consumption rates

Many people provided specific recommendations on what they believed was an appropriate default fish consumption rate for Washington. However, some of those recommendations were based on certain assumptions or qualifiers. For example, some people providing recommendations also expressed the opinion that a single statewide number did not fully account for the wide variations in waterbodies and population groups.

The recommendations fell into four general categories:

Default fish consumption rate between 157 and 267 grams/day

Several people expressed support for selecting a default fish consumption rate from the range described in the Technical Support Document. For example:

Existing default rates for fish consumption used in cleanup, sediment management, and water quality standards in Washington State are clearly inadequate to protect public health from persistent toxic contaminants. The proposed range offered in the Technical Support Document for a range of 157 to 267 grams per day as a default fish consumption rate represents a substantial improvement over existing rates and is thus a step forward. However, many tribes have already documented higher fish consumption rates among tribal citizens and thus support revised state rates that are at or above the high end of the range. The higher end of the range reflects a more protective level, particularly since the proposed range does not account for the suppression factors described above, or the increasing trend of seafood consumption in the state and nation.

The proposed range of 157 to 267 grams per day is based on real consumption in Washington, not an imaginary or artificial standard. The range represents a statistical composite of locally-derived fish consumption data, set at the 80th to 95th percentile of fish-consuming populations. Some of · our individual tribes and tribal citizens clearly consume more on a regular basis. The low end of the range (157 gpd) is less than the mean fish consumption rate derived in one Puget Sound tribe's dietary survey. Washington State is required to use local data, establish a high level of protection for populations throughout the state, and protect high-risk populations including tribes. Washington State standards should be at least as protective as the fish consumption rate of 175 grams per day that was recently approved by the EPA for the state of Oregon. In addition to establishing a more protective rate, the key to keeping fish safe for consumption will be a rigorous program of implementation as the standards are applied in the future ***(Frank (NWIFC))***

****

The report recommends a fish consumption rate in the range of 157 to 267 grams per day. These results are consistent with the findings of CRITFC's comprehensive fish consumption study that was conducted in 1991-1992, which documented that a fish consumption rate of 176 grams per day would be protective of 95 percent of the adult population and 389 grams per day would be protective of 99 percent of the adult population. Based on the CRITFC study, the current fish consumption rate of must be increased in order to be protective of Washington fish consumers. ***(Lumley (CRITFC))***

However, some of the people expressing support for a default rate between 157 g/day and 267 g/day noted that many groups and individuals eat larger amounts of fish and shellfish on a regular basis. They recommended that Ecology view default fish consumption rates in this range as an interim step. They also recommended that Ecology's decisions on a default rate should not limit tribal governments from adopting standards based on a higher rate. For example:

The Squaxin Island Tribe will support an increase in the Washington state, regulatory fish consumption rate to a minimum range between 157 and 267 grams per day for the current rulemaking processes related to sediment management and water quality standards, if the following conditions are met:

1. Any fish consumption rate adopted not be considered a "tribal" fish consumption rate;

2. The state and tribes memorialize a process with explicit milestones to gradually increase the fish consumption rate to eventually reflect what people who consume large quantities of fish actually eat;

3. Salmon and shellfish are included in the fish consumption rate; and,

4. Other variables in the health risk assessment like cancer risk rates do not change to dilute the increased safety gained from a higher fish consumption rate. ***(Squaxin Island Tribal Council)***

****

Puget Sound Region and the 1994 Asian and Pacific Islander Study. It would be preferable that there would be even more studies conducted and especially those done by the tribes themselves to ensure that in the future Washington's fish consumption assumptions reflect the real health risks posed by fish consumption. We do not suggest that Ecology should postpone a timely resolution to a long overdue revision to Washington's standards but, rather, that Ecology not see this needed step as necessarily resolving the issue. ***(Trim (PFPS)/Bell (NWEA))***

One person agreed that the draft range characterizes the upper percentile of high seafood consumers. However, she questioned whether these values were applicable to all waterbodies.

King County agrees that the recommended 157-267 gm/day consumption range characterizes the upper percentile of "high end seafood consumer" exposure. However, we believe that values in this range are not applicable for all waterbodies on a statewide basis as elaborated below. We also have concerns regarding the technical feasibility of implementing these rates that will ultimately need to be addressed. ***(True, King County DNRP))***

However, several people expressed the opinion that the draft range was much higher than the amount of fish and shellfish consumed by the general population. For example:

The proposed range of default FCRs overstates the fish consumption rates for the vast majority of residents of the state. 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 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. ***(Louch and Stratton (NCASI))***

****

The City of Spokane acknowledges that, according to surveys conducted for the technical support document, a relatively small percentage of Washingtonians may consume more than the current EPA standard of 6.5 grams per day. (Table A-1 shows that Ecology used data

*from 1,188 surveyed adults to develop the proposed default fish consumption rate; there are about 6.7 million Washington residents according to the 2010 census.)**(Arnold (City of Spokane))***

Default fish consumption rate based on general population

Several people recommended that if Ecology elected to establish a default fish consumption rate, that rate should be based on the amount of fish and shellfish eaten by the general population. For example:

… 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 population6. Based on these data, EPA 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. ***(Louch and Stratton (NCASI))***

Default fish consumption rate equal to or greater than 267 grams/day

Several people expressed support for a default fish consumption rate between 157 and 267 grams/day, but concluded that a higher rate was needed to protect population groups who are known to eat larger amounts of fish and shellfish. For example:

*….In reviewing the literature and in speaking with members of subsistence and indigenous groups, we believe the seafood consumption rate should be set close to 300 g/day, if not higher. The setting of a subsistence rate for non-tribal peoples should be in no way construed as a substitute for individual tribal consumption rates….****(Branch et al. (Environmental Coalition))***

****

The proposed range offered in the Technical Support Document for a range of 157 to 267 grams per day as a default fish consumption rate represents a substantial improvement over existing rates and is thus a step forward. However, many tribes have already documented higher fish consumption rates among tribal citizens and thus support revised state rates that are at or above the high end of the range. The higher end of the range reflects a more protective level, particularly since the proposed range does not account for the suppression factors described above, or the increasing trend of seafood consumption in the state and nation. ***(Frank (NWIFC))***

****

Page 77 there is a reference to the EPA recommendations to states it appears that the options range is all over the place but I think that the Suquamish rate as the highest average rate is the most appropriate to use when setting the standards. Using the lowest recommended standard of the mean it will give a 214 grams per day number which is protective of all non-native consumers and some native consumers to the 85% or better, though 267 would be protective of most groups to the 90% which is the standard percentile used for MTCA.

The high end of your recommendations (267 g/day) is the most appropriate default number particularly for cleanups and based upon the recent studies of salmon the water quality program as well. It should be noted on page 105 bullet #4 that … default fish Consumption rate in the proposed range would be protective of "most" fish consumers. ***(Dunn (LEKT))***[31]

****

Based on the technical assessment, Ecology has concluded that available scientific studies support the use of a default fish consumption rate in the range of 157 to 267 grams per day (g/day). We support a rate that is at least this high. Fish consumption rates should seek to protect no less than the 90 percentile of any affected population. As has been pointed out in comment letters to you from tribes, the fish consumption rates proposed by Ecology are not high enough to provide adequate protection for all tribes, some of whom will likely set their own standards…. ***(Trim (PFPS)/Bell (NWEA))***

Use the Oregon DEQ fish consumption rate (175 g/day)

Several people recommended that Ecology establish a default fish consumption rate that is at least as stringent as the fish consumption rate adopted by the Oregon Department of Environmental Quality. For example:

Adopt the new Oregon rules, 175 grams. ***(Shaw)***

****

State standards should be at least as protective as the fish consumption rate of 175 grams per day that was recently approved by the EPA for the state of Oregon. In addition to establishing a more protective rate, the key to keeping fish safe for consumption will be a rigorous program of implementation as the standards are applied in the future ***(Frank (NWIFC))***

****

The Washington Waterkeepers also agree with the comments of the Northwest Indian Fisheries Commission ("NWIFC"): at a minimum, the fish consumption rate should be no lower than the 175 g/day rate adopted by Oregon's Environmental Quality Commission. ***(Waterkeepers)***

[31] However, Mr. Dunn also stated that "…[u]nder the Preliminary recommendation section it should be noted that the 157 to 267 gram per day rate is not protective of most of the Salish tribes. Therefore individual tribal rates should be considered and will be necessary in many cases. It needs to remain clear that this rate is not to be construed as a tribal default rate. If it becomes the water quality rate then it will be the default for all water quality programs, is that correct? If it is then I think that it should be clearly stated as such."

9.6 Method for developing recommended range

Ecology considered multiple ways of approaching the data from the Pacific Northwest regional fish consumption rate surveys. Ecology chose a method that involved fitting the individual studies to lognormal probability distributions, combining the distributions, and developing a composite lognormal distribution based on the combined data. This was described in Appendix C of the Technical Support Document.

Ecology used the descriptive statistics from four consumption surveys to prepare this analysis. Several people noted the difficulties associated with performing this type of analysis when the underlying data are not available. For example:

> *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.* ***(Louch and Stratton (NCASI))***

****

> *I did not have time to review and comment on the approach used to combine, transform, and statistically analyze the fish consumption data. However, a significant limitation/uncertainty associated with these data is the fact that Ecology (reportedly) was not provided with the raw survey results that would allow them to independently assess the data prior to using them in their analysis.* ***(Waldron (PTC))***

Several people stated that the datasets used in this analysis should be adjusted to exclude fish that are not regionally harvested. For example:

> *As noted above, these datasets should be adjusted (per EPA Region 10) to eliminate fish that are not regionally harvested before developing composite distributions….* **(*Louch and Stratton (NCASI)*)**

Several people[7] recommended that Ecology include information on the general population when performing this evaluation. For example:

> *Ecology 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, 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…* ***(Louch and Stratton (NCASI))***

Ecology performed this analysis using several different approaches for weighting the results from the individual studies. Several people recommended that Ecology use a weighting approach based on the estimated adult population represented by each survey. For example:

> *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). Regardless of the outcome, it would be more correct to weigh each of these studies according to the estimated total adult populations represented by each survey (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 or other appropriate studies). ***(Louch and Stratton (NCASI))***

****

Why would Ecology not weigh fish consumption by identified sub-populations based on the percentage of the total population of the state (or, at the very least, as the percentage of the total surveyed population)? Can Ecology quantify the benefit to the overall health of the state's population it expects to result from the approach taken in the current TSD (assigning equal weights to each sub-population regardless of the relative sizes of these different sub-populations)? ***(McCabe (February 24th e-mail)***

References

Ahlborg U.G., Becking GC, Birnbaum LS, Brouwer A, Derks HJGM, Feeley M, Golor G, Hanberg A, Larsen JC, Liem AKD, et al. 1994. Toxic equivalency factors for dioxin-like PCBs; report on a WHO-ECEH and IPCS consultation. Chemosphere 28 (6): 1049-1067.

CRITFC (Columbia River Inter-Tribal Fish Commission). 1994. A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin. Technical Report 94-3. Portland, Oregon. 1994.

CRITFC. 2012. Columbia River Inter-tribal Fish Commission Correspondence from Babtist Paul Lumley, Executive Director of Columbia River Inter-Tribal Fish Commission, to Ted Sturdevant, Director, Washington Department of Ecology, Dated March 19, 2012.

Confederated Tribes of the Colville Reservation and U.S. EPA Region 10. 2012. Food Questionnaire Data Report, Upper Columbia River Resources Survey, June 12, 2012 Appended to Upper Columbia River Site Remedial Investigation and Feasibility Study Tribal Consumption and Resource Use Survey. Final Report. June 22, 2012.

Confederated Tribes of the Umatilla Indian Reservation. 2004. Exposure Scenario for CTUIR Traditional Subsistence Lifeways. Confederated Tribes of the Umatilla Indian Reservation. Department of Science & Engineering. Stuart Harris, Director. September 15, 2004. Quoted from page 4. Web location: http://www.hhs.oregonstate.edu/ph/sites/default/files/CTUIR-SCENARIO.pdf

Conservation Foundation, 1984. State of the Environment: An Assessment at Mid-Decade. Washington D.C.

Daniell, W. 2012. University of Washington School of Public Health Correspondence from William Daniell, Associate Professor, Department of Environmental and Occupational Health Sciences, to Craig McCormack, Washington Department of Ecology, Dated March 20, 2012.

Dodd K.W., Guenther PM, Freedman LS, Subar AF, Kipnis V, Midthune D, Tooze JA, Krebs-Smith SM. 2006. Statistical methods for estimating usual intake of nutrients and foods: a review of the theory. *J Am Diet Assoc*; 106(10):1640-50.

Donatuto, J. and B.L. Harper. 2008. Issues in evaluating fish consumption rates for Native American tribes. Perspective. *Risk Analysis*, Vol. 28, No. 6, 2008, pages 1497–1506.

Ebert, E.S., P. Price, and R.E. Keenan. 1994. Selection of fish consumption estimates for use in the regulatory process. *Journal of Exposure Analysis and Environmental Epidemiology* 4:373-393.

Ecology. 2011. Fish Consumption Rates; Technical Support Document. *A Review of Data and Information About Fish Consumption in Washington.* September 2011. Publication no. 11-09-050.

Ecology. 2012a. Fish Consumption Rates; Technical Support Document. *A Review of Data and Information About Fish Consumption in Washington.* Public Review Draft August 27, 2012, Version 2.0. Publication no. 12-09-058.

Ecology. 2012b. Supplemental Information to Support the Fish Consumption Rates Technical Support Document. Washington State Department of Ecology, Olympia, WA. July 20, 2012.

Finkel, A. 2011. "Solution-focused risk assessment": A proposal for the fusion of environmental analysis and action. *Human and Ecological Risk Assessment 17:754-787.*

Governor's Office of Indian Affairs, 2010. July 2010 access to web link: Tribal Map at the following link: http://www.goia.wa.gov/tribal_gov/documents/WAStateTribalMap.pdf and Governors Office of Indian Affairs at: http://www.goia.wa.gov/.

Harper, B.L., B. Flett, S. Harris, C. Abeyta, and F. Kirschner. 2002. The Spokane Tribe's Multipathway Subsistence Exposure Scenario and Screening Level RME. *Risk Analysis*, Vol 22, No. 3, 2002, pages 513–526.

Harper, B.L., A.K. Harding, T. Waterhouse, and S. Harris. 2007. *Traditional tribal subsistence exposure scenario and risk assessment guidance manual.* Oregon State University Department of Public Health, Confederated Tribes of the Umatilla Indian Reservation; Oregon State University Departments of Public Health and Nutrition and Exercise Sciences, August 2007.

Harper, B.L. and S. Harris. 2008. A possible approach for setting a mercury risk-based action level based on tribal fish ingestion rates. *Environmental Research, 107 (2008) 60-68.* May 2008.

Harris, S.G. and B.L. Harper. 1997. A Native American exposure scenario. *Risk Analysis*, Vol. 17, No. 6. pages 789–795.

Harris, S.G. and B.L. Harper. 2001. Lifestyles, diets, and Native American exposure factors related to possible lead exposures and toxicity. *Environmental Research Section A*, 86. pages 140–148.

Hope, B. K. 2012. Acquisition of polychlorinated biphenyls (PCBs) by Pacific Chinook salmon: An exploration of various exposure scenarios. Integrated Environ. Assess. Manag. 8(3): 553-662. (First published online on March 29, 2012)

Hugo, Victor, and Lorenzo O'Rourke (trans.) *Victor Hugo's Intellectual Autobiography: (Postscriptum de ma vie)* (1907), 237.

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.* Office of Environmental Assessment, U.S. Environmental Protection Agency Region 10, Seattle, WA.

Mayfield, D.B., Robinson, S., and Simmonds, J. 2007. Survey of fish consumption patterns of King County (Washington) recreational anglers. *Journal of Exposure Analysis and Environmental Epidemiology*, 17:604-612.

Model Toxics Control Act Policy Advisory Committee (MTCA PAC). 1996. *Final Report of the Model Toxics Control Act Policy Advisory Committee*. December 15, 1996.

Moya, J. 2004. Overview of fish consumption rates in the United States. *Human and Ecological Risk Assessment*, 10: 1195-1211.

National Research Council. 1983. *Risk Assessment in the Federal Government: Managing the Process.* National Academy Press. Washington D.C.

National Research Council. 1994. *Science and Judgment in Risk Assessment*. Committee on Risk Assessment of Hazardous Air Pollutants. Board on Environmental Studies and Toxicology. Commission on Life Sciences. National Academy Press. Washington, D.C.

National Research Council. 1996. *Understanding Risk: Informing Decisions in a Democratic Society*. National Academy Press. Washington D.C.

National Research Council. 2009. *Science and Decisions: Advancing Risk Assessment*. Committee on Improving Risk Analysis Approaches Used by the U.S. EPA. National Academy Press. Washington D.C.

O'Neill, S.M., J.E. West, and J.C. Hoeman. 1998. Spatial Trends in the Concentration of Polychlorinated Biphenyls (PCBs) in Chinook (*Oncorhynchus tshawytscha*) and Coho Salmon (*O. kisutch*) in Puget Sound and Factors Affecting PCB Accumulation: Results from the Puget Sound Ambient Monitoring Program. Published in *Puget Sound Research '98 Proceedings, Seattle, Washington,* Volume 1, pages 312–328.

O'Neill S.M., G.M. Ylitalo, J.E. West., J. Bolton, C.A. Sloan, and M.M. Krahn. 2006. Regional patterns of persistent organic pollutants in five Pacific salmon species (*Oncorhynchus* spp) and their contributions to contaminant levels in northern and southern resident killer whales (*Orcinus orca*). *Extended Abstract in 2006 Southern Resident Killer Whale Symposium*. April 3-5, 2006.

Oregon Department of Environmental Quality (Oregon DEQ). 1999. *Guidance for Use of Probabilistic Analysis in Human Health Risk Assessments (Interim final).* Portland, OR. [Note: Guidance was published in January 1998 with updates in November 1998 and March 1999.]

Oregon DEQ. 2008. *Human Health Focus Group Report Oregon Fish and Shellfish Consumption Rate Project*. Adapted from Table 3, page 28 of the DEQ Water Quality Division. June 2008.

Pierce, D., Noviello, D.T., and Rogers, S.H. 1981. Commencement Bay seafood consumption study. Preliminary Report. Tacoma-Pierce County Health Department, Tacoma, Washington. December 1981.

Polissar, N.L., M. Neradilek, A.Y. Aravkin, P. Danahar, and J. Kalat. 2012. *Statistical Analysis of National and Washington State Fish Consumption Data*. Draft. Prepared for the Washington State Department of Ecology by The Mountain-Whisper-Light Statistics, Seattle, WA. July 22, 2012.

Sechena, R., C. Nakano, S. Liao, N. Polissar, R. Lorenzana, S. Truong, and R. Fenske. 1999. Asian and Pacific Islander Seafood Consumption Study in King County, Washington. EPA 910/R-99-003. May 1999. http://www.epa.gov/region10/pdf/asian_pacific_islander_seafood_consumption_1999.pdf .

Sechena, R., S. Liao, R. Lorenzana, C. Nakano, N. Polissar, and R. Fenske. 2003. Asian American and Pacific Islander seafood consumption – A community-based study in King County, Washington. *Journal of Exposure Analysis and Environmental Epidemiology*. (2003) 13, 256-266.

Schmidt, A. "An evaluation of fish consumption and environmental concern in low income and food insecure populations in Seattle," Master in Science Thesis, University of Washington, Seattle, 2011.

Subar A. K. Dodd, P. Guenther, V. Kipnis, D. Midthune, M. McDowell, J. Tooze, L. Freedman, Krebs-Smith SM, 2006. The food propensity questionnaire: Concept, development, and validation for use as a covariate in a model to estimate usual food intake. *Journal of the American Dietetic Association.* 106:10, pp 1556-1563.

The Suquamish Tribe, M.Duncan. 2000. Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation. Puget Sound Region. August 2000.

Tooze, J.A., D. Midthune, K.W. Dodd, L.S. Freedman, S.M. Krebs-Smith, A.F. Subar, P.M. Guenther, R.J. Carroll, and V. Kipnis. 2006. A new statistical method for estimating the usual intake of episodically consumed foods with application to their distribution. *Journal of the American Dietetic Association* 106:10, pp 1575-1587.

Toy, K.A., N.L. Polissar, S. Liao, and G.D. Mittelstaedt. 1996. *A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region*. Tulalip Tribes, Department of Environment, 7615 Totem Beach Road, Marysville, Washington 98271. 1996.

U.S. Department of Agriculture (USDA). Continuing Survey of Food Intakes by Individuals in 1994-96, and 1998 Children's Supplement.

U.S. Department of Agriculture. 2007. USDA national nutrient database for standard reference, release 20. Available online at http://www.ars.usda.gov/ba/bhnrc/ndl

U.S. EPA, 1992. Guidelines for exposure assessment. Washington, DC: Office of Research and Development, Office of Health and Environmental Assessment. EPA/600/Z-92/001. Available at: http//www.epa.gov/NCEA/raf/pdfs/exposure.pdf

U.S. EPA. 1998. *Guidance for Conducting Fish and Wildlife Consumption Surveys*. EPA-823-B-98-007. November 1998.

U.S. EPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. Final methodology document (EPA-822-B-00-004). Volume 1: Risk Assessment (EPA-822-B00-005). October 2000 http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/index.cfm

U.S. EPA. 2002. *Fish Consumption and Environmental Justice*. A report developed from the National Environmental Justice Advisory Council Meeting of December 3-6, 2002. A Federal Advisory Committee to the U.S. Environmental Protection Agency. November 2002 (revised) Page 31.

U.S. EPA. 2002a. Estimated Per Capita Fish Consumption in the United States. *EPA-821-C-02-003*. Table 4, Section 5.1.1.1. August 2002.

U.S. EPA. 2002c. *Overview of the EPA quality system for environmental data and technology*. Office of Environmental Information, Washington DC; EPA/240/R-02/003. Accessed online at http://www.epa.gov/QUALITY/qsdocs/overview-final.pdf

U.S. EPA. 2003a. *A summary of general assessment factors for evaluating the quality of scientific and technical information*. Science Policy Council, Washington DC; EPA/100/B-03/001. Available online at http://www.epa.gov/osa/spc/pdfs/assess2.pdf

U.S. EPA. 2004. *An Examination of EPA Risk Assessment Principles and Practices*. Science Policy Council. Washington D.C. *EPA/100/B-04/0001*.

U.S. EPA. 2006. *Guidance on systematic planning using the data quality objectives process*. Office of Environmental Information, Washington, DC; EPA/240B/06/001. Available online at http://www.epa.gov/quality/qs-docs/g4-final.pdf

U.S. EPA. 2007. *Region 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*. August 2007.

U.S. EPA. 2008. *Child-Specific Exposure Factors Handbook*. (Final Report) EPA/600/R-06/096F. September 2008 http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=199243.

U.S. EPA. 2009. *Exposure Factors Handbook: 2009 Update*. EPA/600/R-09/052A. July 2009.

U.S. EPA. 2011. *Exposure Factors Handbook: 2011 Edition.* National Center for Environmental Assessment. Office of Research and Development. September 2011. EPA/600/R-090/052F.

Van den Berg M, Birnbaum L, Bosveld, ATC, Brunstrom B, Cook P, Feeley M, Giesy JP, Hanberg A, Hasegawa R, Kennedy SW, et al. 1998. *Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife*. Environmental Health Perspectives 106(12):775-792.

Washington State Department of Transportation (WSDOT). 2008. Model Comprehensive Tribal Consultation Process for the National Environmental Policy Act (NEPA), Appendix B: Summaries of Usual and Accustomed Areas prepared by the Washington Attorney General's Office.

West, J.E., J. Lanksbury, and S.M. O'Neill. 2011a. Persistent Organic Pollutants in Marine Plankton from Puget Sound. Washington Department of Ecology. Publication number 11-10-002. March, 2011. Web location: http://www.ecy.wa.gov/biblio/1110003.html

West, J.E., J. Lanksbury, S.M. O'Neill, and A. Marshall. 2011b. Persistent Bioaccumulative and Toxic Contaminants in Pelagic Marine Fish Species from Puget Sound. Washington Department of Ecology. Publication number 11-10-003. March, 2011. Web location: http://www.ecy.wa.gov/biblio/1110002.html

Windward Environmental. 2007. Lower Duwamish Waterway Remedial Investigation Report. Appendix B: Baseline Human Health Risk Assessment. Final. Prepared for U.S. Environmental Protection Agency Region 10 and Washington State Department of Ecology. November 12, 2007.