DEPARTMENT OF
ECOLOGY
State of Washington

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

Overview of key decisions in rule amendment

August 2016
Publication no. 16-10-025

Publication and Contact Information

This report is available on the Department of Ecology's website at
https://fortress.wa.gov/ecy/publications/SummaryPages/1610025.html

For more information contact:

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

Phone: 360-407-6600

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

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

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

Overview of key decisions in rule amendment

Water Quality Program
Washington State Department of Ecology
Olympia, Washington

This page intentionally left blank

Table of Contents

List of Figures and Tables

Figures

Tables

Glossary and List of Acronyms

303(d)	Ecology's list of impaired waters that violate the Water Quality Standards.
BCF	Bioconcentration Factor
BMP	Best Management Practices
BSAF	Biota Sediment Accumulation Factor
BW	Body Weight
CFR	Code of Federal Regulations
CSF	Cancer Slope Factor
CSO	Combined Sewer Overflow
DI	Drinking water Index
DOC	Dissolved Organic Carbon
Ecology	Washington State Department of Ecology
EIM	Environmental Information Management system
EPA	United States Environmental Protection Agency
ESA	Endangered Species Act (US Federal)
FCR	Fish Consumption Rate
HHC	Human Health Criteria
HQ	Hazard Quotient
IRIS	Integrated Risk Information System
Kg	Kilograms
K_{OW}	chemical specific octanol-water partition coefficient
mg/l	Milligrams Per Liter
NOAA	National Oceanic and Atmospheric Administration
NPDES	National Pollutant Discharge Elimination System Permitting Program

NRWQS	National Recommended Water Quality Criteria
NTR	National Toxics Rule
PBDEs	Polychlorinated Biphenyls
PCBs	Polychlorinated Biphenyls; manufactured chemicals which persist and accumulate in food chains
POC	Particulate Organic Carbon
RAGS	Risk Assessment Guidance for Superfund
RCW	Revised Code of Washington
RfD	Reference Dose
RL	Risk Level
RSC	Relative Source Contribution
SDWA	Safe Drinking Water Act
TMDL	Total Maximum Daily Load, or Water Clean-Up Plan
µg/L	Micrograms per liter
USFWS	United States Fish and Wildlife Service
WAC	Washington Administrative Code (The Water Quality Standards for Surface Waters of the State of Washington are in WAC 173-201A)

Overview

What is this rulemaking about and is it required of the state?
This state rulemaking is a revision to the Water Quality Standards for Surface Waters of the State of Washington (Chapter 173-201A WAC). This rulemaking addresses two specific areas of the water quality standards:

1. Development and adoption of new human health criteria (light grey highlighted area in Figure 1); and
2. Revision, expansion, and clarification of some of the tools in the standards that help in criteria implementation (darker grey highlighted area in Figure 1).

This document explains the changes and the rationale supporting the changes, including specific risk management input to Ecology by Governor Inslee. The rule language can be seen at Ecology's Water Quality Standards website:
www.ecy.wa.gov/programs/wq/ruledev/wac173201A/1203ov.html.

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

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

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

Washington State law gives Ecology authority and responsibility to protect the quality of Washington waters and implement federal Clean Water Act programs. The authority and responsibility regarding water quality standards can be found in the Revised Code of Washington (RCW): RCW 90.48.030, RCW 90.48.035, and RCW 90.48.260(1).

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

- Designated uses (also called beneficial uses) for all surface waters, such as aquatic life habitat, recreational uses, harvest, public and industrial water supply, and others.
- Water quality concentrations or levels (called criteria) necessary to protect the uses. These criteria can be numeric (such as concentrations of chemicals or maximum

temperatures) or narrative (descriptions such as "…must not … offend the senses of sight, smell, touch, or taste…").

- Antidegradation provisions that prevent degradation of the water quality.

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

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

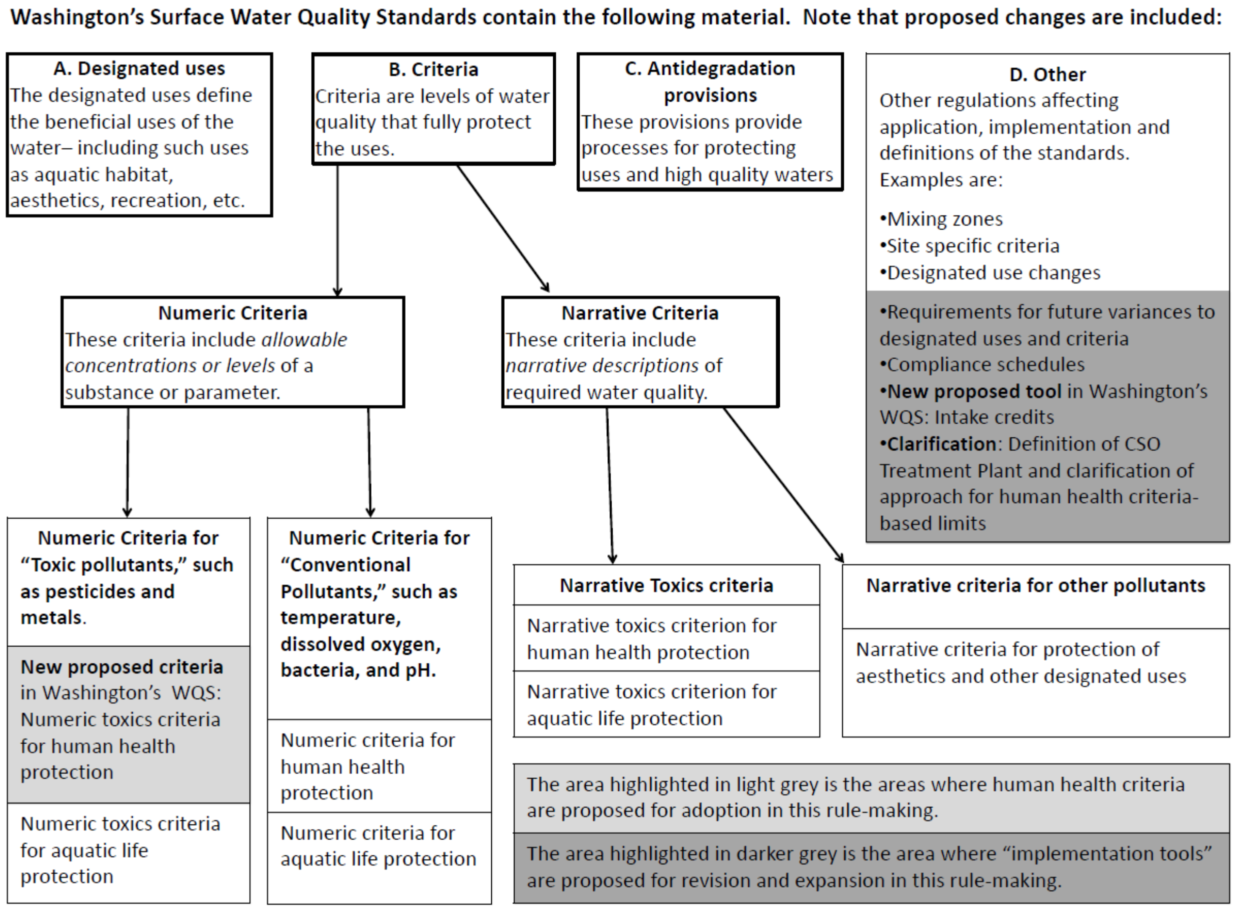


Figure 1: Description of Washington water quality standards with changes highlighted

How are water quality standards revised?

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

(USFWS) regarding effects of the new water quality standards on the ESA-listed species prior to federal approval.

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

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

Because the triennial review and subsequent rulemaking processes are an ongoing set of actions, this approach results over time in a balanced ongoing update to the water quality standards, with higher priority items taking precedence in rulemaking efforts:

Selection of rulemaking topics

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

What are the specific areas of the rule that were modified?

This rulemaking modified two specific areas of the water quality standards: (1) adoption of new human health criteria: and, (2) revision and expansion of some of the tools in the standards that help in implementation. These are discussed separately below.

New human health criteria

Numeric criteria: The human health criteria (HHC) are water concentrations for toxic substances that protect people who consume fish and shellfish from local waters and who drink untreated water from local surface waters. HHC for Washington waters are also under the federally promulgated National Toxics Rule (NTR). The NTR criteria are applicable to Washington until EPA approves the state's new HHC.

HHC are calculated from a variety of different factors, including chemical-specific toxicity to humans, how chemicals move from water into fish and shellfish and then into humans, as well as other factors. The criteria calculation and these factors are discussed at more length in the section on HHC Variables. Specific information on arsenic is found in the section on Challenging Chemicals: Arsenic. The development and adoption of new HHC includes consideration of new science on toxicity factors and new information on body weight and Washington-specific fish consumption. The factors that are included in the criteria calculations are a mix of average and higher percentile values, and in general are consistent with EPA guidance and practice. This approach results in high levels of consumer protection from pollutants that could be found in untreated surface water, fish, and shellfish from Washington. These factors were applied to 94 of 97 different chemicals in this rule (see section on Criteria Chemicals). The criteria for arsenic, copper, and asbestos are not calculated values. Instead, they are based on the regulatory level used in the Safe Drinking Water Act (SDWA; 42 U.S.C. § 300f and as amended).

As well as incorporation of new science, this rulemaking also included several risk management decisions that affected the final criteria values. Governor Inslee announced a proposal for the new criteria on October 8, 2015 (http://www.governor.wa.gov/news-media/inslee-announces-new-path-water-quality-rule-continues-work-broader-toxics-reduction). This included direction to use an updated fish consumption rate in the criteria calculations for carcinogens and non-carcinogens (an average fish consumption rate of 175 g/day) and to continue use of the existing risk level in the water quality standards: one-in-one-million (10^{-6}). Criteria for arsenic, copper, and asbestos are values based on the Safe Drinking Water Act, and a chemical-specific approach is used for PCBs.

Narrative criteria: The water quality standards include narrative provisions that address chemicals that are not included in the list of 97 chemicals for which Ecology is developing criteria.

Revised and expanded implementation tools.

The water quality standards contain a number of tools that relate directly to how the criteria are met. These tools are implemented both in permits and in orders, and specify how the current designated uses and criteria can be changed if certain factors can be demonstrated. Ecology revised two of the tools (compliance schedules and variance requirements) that were already in the water quality standards, and added a new tool (intake credits). These three tools and the rule changes associated with them are fully discussed in this document under implementation tools. Ecology also added implementation clarification language for Combined Sewer Overflows (CSOs). Here is a brief summary of the three tools and CSO language changes:

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

Variances: A variance is a time-limited designated use and criterion as defined in 40 CFR 131.3, and must be adopted by EPA. A variance temporarily waives water quality standards for a specific chemical criterion and designated use for either a single discharge or for multiple discharges, or, for specified stretches of surface waters (e.g., for a specific tributary, a lake, a watershed). Variances are used in situations where it can be demonstrated that: (1) a discharge can eventually meet the permit limit or a water body can eventually meet the criteria and designated use, but a longer time frame is needed than allowed in a compliance schedule, or, (2) it is not known whether the discharge will ever be able to meet the permit limit or whether a waterbody will meet a criterion and/or designated use. Because a variance is a temporary change to a criteria and use, variances are considered changes to the water quality standards and must go through a rulemaking and subsequent EPA Clean Water Act approval to be effective. The prior water quality standards gave a brief list of the requirements for granting variances and set a maximum five-year period. The federal water quality standards regulations were recently revised and now include substantial requirements for granting variances (40 CFR 131.14; http://www2.epa.gov/wqs-tech/final-rulemaking-update-national-water-quality-standards-regulation). The new state rule language on variances expands on the prior rule language and is consistent with the new EPA regulations. Demonstrating the need for a variance could be very labor intensive, depending on the specific situation. More detailed specifications in the water quality standards will help set clearer expectations for both dischargers and the state, and will result in more predictable outcomes for dischargers.

This rule change does not grant any specific variances to water quality standards. Instead, this rule change gives more details on the information requirements for granting variances, and on the types of actions that would be required of dischargers during variance periods. This includes extending the duration of variances beyond five years if necessary.

Intake credits: Intake credits are a permitting tool that allows a discharge limit to be calculated in a way that does not require the discharger to “clean-up” pollutants in the discharge that are in the intake water, when the intake water and receiving water for the discharge are the same water body. This tool is also used to calculate technology-based limits. This tool is used to calculate water quality-based limits in several other states, including Oregon and the Great Lakes states.

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

Implementation Clarification for Combined Sewer Overflows Treatment Plants (CSOs): Ecology adopted new language to be explicit about how the permitting process of combined sewer overflow treatment facilities occurs. A new definition has been added to define a Combined Sewer Overflow (CSO) Treatment Plant as “a facility that provides At-Site treatment as provided for in chapter 173-245 WAC. A CSO treatment plant is a specific facility identified in a department-approved CSO Reduction Plan (Long-term Control Plan) that is designed, operated, and controlled by a municipal utility to capture and treat excess combined sanitary sewage and stormwater from a combined sewer system."

Ecology also added new language at 173-201A-510 WAC to describe implementation of these facilities: "The influent to these facilities is highly variable in frequency, volume, duration, and pollutant concentration. The primary means to be used for requiring compliance with the HHC shall be through the application of narrative limitations, which includes but is not limited to, best management practices required in waste discharge permits, rules, orders and directives issued by the department."

CSOs are driven by influxes of stormwater into combined sanitary and stormwater collection systems. Because of the episodic and short-term nature of CSO discharges, it is infeasible to calculate effluent limits that are based on criteria with durations of exposure up to 70 years. The federal regulations (40CFR122.44(k)) allow use of best management practices (BMP)-based limits in NPDES permits if it is infeasible to calculate numeric limits.

Public Discussion

In December 2011, Ecology started public discussions around implementation tools, and in October 2012, started public discussions around state adoption of HHC. The agency has held many public meetings in a variety of formats to encourage participation. These meetings, and the materials used for the meetings, are at Ecology's Water Quality Standards rule website www.ecy.wa.gov/programs/wq/ruledev/wac173201A/1203ov.html. Ecology has also met many times with various interested groups, including business, municipalities, environmental groups, counties, the US EPA, and Tribes. Ecology received comment from the public and has provided a Response to Comments in its Concise Explanatory Statement.

First Proposed Rule and Supporting Risk Management Decisions

The first proposed rule for HHC and implementation tools was released in January 2015, but was not finalized. The first proposed rule was coupled with an innovative and comprehensive approach to toxics reduction. On July 9, 2014, Governor Inslee released an integrated strategy to reduce pollutants that end up in fish and water. This strategy was based on two joined parts: (1) adoption of HHC and revised and new implementation tools into the state's water quality standards, and, (2) passage of a toxics reduction bill as part of the state's water quality standards rule submittal to the U.S. Environmental Protection Agency.

This strategy included two risk management decisions in the proposed rule: (1) an increase in the risk level from one-in-one-million (10^{-6}) to one-in-one-hundred thousand (10^{-5}); and (2) a risk overlay that dictated that no criterion, except arsenic, would be a higher concentration than the NTR criterion. Adoption of HHC using these risk management decisions, coupled with the draft legislative bill, would have resulted in reductions to a broad suite of toxics at their sources.

July 9, 2014 http://www.governor.wa.gov/news-media/inslee-takes-new-approach-create-meaningful-effective-state-clean-water-standards?id=293

Excerpts from Governor Inslee's 2014 announcement on the first proposed rule

"Gov. Jay Inslee today announced his proposed update to the state's water quality standards, saying he worked until he found a solution that advanced the values of human, environmental and economic health."

"Washingtonians' actual risk to cancer and other harmful effects will be reduced by this proposal," Inslee said. "We are making our waters cleaner and safer."

"But Inslee said the state must also act on the many toxic chemicals from other unregulated sources that the Clean Water Act doesn't address. Inslee said ***he is calling on the Legislature next year to pass a toxics reduction bill as part of the state's submittal to the U.S. Environmental Protection Agency."***

"We could set standards at a thousand grams per day with a cancer risk rate of 10^{-20}, but it still wouldn't do anything to protect our children from exposure to too many toxics that cause neurological and reproductive damage," Inslee said. "This toxics reduction bill gives us the tools to tackle pollutants at their source and make meaningful improvements in the health of our water, our fish and our children."

"Inslee is directing the Department of Ecology to issue a preliminary draft rule no later than Sept. 30 (2014). ***He will submit legislation to the Legislature in 2015 and will make a decision on whether to adopt the final rule only after seeing the outcome of the session. He will ask the EPA to consider the benefits of the full package in determining federal approval of Washington's clean water standards."***

"I believe this approach honors our commitment to keep our children healthy and protect those who regularly eat fish, and doesn't create ineffective and undue requirements on a small number of businesses and governments," Inslee said. "I look forward to working with legislators, businesses, tribes, health care professionals and others to ensure we do the right thing for Washington state and work together for successful implementation of this integrated plan."

Figure 2: Excerpt from Governor Inslee's July 9, 2014 Announcement

In December 2014, Governor Jay Inslee reiterated his comprehensive plan combining the proposed water quality standards with proposed legislation and funding to provide stronger and broader controls on toxic threats in our environment (see the Governor's Policy Brief at: http://www.ecy.wa.gov/water/standards/Gov-Dec2014-ReducingToxicPollution.pdf). In January 2015, Ecology issued a proposed rule establishing new HHC to protect designated uses and provide predictable regulatory implementation tools to help dischargers comply with existing and new source control requirements or discharge limits. The Governor's proposed toxics reduction bill passed the House during the regular legislative session, but the Senate failed to act on it before the legislative session concluded.

Based on the Governor's decision to hold up adoption, Ecology did not adopt the initial proposed rule. Instead, Ecology proposed a new water quality standards rule.

The Second Proposed Rule

Governor Inslee announced a new direction on the second proposed rule on October 8, 2015. That direction included proposing a fish consumption rate of 175 grams per day, staying with the state's currently adopted risk rate of one-in-one-million (10^{-6}), continuing forward with implementation tools, and chemical-specific approaches to arsenic and PCBs. The second proposed rule incorporated the risk management directions given by Governor Inslee. However, the second proposed rule was not linked with any proposed legislation to reduce toxics.

The Final Rule

The final rule was adopted on August 1, 2016. After adoption, Ecology will submit the rule to the EPA for Clean Water Act approval. The new water quality standards do not become effective for Clean Water Act purposes until approved by the EPA.

The new toxics table gives a different look to the water quality standards

The new HHC adds several additional pages of information to the standards. In the new rule, the aquatic life and human health criteria for toxics are combined into one large table.

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

Other changes since the first proposed rule

Subsequent to the publication of the first proposed rule, three federal regulatory actions were taken that affected HHC development in Washington:

1. ***June 2015***. EPA finalized new Clean Water Act 304(a) National Recommended Water Quality Criteria (NRWQC) for human health (80FR No.124, Monday, June 29, 2015, pages 36986-36989: See: (http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhfinal.cfm). Several of the inputs to the new 304(a) guidance values were changed from earlier versions. Because the federal regulations recommend that states consider EPA's 304(a) Guidance when adopting criteria (40 CFR §131.11 (b); see the following text box), this Decision Document for the second rulemaking includes discussion of EPA's most recent NRWQC.

> **40 CFR §131.11**
>
> **(b)** *Form of criteria:* In establishing criteria, States should:
>
> **(1)** Establish numerical values based on:
>
> **(i)** 304(a) Guidance; or
>
> **(ii)** 304(a) Guidance modified to reflect site-specific ...

2. ***August 21, 2015***. EPA published a final rule updating six key areas of the federal water quality standards regulation that helps implement the Clean Water Act. The final rule was published in the Federal Register on August 21, 2015 (80 FR 51019) and is in 40 CFR 131. Several different program areas are addressed in the final rule, including water quality standards variances. The new language on variances in this revised rule is aligned with the new EPA regulation on variances.
3. ***September 2015***. EPA proposed a new regulation (80 FR No. 177, Monday, September 14, 2015. Pages 55063 – 55077) that would promulgate new federal HHC applicable to Washington's waters. In 1992 and 1999, EPA finalized HHC for Washington State in the NTR, and this federal regulation contains HHC currently applied to Washington waters. The newest EPA proposal (September 2015) contains updates for 99 priority pollutants. If Ecology submits the final HHC criteria to EPA for Clean Water Act review and approval before EPA finalizes the new federal regulation containing human health water quality criteria for Washington, EPA will review and act upon the state's submission prior to any final action on the federal criteria. If EPA approves criteria submitted by the state, the corresponding federal criteria will not be finalized. See: (http://www.epa.gov/sites/production/files/2015-09/documents/washington-rule-factsheet-2015.pdf).

Specific decisions used to develop the new criteria and implementation tools

The following sections in this document explain the rationale for the substantive portions of this rule revision.

This page intentionally left blank

What Chemicals and Criteria Are Included

Decision

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

The state's prior HHC are found in the federal NTR. The NTR contains calculated HHC for 85 priority pollutants, which includes 84 pollutants with calculated criteria values and one pollutant (asbestos) with a Safe Drinking Water Act-based human health criterion. Ecology's revised rule contains calculated and Safe Drinking Water Act-based HHC for 97 priority pollutants. The increased number of chemicals (from 85 to 97) is based on EPA's development of new criteria since the NTR was first issued and last revised.

Background

NTR HHC chemicals: HHC that apply to Washington's waters are found in the federal NTR (EPA, 1999). The NTR contains the complete listing of all 126 of the Clean Water Act 307(a) priority toxic pollutants (priority pollutants), and calculated HHC concentrations for 85 of the priority pollutants (some of the priority pollutants names are *not* accompanied by HHC concentrations). Of the 126 priority pollutants, 85 have numeric criteria for fresh water (exposure routes of drinking untreated surface waters and ingestion of fish and shellfish), and 84 have criteria for marine water (ingestion of fish and shellfish only). The NTR HHC apply to Washington's waters until EPA approves the newly adopted HHC.

EPA's recommended national criteria for chemicals: Since the 1992 NTR was published (and subsequently updated in 1999), EPA developed and published several additional Clean Water Act 304(a) recommended national HHC values for both priority pollutants and for non-priority pollutants. EPA's current recommended national criteria table (EPA, 2015) indicates that EPA has developed national recommended HHC for 99 of the priority pollutants and approximately 18 non-priority pollutants. Washington adopted new criteria for 97 of the chemicals that EPA has indicated are priority pollutants. This lower number of proposed chemicals (97) is because Washington is deferring adoption of new criteria for methylmercury, and will stay under the NTR criteria for mercury. Another chemical that Ecology is not adopting criteria for is bis(2-chloroisopropyl) ether, because it was determined that it does not have a 304(a) national recommended criteria associated with it (see further explanation later in this section).

EPA's recommendations to states on selecting chemicals for criteria adoption: EPA's *Water Quality Standards Handbook: Second Edition* (EPA, 2012) provides guidance to states that are choosing chemical criteria. These include recommendations for priority pollutants and nonpriority pollutants, as description follows. An explanation of an exception to adopting the chemical bis(2-chloroisopropyl ether is also included.

Priority pollutants (Clean Water Act 303(c)(2)(B) requirements): the following are excerpts of guidance from EPA's *Water Quality Standards Handbook: Second Edition* (EPA, 2012, Chapter 3.4.1):

Excerpt 1
"*Section 303(c)(2)(B) addresses only pollutants listed as "toxic" pursuant to section 307(a) of the Act, which are codified at 40 CFR 131.36(b). The section 307(a) list contains 65 compounds and families of compounds, which potentially include thousands of specific compounds. The Agency has interpreted that list to include 126 "priority" toxic pollutants for regulatory purposes. Reference in this guidance to toxic pollutants or section 307(a) toxic pollutants refers to the 126 priority toxic pollutants unless otherwise noted."*

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

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

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

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

Exception for Bis(2-chloroisopropyl) ether*:* Ecology has determined that bis(2-chloroisopropyl) ether does not have a 304(a) national recommended criteria associated with it, thus the proposed criteria for this chemical were deleted from the final rule. Ecology has determined that the older NTR criteria for bis(2-chloroisopropyl) ether were incorrect, and were not developed for that particular priority pollutant. Ecology is adopting criteria only for the priority pollutants for which EPA has published 304(a) criteria documents. Further rationale for this decision:

Background information on bis(2-chloroisopropyl) ether: Appendix A to 40 CFR Part 423 lists the 126 Priority Pollutants (PP) published by EPA. Bis(2-chloroisopropyl) ether is priority pollutant number 42 on that list. The priority pollutant list does not specify Chemical Abstract Service numbers (CAS #'s); only names are specified. In EPA's most recent revisions to the 304(a) national recommended criteria for human health, EPA did not publish new criteria for this chemical, and further examination of the history of the criteria for this chemical indicates that the criteria in the NTR for Bis(2-chloroisopropyl) ether were in fact calculated for a different chemical. Bis(2-chloroisipropyl) ether was paired with the CAS # 108-60-1 in the 1992 NTR. This CAS number is incorrect. The CAS # for bis(2-chloroisipropyl) ether is CAS # 39638-32-9.

HHC were promulgated in the NTR for the chemical with CAS # 108-60-1, which is the unique identifier for bis(2-chloro-1-methylethyl)ether. This chemical has a different chemical structure than bis(2-chloroisipropyl)ether, and is an isomer. Bis(2-chloro-1-methylethyl) ether is not on the EPA's Priority Pollutant list at 40 CFR Part 423.

In its most recent (2015) revisions to the 304(a) national recommended criteria for human health EPA published new criteria for bis(2-chloro-1-methylethyl) ether (CAS # 108-60-1). EPA did not publish criteria for the priority pollutant bis(2-chloroisipropyl) ether (CAS # 39638-32-9). It appears that over the years EPA synonymized the two different chemicals during development of criteria, but instead of focusing on the actual pollutant priority name in 40 CFR Part 423, it chose to focus on the CAS # that was paired with the priority pollutant name in the NTR, and developed criteria for the non-priority pollutant. Subsequent information from EPA confirms that EPA drafted the criteria to apply to the non-priority pollutant bis(2-chloro-1-methylethyl) ether (CAS # 108-60-1).

Decision on bis(2-chloroisipropyl) ether for this Rulemaking: In the proposed rule Ecology included criteria for bis(2-chloroisipropyl) ether (CAS no. 108-60-1), based on EPA's NTR chemical list and CAS #s and the matching CAS # for EPA's new criteria for bis(2-chloro-1-methylethyl)ether. Subsequent examination (described previously) brought to light the differences in CAS #'s and chemical names for these two compounds, and the lack of criteria values for the priority pollutant bis(2-chloroisipropyl) ether (CAS # 39638-32-9).

Because the chemical bis(2-chloro-1-methylethyl) ether (CAS no. 108-60-1) is not on EPA's priority pollutant list at Appendix A to 40 CFR Part 423, and because Ecology has made the decision to adopt HHC for priority pollutants only, Ecology is not adopting HHC for this chemical. Because the older criteria for bis(2-chloroisipropyl) ether in the NTR was developed for the non-priority pollutant bis(2-chloro-1-methylethyl) ether (CAS no. 108-60-1) Ecology is not adopting the NTR criteria for this chemical. When Ecology submits final adopted water quality standards to EPA for approval, it will include a recommendation that EPA revise the priority pollutant list at Appendix A to 40 CFR Part 423 to reflect the chemical name that it considers to be the original intended name.

Basis for Ecology's Decisions on HHC

Ecology adopted HHC for all Clean Water Act Sec. 307(a) priority toxic pollutants (except mercury/methyl mercury) for which EPA has developed national recommended numeric HHC, regardless of whether the pollutants are known to be present (EPA guidance for option 1, Priority Pollutants Excerpt 2, described previously). This includes criteria for 97 different pollutants. The exception is that Ecology is not proposing new criteria for methyl mercury, therefore it will remain under the NTR. The state water quality standards include a narrative statement for priority pollutants that do not have numeric criteria and for non-priority toxic pollutants. This approach is consistent with Option 1 from EPA's guidance cited previously.

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

Ecology added an additional statement on downstream protection to the draft rule in language preceding the toxics table. This language is duplicative of existing implementation language in WAC 173-201A-260(3)(b), requiring that upstream waters be conducted in manners that meet downstream water body criteria and will not change any requirements for implementation of the new HHC criteria. The language was added at EPA's recommendation to states to ensure downstream protection is considered.

Ecology's chemical choice:

- Ensures that Washington will satisfy the intent of the Clean Water Act.
- Is within a state's legal authority under the Clean Water Act to adopt broad water quality standards.

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

References

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

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

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

EPA, 2015. U.S. Environmental Protection Agency. National Recommended Human Health Criteria list: *http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm (Note: This website was referenced 10/2015)*

This page intentionally left blank

Human Health Criteria Equations and Variables

Decision

Ecology adopted surface water HHC for 97 priority toxic pollutants. Of those chemicals, 94 have criteria calculations associated with them that are reflected in the following discussion. The other three chemicals (arsenic, copper, and asbestos) are based on Safe Drinking Water Act regulatory levels, and thus their criteria do not involve using human health criteria calculations. The following discussion does not apply to these three chemicals, except where arsenic information is discussed below in the section on Cancer Slope Factor (CSF).

Table 1 provides a comparison of the explicit variables that are found in the human health equations for the federal NTR (applied in Washington), and the new criteria in the WQS. Discussion of the new EPA 304(a) guidance values is also included as needed. In almost all cases, values for chemical-specific toxicity factors are taken from EPA's Integrated Risk Information System (IRIS) or from the EPA National Recommended Water Quality Criteria documents, noted in Table 1. There are also implicit variables in the equations that Ecology did not change from the approach used in the NTR. They are further described in the background section of this document. See Appendix A of this document for the individual chemical-specific values used to calculate the new criteria.

Table 1: Comparison of equation variables for Washington's proposed rule

Explicit variables	NTR Criteria	Washington's new rule (2016)
Fish and shellfish consumption rate (FCR)	6.5 grams/day	175 g/day
Risk level (RL)	Additional lifetime risk of 1 in a million ($1x10^{-6}$)	Additional lifetime risk of 1 in one million ($1x10^{-6}$) (no change)
Relative source contribution (RSC)	1	1 (no change)
Body weight (BW)	70 kilograms (154 pounds).	80 kilograms (176 pounds)
Drinking water intake (DI)	2 liters/day	2.4 liters/day
Reference dose (RfD) for specific chemicals	EPA IRIS values and other sources	Updated values in EPA IRIS and EPA NRWQC documents
Cancer slope factor (CSF) for specific chemicals	EPA IRIS values and other sources	Updated values in EPA IRIS and EPA NRWQC documents
Bioconcentration factor (BCF)	BCFs found in the NTR	Values from 1992 NTR and 1999 revision; EPA's 2002 HHC Calculation Matrix (EPA, 2002), and pre-2015 NRWQC. Two additional BCFs calculated based on EPA 1980.

Background

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

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

Ecology used best available science in developing this rule. Note that what is considered "best available science" is subjective and changes over time. An assessment of "best" at any specific time includes the perspectives of the evaluators, the context of the evaluation, and other factors important to the specific type of decision. The topic of best available science is comprehensively discussed in Sullivan et al (2006). Ecology used the best available science in developing new HHC applicable to Washington State. The input variables were chosen to provide full protection for the designated uses addressed by the HHC. Ecology's rule process acknowledged scientific uncertainties in the inputs to the criteria equations (e.g., the use of uncertainty factors in reference dose development). Ecology developed clear science and/or policy statements to support the final criteria, and has clearly stated the basis of these in materials supporting the proposed and new rule, in particular where new science is emerging or underway. These are discussed in this document. In particular this has been clarified for arsenic, PCBs, and dioxin, where issues of toxicity factors, alternative approaches to criteria development, and risk levels have been addressed. The use of a bioconcentration-based approach over the EPA-recommended bioaccumulation factors in criteria calculation is also clarified in this document.

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

HHC equations and types of variables considered in the equations: In total, four equations are used to calculate HHC. These equations are based on chemical effects (carcinogens or noncarcinogens) and routes of exposure (fresh or marine water):

- *Chemical effects*: HHC equations are used to calculate criteria for both cancer-causing chemicals, called carcinogens, and non-cancer causing chemicals, called noncarcinogens.

The criteria for any one chemical are based on the acceptable level of risk (the effect that would occur at the lowest water concentration).

- *Routes of exposure*: Washington has both marine and fresh waters that are regulated under the Clean Water Act and under state jurisdiction. Therefore, separate equations are needed for each type of water to account for presence or absence of an untreated drinking water exposure route. Marine waters are assumed to include estuarine waters, and both of these do not have the drinking water use applied.

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

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

EPA publishes Clean Water Act Sec. 304(a) national recommended HHC guidance values for approximately 117 chemicals, including priority and non-priority pollutants. The recommended criteria are calculated using a combination of default and chemical-specific pieces of information recommended for state use by EPA. Some of the recommended criteria are based on Safe Drinking Water Act MCLs (maximum contaminant levels). Values for some variables can differ among states, based on location or regional information, science, science policy, and risk management, and can result in criteria that may differ from those recommended by EPA. For other variables, states generally use standard values, supported by national scientific research, that tend to remain constant across states even when developing state-specific criteria. The following variables are explicitly used in the HHC calculation, and are discussed later in this document:

Values for these variables vary among states:

- Fish Consumption Rate (FCR)
- Risk level (RL)
- Relative Source Contribution (RSC)

States generally use the same values for these variables:

- Body Weight (BW)
- Drinking Water Intake (DI)
- Reference Dose (RfD)
- Cancer Slope Factor (CSF)
- Bioconcentration Factor (BCF).

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

Table 2: Summary of HHC equations

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

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

Basis for Ecology's new criteria:

Variables in the equation

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

Variables where the values vary among states:

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

Variables where the values generally do not vary among states:

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

Variables implicit in the HHC equations:

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

1. Fish Consumption Rate (FCR)

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

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

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

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

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

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

In 2015 EPA published revised National Recommended Water Quality Criteria (NRWQC) for human health and included a new 90th percentile FCR for the national general population of 22 g/day, based on newer national survey data.

EPA 2000 makes the following specific recommendation for protection of highly exposed populations:

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

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

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

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

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

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

The range of average values for the three highest Puget Sound tribal average values are in the Table 3, copied from Table 1 of the FCR Technical Support Document (Ecology, 2013):

Table 3: Fish consumption data from Table 1 FCR Technical Support Document

Population	Source of Fish	Number of Adults Surveyed	Mean	Percentiles		
				50th	90th	95th
General population (consumers only)	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). General population data are for consumers only, as opposed to per capita. See Chapters 4 and 6.

The three highest average (mean) values are from the Tulalip, Squaxin Island, and Suquamish tribal surveys (average FCRs are, respectively, 82 g/day, 84 g/day, 214 g/day). The mean of the three tribal studies combined is 127 g/day. The FCR value of 175 g/day is not a calculated value. It was chosen as part of the risk management process for this rule and is based on the best available science for purposes of this rulemaking and is representative of the average value/values of these surveys.

Ecology compared the Asian Pacific-Islander (API) FCRs from Puget Sound, as summarized in Table 4, to the three tribal studies identified previously. The percentile information from the API survey is comparatively lower than the percentile information for the Suquamish study (the tribe with the highest consumption rates). For example, a median equal to 74 g/day was from the API study, while a median equal to 132 g/day was from the Suquamish study. Average (mean) values were not reported for the API study, but because the mid and upper percentiles are all lower than the Suquamish study, it is reasonable to infer that this population is consuming amounts of fish and shellfish that, at the average, are not greater than the tribal studies used to develop the value of 175 g/day, and are therefore encompassed by the value of 175 g/day.

Table 4: API Consumption rates from Table 30 FCR Technical Support Document (Ecology, 2013)

Population API	Species Group	Source of Fish	Descriptive Statistics (g/day)		
			50th Percentile	90th Percentile	95th Percentile
Asian-Pacific Islander (API)	Total seafood consumption	All sources	74.0	227	286
	All species	Harvested anywhere	6.5	25.9	58.8
	All species	Harvested from King County	5.7	22.2	48.4
	Non-anadromous species	Harvested anywhere	6.2	37.9	54.1
	Non-anadromous species	Harvested from King County	6.0	20.1	45.5

Sources: Adapted from Kissinger, 2005, Table 5. See also Polissar et al., 2012.

Decision for the rule:

Ecology used a FCR of 175 g/day to calculate the HHC, based on a state-specific risk management decision. (http://www.governor.wa.gov/news-media/inslee-announces-new-path-water-quality-rule-continues-work-broader-toxics-reduction).

2. Risk level (RL)

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

Ecology continued use of the risk level of one-in-one-million (10^{-6}) as specified in 173-201A-240 WAC, except for the chemical-specific risk level for PCBs (discussed later in this document). The new criteria for carcinogens using the risk level are identified in the newly formatted toxics criteria table at 173-201A-240 WAC.

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

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

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

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

General information: The choice of risk level is a policy decision by the state. Nationwide, states (including Washington) and tribes, have typically chosen to use a risk level of one additional occurrence of cancer in 100,000 people (1×10^{-5}) or one in 1,000,000 people (1×10^{-6}) for HHC. This is demonstrated in a list of state and tribal risk levels provided to Ecology by EPA Region 10 (see http://www.ecy.wa.gov/programs/wq/swqs/RiskLevelCarcinogens.pdf). This list was presented as part of Ecology's Policy Forum #3, held February 8, 2013 (http://www.ecy.wa.gov/programs/wq/swqs/hhcpolicyforum.html). EPA guidance advises that states and tribes using these risk levels must ensure that the risk level for the most highly exposed subpopulations does not exceed one additional occurrence of cancer in 10,000 people (1×10^{-4}), (EPA, 2000). Section 303(c) of the Clean Water Act directs the requirements for setting and revising water quality standards, but does not specify risk levels.

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

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

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

> *"EPA's Guidelines For Exposure Assessment (USEPA, 1992) describes the extreme difficulty in making accurate estimates of exposures and indicates that uncertainties at the more extreme ends of the distribution increase greatly. On quantifying population exposures/risks, the guidelines specifically state:*

In practice, it is difficult even to establish an accurate mean health effect risk for a population. This is due to many complications, including uncertainties in using animal data for human dose-response relationships, nonlinearities in the dose response curve, projecting incidence data from one group to another dissimilar group, etc. Although it has been common practice to estimate the number of cases of disease, especially cancer, for populations exposed to chemicals, it should be understood that these estimates are not meant to be accurate estimates of real (or actuarial) cases of disease. The estimate's value lies in framing hypothetical risk in an understandable way rather than in any literal interpretation of the term 'cases.'"(EPA 2000, pages 2-1 to 2-1)

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

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

As discussed in prior Sections of this Preamble, the water quality standards program has been established with an emphasis on State primacy. Although this rule was developed to Federally promulgate toxics criteria for States, EPA prefers that States maintain primacy, revise their own standards, and achieve full compliance. EPA is hopeful this rule will provide additional impetus for non-complying States to adopt the criteria for priority toxic pollutants necessary to comply with section 303(c)(2)(B).

Removal of a State from the rule will require another rulemaking by EPA according to the requirements of the Administrative Procedure Act (5 U.S.C. 551 et seq.). EPA will withdraw the Federal rule without a notice and comment rulemaking when the State adopts standards no less stringent than the Federal rule (i.e., standards which provide, at least, equivalent environmental and human health protection). For example, see 51 FR 11580, April 4, 1986, which finalized EPA's removal of a Federal rule for the State of Mississippi.

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

How risk was applied in this new rule: The approach Ecology used to calculate the new HHC is very similar to that used by EPA to calculate their Clean Water Act 304(a) national recommended criteria. EPA's method, however, focuses on providing protection to the general population, while the Ecology approach focuses on protection of highly exposed populations, which in Washington are assumed to include (among others) tribes, API populations, immigrant populations, recreational, and subsistence fishers. Washington implemented this change of focus in the proposed criteria equations by changing the FCR variable from a statistic (the average) that represents the general population FCR distribution to an equivalent statistic (the average) representative of FCR distributions of highly exposed populations. The body weight input to the equations is representative of average adults of both the national general population, for the adult average of at least three tribes in Washington, and is used by EPA in its 2015 NRWQC (see Body Weight (BW) discussion later in this document). The Drinking Water Intake (DI) input to the equations is representative of average adults and the national general population, and is used by EPA in its 2015 NRWQC. (see Drinking Water Intake (DI) discussion later in this document). The risk level used in the HHC equations is one to one million (10^{-6}), the risk level currently in Washington's water quality standards (see Overview section of this document for a description of this risk management decision). However, a state-specific risk level was chosen for PCBs (see section on Challenging Chemicals: PCBs.).

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

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

Most states follow EPA's approach and apply the state's default risk level to a general population (as EPA also does in its Clean Water Act §304(a) national recommended criteria) and then ensure that highly exposed populations do not exceed EPA's upper levels of allowed risk. In this new rule Washington has taken the extra protective measure of basing the FCR on

Washington's most highly exposed populations, and the important local food sources of "all fish and shellfish" (which includes the additional protective step of including local and non-local sources, such as all salmon, restaurant, locally caught, imported, and from other sources). The new rule also includes the additional protective step of applying the more broadly protective FCR to a risk level most frequently applied to the general population. The Washington approach ensures that highly exposed populations in Washington will be protected by HHC calculated using the same risk level and FCR statistic (representative of the arithmetic mean) that is currently applied to the NTR HHC calculated for the general population.

Decision for proposed rule: Ecology continued use of the risk of *one-in-one-million or* 10^{-6}. This risk management decision is described in the Overview section of this Decision Document.

3. Relative Source Contribution (RSC)

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

Ecology applied a relative source contribution value of one (1), which is the same value used to calculate the criteria in the NTR.

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

The HHC are used to regulate pollution sources that discharge to waters of the state and are under the authority of the Clean Water Act, in order to control chemical exposure from untreated surface-water used for drinking water, and eating fish and shellfish that live in those waters. The RSC is intended to account for secondary sources of pollutants, outside of the authority of the Clean Water Act, such as atmospheric deposition or marine fish sources (e.g., mercury in tuna).

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

The 1980 EPA guidance for HHC (EPA 1980), used to develop the pre-2000 HHC, included the alternative of considering total exposure from all sources in the criteria calculations, but the Clean Water Act 304(a) HHC, developed following these guidelines, assumed an RSC of 1.0

(EPA, 2002). The 1992 NTR HHC applied a RSC of 1.0 (100% allocation of exposure given to sources regulated by the Clean Water Act). In 2015, EPA published revised NRWQC for a large number of pollutants using RSCs based on EPA 2000 guidance. These RSCs are largely limited to RSC = 0.2.

The EPA 2000 guidance and follow-up clarifications from EPA (2013 and 2015), recommend new default values for the RSC to be used in the HHC equations for noncarcinogens:

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

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

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

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

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

- ➢ If the RSC is 1.0, then it does not change the resulting criteria calculation.
- ➢ If the RSC is 0.8, then the criterion becomes more stringent by 20%.
- ➢ If the RSC is 0.5, then the criterion becomes more stringent by 50%.
- ➢ If the RSC is 0.2, then the criterion becomes more stringent by 80%.

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

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

"Human Exposure Considerations: *A complete human exposure evaluation for toxic pollutants of concern for bioaccumulation would encompass not only estimates of exposures due to fish consumption but also exposure from background concentrations and other exposure routes. The more important of these include recreational and occupational contact, dietary intake from other than fish, intake from air inhalation, and drinking water consumption. For section 304(a) criteria development, EPA typically considers only exposures to a pollutant that occur through the ingestion of water and contaminated fish and shellfish. This is the exposure default assumption, although the human health guidelines provide for considering other sources where data are available (see 45 F.R. 79354). Thus the criteria are based on an assessment of risks related to the surface water exposure route only (57 F.R. 60862-3)." (text copied from EPA web site on 11/10/2015):*

http://www2.epa.gov/sites/production/files/2014-10/documents/handbook-chapter3.pdf

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

Decision for new rule: Because the geographic and regulatory scope of the Clean Water Act addresses contaminant discharge directly to waters of the state (not other sources or areas), Ecology made a risk management decision that the human health criteria in the new rule be based on a relative source contribution of one (RSC = 1). Given the limited ability of the Clean Water Act to control sources outside its jurisdiction, Ecology firmly believes that this is a prudent decision.

4. Body Weight (BW)

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

Ecology updated the BW value used in the equations, based on new science and local data, from 70 kg to 80 kg.

Background: The BW approach included in the 1992 NTR, EPA's 2000 guidance, and EPA's published recommended national Clean Water Act 304(a) criteria values is to use an average adult BW in the HHC calculation. The BW historically used in EPA guidance and regulation is 70 kilograms (154 pounds). EPA's revised NRWQC from 2015 use a BW of 80 kg. (176 pounds). EPA's most recent Exposure Factors Handbook (EPA, 2011) provides an updated average BW of 80 kilograms, which also closely aligns with the tribal average adult BWs of the Tulalip and Suquamish tribes (EPA, 2007) of 81.8 and 79 kilograms, respectively. This newer science and local data compelled Ecology to use the updated BW value in the HHC equations. Table 5 provides HHC-relevant information on use of the body weight exposure factor.

Table 5: Summary of guidance and studies on body weight

Date	Source	BW input
1992	National Toxics Rule (40CFR131.36)	70 kg = average adult body weight
2000	EPA 2000 HHC Methodology (EPA -822-B-00-004)	EPA recommends using 70 kg = average adult body weight as "a representative average value for both male and female adults:" "EPA recommends maintaining the default body weight of 70 kg for calculating AWQC as a representative average value for both male and female adults."
2007	Tribal FCR studies – as summarized in: US EPA Reg. 10, Framework for Selecting and Using Tribal Fish and Shellfish Consumption Rates for Risk-Based Decision Making at CERCLA and RCRA Cleanup Sites in Puget Sound and the Strait of Georgia, Working Document, To Be Applied in Consultation with Tribal Governments on a Site-specific Basis, Revision 00.2007 (EPA, 2007, Tables B-1 and B-2 in Appendix B).	Tulalip Tribe = 81.8 kg average adult Suquamish Tribe = 79 kg average adult
2011	EPA Exposure Factors Handbook - 2011 edition. EPA 600/R-090/052F. (EPA, 2011)	EPA recommends 80 kg for average adult body weight
2015	EPA revised NRWQC for human health	EPA revisions used 80 kg. average adult body weight

Decision for new rule: Based on this information Ecology updated the body weight value used in the equations for the new HHC, based on new science and local data, from 70 kg to 80 kg.

5. Drinking Water Intake (DI)

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

Ecology used the new EPA-recommended drinking water intake (as per revised 2015 EPA NRWQC) value of 2.4 L/day to calculate criteria in the new rule.

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

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

> *"EPA recommends maintaining the default drinking water intake rate of 2 L/day to protect most consumers from contaminants in drinking water. EPA believes that the 2 L/day assumption is representative of a majority of the population over the course of a lifetime. EPA also notes that there is comparatively little variability in water intake within the population compared with fish intake (i.e., drinking water intake varies, by and large, by about a three-fold range, whereas fish intake can vary by 100-fold). EPA believes that the 2 L/day assumption continues to represent an appropriate risk management decision…" (EPA, 2000,* (pages 4-22 to 4-23)

EPA's most recent Exposure Factors Handbook (EPA, 2011, Tables 3-10, 3-26, and 3-27) provides examples of updated 90th percentile adult (ages 18-65) drinking water intake values between 2.1 and 3.1 liters/day, based on national data. These values are for direct and indirect (water added in the preparation of a food or beverage) consumption of water, and are further explained in the previous tables. EPA released new *Supplemental Guidance for Superfund* on February 6, 2014 (memo from Dana Stalcup, USEPA to Superfund National Policy Managers, Regions 1-10; OSWER Directive 9200.1-120) that incorporates and adopts updates to *Risk Assessment Guidance for Superfund(RAGS): Human Health Evaluation Manual, Part A through E*, based on data in the 2011 Exposure Factors Handbook. This includes a recommended 90th percentile adult drinking water intake value of 2.5 L/day. EPA's revised 2015 NRWQC for human health use a 90th percentile drinking water intake of 2.4 L/day.

Table 6 is information on the drinking water exposure factor:

Table 6: Drinking water exposure factor

Date	Source	Drinking Water Intake (DI) input
1992	National Toxics Rule, 40CFR131.36 (EPA 1992)	2 L/day = approximate 90^{th} percentile
2000	EPA 2000 HHC Methodology, EPA -822-B-00-004 (EPA, 2000)	EPA recommends using 2 L/day: "EPA recommends maintaining the default drinking water intake rate of 2 L/day to protect most consumers from contaminants in drinking water. EPA believes that the 2 L/day assumption is representative of a majority of the population over the course of a lifetime. EPA also notes that there is comparatively little variability in water intake within the population compared with fish intake (i.e., drinking water intake varies, by and large, by about a three-fold range, whereas fish intake can vary by 100-fold). EPA believes that the 2 L/day assumption continues to represent an appropriate risk management decision…" (pages 4-22 to 4-23)
2011	EPA Exposure Factors Handbook - 2011 edition. EPA 600/R-090/052F (EPA 2011)	The Exposure Factors Handbook contains new information on drinking water intake for various ages, groups, consumer types, and water sources. It provides updated 90^{th} percentile adult drinking water intake values, based on national data, See Chapter 3.
2014	EPA 2014; OSWER Directive 9200.1-120.	Previous default value was 2 L/day. Currently recommended value is 2.5 L/day, which is the 90th percentile of consumer-only ingestion of drinking water (≥ 21 years of age)
2015	EPA, 2015: FR V80, Number 124 (Monday, June 29, 2015)Pages 36986-36989	Previous default value (EPA 2000) was 2 L/day. The updated drinking water intake is 2.4 L/day for consumer-only water ingestion at the 90th percentile for adults (≥21 years of age)

Decision for new rule: Ecology used the EPA 2015 recommended drinking water intake value of 2.4 liters/day to calculate criteria for the proposed rule.

6. Reference Dose (RfD)

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

Background: The reference dose is an estimate of the daily exposure to the human population (including sensitive subgroups) via ingestion to a chemical that is likely to be without appreciable risk of deleterious health effects during a lifetime. The reference dose applies only to non-carcinogens. EPA has developed chronic reference doses for use in regulatory programs. These can be found in EPA's Integrated Risk Information System (IRIS) and in EPA's NRWQC documents (EPA, 2015).

Decision for new rule: Ecology used reference doses found in either EPA's IRIS or NRWQC documents to calculate the criteria for non-carcinogens for the new rule.

7. Cancer Slope Factor (CSF)

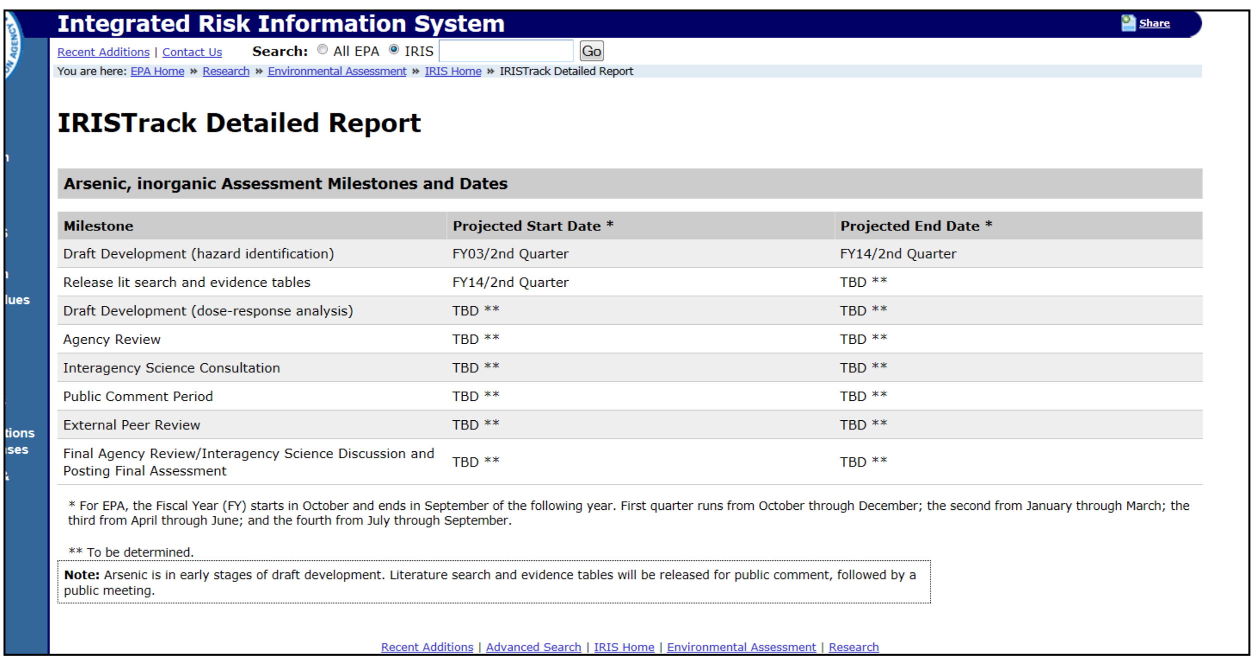
Application: This explicit variable ***applies only to carcinogens****: carcinogen/fresh water and carcinogen/marine water.*

Ecology used EPA 2015 cancer slope factors (most from IRIS) for carcinogens to calculate the criteria in the proposed rule.

Background: The ***cancer slope factor (CSF)*** provides a measure of the toxicity of an identified carcinogen. This slope factor is used for chemicals where the carcinogenic risk is assumed to decrease linearly as the chemical dose decreases. The CSF is specific to each chemical and can be found in the EPA IRIS (EPA, 2014) and in EPA 2015 individual criteria documents.

Ecology used, with few exceptions, the EPA 2015 CSFs for carcinogens to calculate the criteria in the new rule. Ecology made the decision not to use the CSFs in HHC calculations for inorganic arsenic and 2,3,7,8-TCDD based on recent scientific information and uncertainty surrounding assessment of carcinogenicity. Rationale for each of these chemicals varies. The explanation follows:

At any given time, there will be some IRIS toxicity factors undergoing review. In these cases, EPA has a specific process that is followed to review and develop revised factors. At present, several toxicity factors are under review, two of which have been under review for many years: the carcinogenicity reviews of inorganic arsenic and 2,3,7,8-TCDD. Information of the status of the reviews (copied from the EPA IRIS website March 2014) is in Figures 3 and 4. The uncertainty around agreed-upon cancer slope factors for these chemicals is considerable, as evidenced by the long history of the review processes as well as the lack of a prospective date for completion.



Integrated Risk Information System

Share

Recent Additions | Contact Us Search: All EPA IRIS Go

You are here: EPA Home » Research » Environmental Assessment » IRIS Home » IRISTrack Detailed Report

IRISTrack Detailed Report

Arsenic, inorganic Assessment Milestones and Dates

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

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

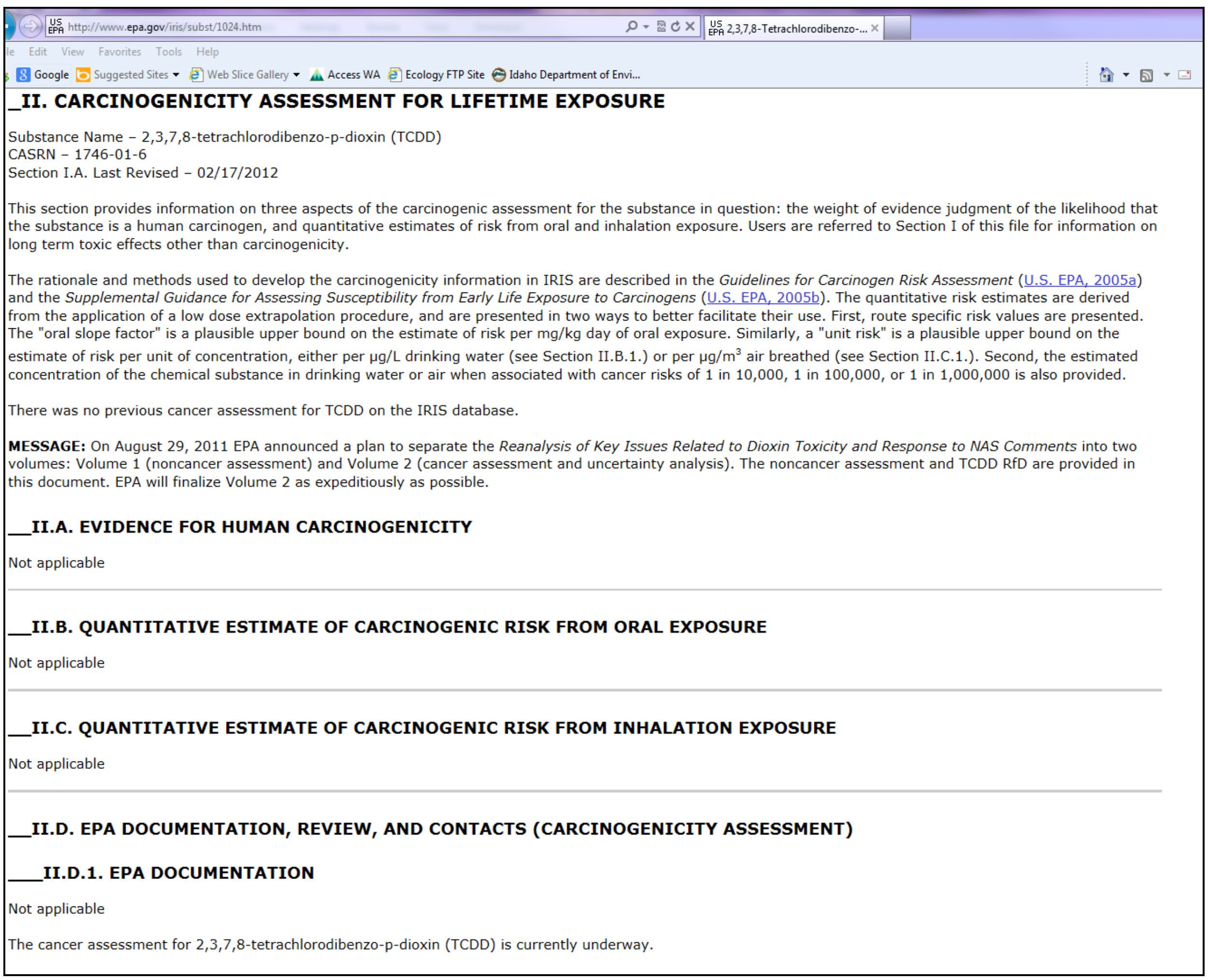
** To be determined.

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

Recent Additions | Advanced Search | IRIS Home | Environmental Assessment | Research

Figure 3: Integrated Risk Information System report for arsenic

Without a reliable toxicity factor for cancer, Ecology cannot calculate arsenic criteria based on cancer. EPA agrees that new cancer-based criteria for arsenic cannot be calculated at this time. In a May 6, 2016 filing with the United States District Court for the Western District of Washington, EPA stated that it will withdraw its proposed arsenic criteria for Washington because “extensive additional scientific analysis is necessary before revised criteria” for arsenic can be promulgated. *Puget Soundkeeper Alliance et. al. V. U.S.E.P.A.*, Case No. 2:16-cv-00293-JLR, EPA’s Motion for Summary Judgment (May 6, 2016) at 13. As EPA explained in the Declaration of Elizabeth Southerland, Director of the Office of Science and Technology with EPA’s Office of Water, “EPA did not update its CWA section 304(a) recommended criteria” for arsenic in 2015, and “EPA recognizes that there is substantial uncertainty surrounding the toxicological assessment of arsenic with respect to human health effects.” Declaration of Elizabeth Southerland (May 5, 2016).



http://www.epa.gov/iris/subst/1024.htm

_II. CARCINOGENICITY ASSESSMENT FOR LIFETIME EXPOSURE

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

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

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

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

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

__II.A. EVIDENCE FOR HUMAN CARCINOGENICITY

Not applicable

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

Not applicable

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

Not applicable

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

___II.D.1. EPA DOCUMENTATION

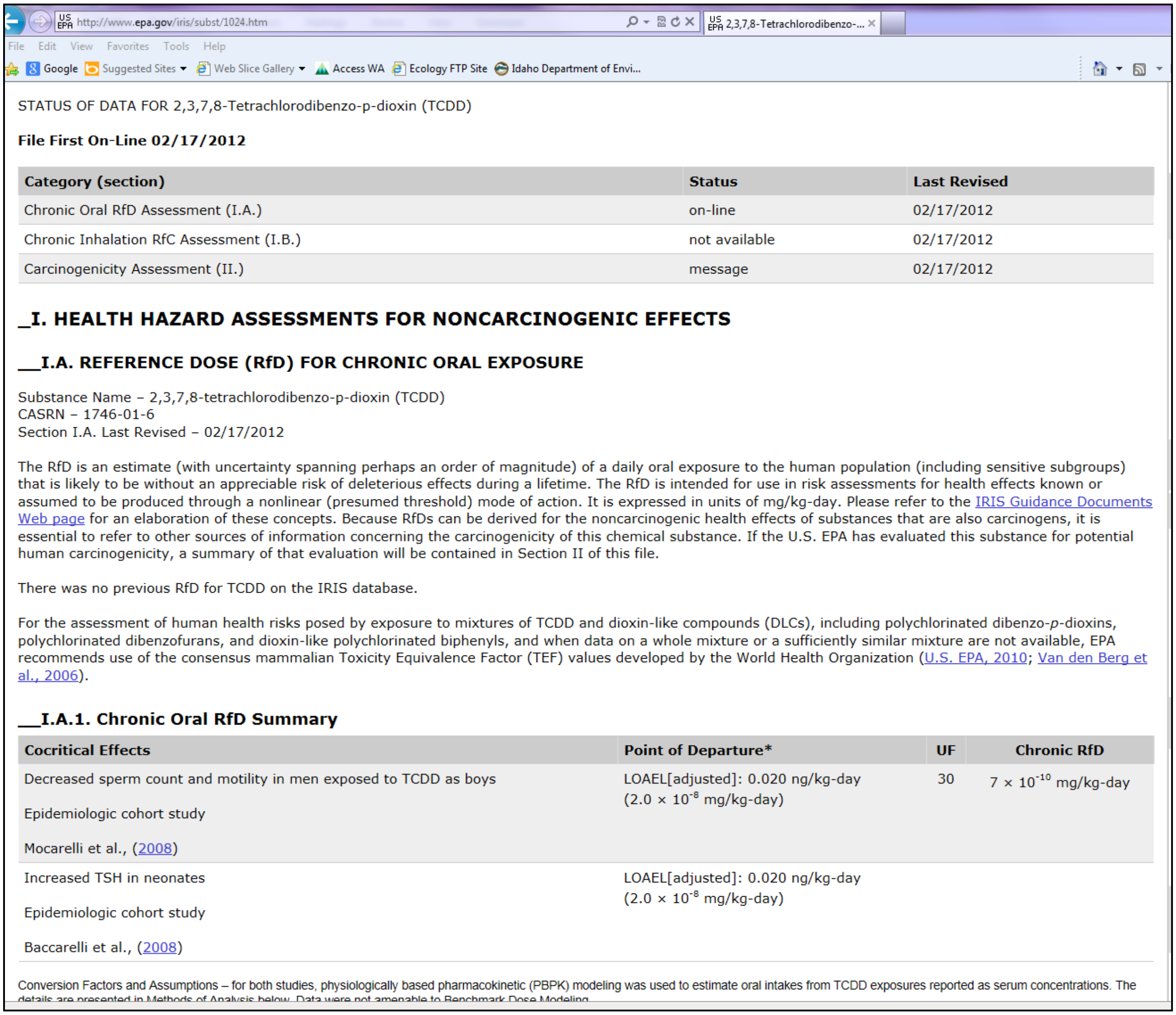
Not applicable

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

Figure 4: Carcinogenicity assessment for 2,3,7,8-TCDD

Without a reliable toxicity factor for cancer, Ecology cannot calculate dioxin criteria based on cancer. EPA agrees that new cancer-based criteria for dioxin cannot be calculated at this time. In a May 6, 2016 filing with the United States District Court for the Western District of Washington, EPA stated that it will withdraw its propose dioxin criteria for Washington because "extensive additional scientific analysis is necessary before revised criteria" for dioxin can be promulgated. *Puget Soundkeeper Alliance et. al. V. U.S.E.P.A.,* Case No. 2:16-cv-00293-JLR, EPA's Motion for Summary Judgment (May 6, 2016) at 13. As EPA explained in the Declaration of Elizabeth Southerland, Director of the Office of Science and Technology with EPA's Office of Water, "EPA did not update its CWA section 304(a) recommended criteria" for dioxin in 2015, and "IRIS does not currently contain a quantitative carcinogenicity assessment" for dioxin. Declaration of Elizabeth Southerland (May 5, 2016). These statements indicate that the existing science does not allow either Ecology or EPA to adopt new cancer-based dioxin criteria for Washington.

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



http://www.epa.gov/iris/subst/1024.htm

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

File First On-Line 02/17/2012

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

_I. HEALTH HAZARD ASSESSMENTS FOR NONCARCINOGENIC EFFECTS

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

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

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

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

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

__I.A.1. Chronic Oral RfD Summary

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

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

Figure 5: Health hazard assessments for noncarcinogenic effects for 2,3,7,8 TCDD

Decision for new rule: Ecology used, with few exceptions, the EPA NRWQC cancer slope factors for carcinogens to calculate the criteria in the proposed rule. Ecology decided, based on scientific information and/or uncertainty, not to use cancer slope factors (either in IRIS or outside of IRIS) in HHC calculations for arsenic and 2,3,7,8-TCDD.

8. Bioconcentration Factor (BCF)

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

Ecology used a bioconcentration factor-based approach for criteria calculation.

Background: The HHC are expressed as chemical concentrations in water, but are based on information and assumptions about how those chemicals move from water into edible tissues of aquatic organisms and then into consumers of those tissues. This section addresses the factor in the HHC equations that is used to describe how chemicals accumulate from water into aquatic organisms.

Predicting the accumulation of toxics into aquatic organisms from the surrounding water media is a complex task. Accumulation into aquatic organisms can be affected on a site-specific basis by many factors, some of which are discussed in the following paragraph. The HHC equations depend on a single variable to account for the accumulation step: either the bioconcentration factor (BCF) or the bioaccumulation factor (BAF). This variable in the equations is likely more affected by site-specific waterbody factors than any other variable used in the HHC calculations.

> Osterberg and Pelletier, 2015. *Puget Sound Regional Toxics Model…; Page* 94, (for PCBs and PBDEs)
> https://fortress.wa.gov/ecy/publications/documents/1503025.pdf
> "In sum, the sensitivity tests showed that in relatively uncontaminated areas where contaminant concentrations in the sediments were low, predicted concentrations of contaminants in biota were more strongly influenced by changes to contaminant concentrations in the water column than by comparable changes in sediment concentrations. Although the majority of PCB and PBDE mass in the Sound is stored in the sediments, these results indicate the importance of contaminants in water as an exposure route and driver of bioaccumulation in many areas. Efforts to decrease contaminant concentrations in Puget Sound marine waters (e.g., by actions to reduce loads or prevent releases) may therefore be a critical component of strategies to achieve ecosystem health goals. Sensitivity analyses also indicated that the influence of sediments was greater in areas where sediment concentrations were elevated. These results underscore the importance of sediment cleanup activities for reducing contaminant uptake and bioaccumulation in the urban bays and at regional contaminant "hot spots."

Bioconcentration is the process of absorption of chemicals into an organism only through respiratory and dermal surfaces (Arnot and Gobas, 2006). For purposes of the HHC equations, bioconcentration refers to the accumulation of a chemical directly from the water by fish and shellfish. Using a bioconcentration factor (BCF) accounts for any pollution uptake fish or shellfish are exposed to in their surrounding water. Because BCFs look at a specific portion (water only) of the total uptake of a chemical, the BCFs are generally laboratory-derived or modeled values. Bioaccumulation is a broader term that refers to the accumulation of chemicals from all sources, including water, food, and sediment. Bioconcentration is a subset of bioaccumulation. Models to describe both bioconcentration and bioaccumulation have evolved over the past several decades (e.g., see Arnot and Gobas, 2004 and 2006, Gobas 2001, and Veith 1979) and have been used for many purposes, including risk assessment, chemical prioritization for toxics control strategies, and for HHC development.

The amount of accumulation tied directly to water or to sediments is unknown in most waterbodies, and pathways vary based on many factors, including waterbody-specific physical characteristics, properties of the chemical of concern, and biota. For instance, Puget Sound-specific modelling (Osterberg and Pelletier, 2015; see text box) for open waters indicates that PCBs and PBDEs accumulation is more closely tied to water concentrations than to sediment concentration. In more contaminated embayments around Puget Sound the sediments are a larger driver for accumulation.

EPA Guidance and use of accumulation factors. EPA HHC guidance on how to describe and predict accumulation into aquatic organisms has changed throughout the years. For example, the 1980 guidance includes use of a BCF-based approach and the 2000 guidance modifies that earlier guidance to use a BAF-based approach. Both older and newer guidance recommend use of steady state accumulation factors.

EPA and states have generally defaulted to the use of EPA's older lipid-normalized BCFs when calculating criteria. These values were used in the 1992 NTR. The majority of BCFs used in the calculation of NRWQC (as listed in EPA 2002 and prior to the 2015 EPA 304(a) guideline updates) were carried over from 1980 criteria documents. BCFs reported in the 1980 criteria documents were generally determined by laboratory experiments, except when field data (e.g., "Practical BCFs (PBCFs)" for mercury (USEPA 1980); in effect, a field derived BAF) contradicted laboratory BCFs. If both laboratory and field data were lacking, the BCFs for lipid soluble compounds used to calculate the 1980 criteria were based on chemical specific octanol-water partition coefficients (K_{ow}'s; the K_{ow} is correlated with the potential for a chemical to bioconcentrate in organisms). In summary, the 1980 BCFs reflect a combination of laboratory measured BCFs, modeled BCFs, and field-measured BAFs. In this discussion all these values are generally referred to as BCFs or as a "BCF-based approach." The approaches for lipid soluble and for non-lipid soluble compounds (USEPA 1980) used to develop the early BCFs follow.

> *"For lipid-soluble compounds, when a measured BCF is available and corresponding lipid content is known* the equation below is used to estimate the weighted average BCF for an average diet.
>
> $$Weighted\ average\ BCF\ for\ average\ diet = Measured\ BCF\ x\ \frac{Weighted\ average\ percent\ lipids\ for\ average\ diet}{Species\ specific\ lipid\ content}$$
>
> *For lipid-soluble compounds, when measured BCF and corresponding lipid content is unknown* the equation below is used to estimate the BCF for aquatic organisms containing about 7.6 percent lipids (Veith 1979; USEPA 1980). This includes an adjustment for 3% lipids in the average diet versus 7.6% in order to derive the weighted average BCF.
>
> $$Log\ BCF = (0.85\ Log\ Kow) - 0.70$$
>
> *For non-lipid soluble compounds,* the available BCFs for the edible portion of consumed freshwater and estuarine fish and shellfish are weighted according to consumption factors to determine a weighted BCF representative of the average diet." (EPA 1980)

Subsequent to the EPA 1980 approach, EPA 2000 guidance recommends the use of a BAF in criteria calculation, and recommends that states and tribes use the methodology outlined in EPA 2000 to develop locally appropriate BAFs. Figure 6 shows the process as summarized by EPA (EPA 2000, page 5-13) in its Figure 5-1):

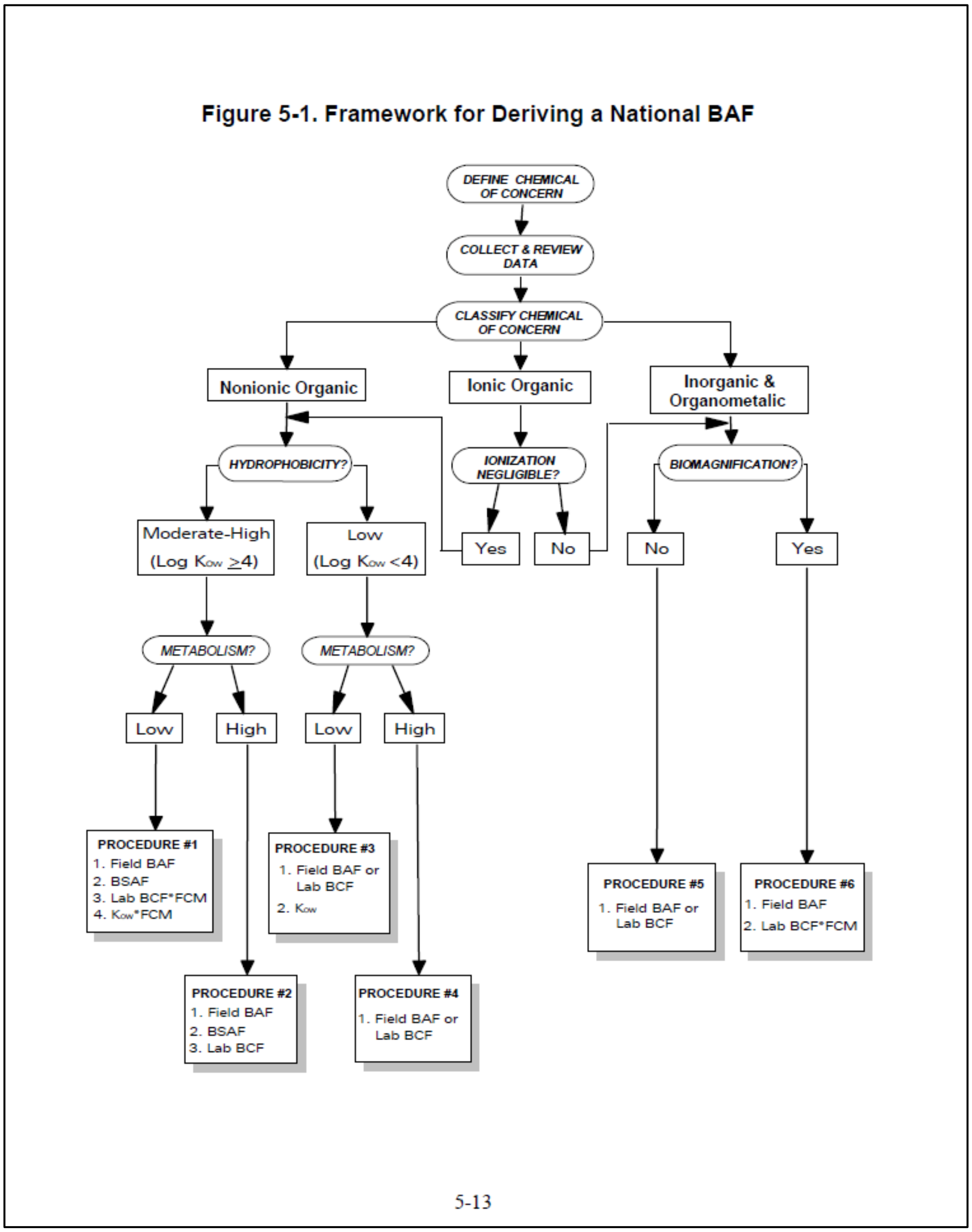


Figure 6: Framework for deriving BAF taken from EPA 2000, Figure 5-1

Subsequent to the 2000 guidance, EPA (2014, 2015) developed Clean Water Act 304(a) draft and final guidance criteria that were calculated using BAFs:

- In May 2014 EPA published 94 draft 304(a) nationally recommended HHC that included use of model-derived BAFs. These BAFs were developed using EPA's EPI Suite™ of models.
- In June 2015 EPA published final 304(a) criteria documents that used the BAF development approach described in EPA 2000 (see Figure 6), which includes use of lipid normalized BCFs in some cases.
- In September 2015, EPA published a new draft regulation for Washington and a revision to the NTR that included draft criteria that were calculated using chemical-specific trophic level 4 BAFs for the majority of the chemicals. The draft federal regulation also includes draft criteria that were developed using new BCFs and the older 1980 (NTR) BCFs (e.g., the draft criteria for metals other than mercury and copper; see following text box).

Washington Chemicals of Concern: PCBs, Arsenic, and Mercury

The accumulation factors used by EPA for some of the chemicals of greatest concern in Washington have not changed since the 1992 NTR, or, have been removed from the HHC equation entirely:

PCBs and arsenic: Older NTR BCFs are still used for the current 304(a) national recommended criteria and for the 2015 EPA proposed Washington regulation to calculate criteria for total PCBs, arsenic, and dioxin . Ecology used these BCFs for calculating the criteria for total PCBs and for dioxin in the draft rule . The criteria for arsenic are discussed later in this document.

Mercury: The methylmercury tissue residue criterion (part of the current 304(a) national recommended criteria and the 2015 EPA proposed regulation for Washington) does not include either a BAF or a BCF in the criterion equation, and instead accumulation is addressed as part of the implementation approaches that states will determine as they adopt and implement methylmercury criteria . Ecology did not adopt the methylmercury criterion in this rulemaking . This decision is discussed later in this document.

Lipid content affects the applicability of calculated BAFs and BCFs: A chemical's tendency to accumulate in lipids is driven by its hydrophobicity and lipophilicity. BAFs and BCFs for lipophilic chemicals are generally lipid normalized from a modeled or measured value to reflect the average percent lipids for aquatic organisms consumed by people.

Most of the BCFs historically used by EPA in NRWQC development, and by most states in HHC development, are lipid-normalized to an average lipid content of 3% for edible tissues and species (see equations earlier in this section) as consumed in national surveys (see Veith 1980; EPA 1980). The percent lipid of individual species consumed from Washington waters (Osterberg and Pelletier, 2015) are both lower and higher (e.g., spot prawn 1.5%; English sole

1.6%; Chinook salmon (immigrant) 5.4%) than the 3% average used by EPA. Attempting to calculate the average % lipid content of the amount of tissues of species consumed in Washington (as reflected by the proportion of different types of organisms consumed as described in the FCR surveys used to develop the proposed FCR of 175 g/day) would likely result in an estimated value with a large margin of uncertainty because the surveys do not all contain detailed information on the amounts of all specific species consumed. However, even if this information was readily available, it would not necessarily reflect the average lipid content of organisms grown in Washington waters because the proposed FCR includes all fish and shellfish including market, imported, restaurant, ocean-caught, etc.

EPA 2000 recommends that BAFs be used in criteria development to more accurately reflect the total uptake of a chemical into aquatic biota and thus more fully account for consumers' exposure to chemicals. EPA 2000 and EPA 2003 provide detailed information on the theory and methods supporting chemical-specific development of national BAFs, including calculation paths to address chemical-specific factors such as tendency to metabolize, Kow, applicability of biota sediment accumulation factor (BSAF) pathways, assumptions about chemical and physical parameters in ambient waters, food web structure, and many other factors. The EPA guidance is too extensive to present here (refer to EPA (2000, 2003) for more information). The national guidance was used by EPA to develop BAFs for the new EPA 2015 NRWQC, mainly for nonionic organic chemicals (these make up a large number of the new 2015 criteria). The EPA 2015 BAFs for these chemicals include trophic level-specific information on lipids, and incorporate this information in calculated baseline BAFs that can be applied across waterbodies. The baseline BAFs are adjusted to reflect the lipid content of commonly consumed aquatic biota. The default lipid fraction for commonly consumed fish and shellfish is derived from national survey information: 0.019 for trophic level 2 organisms, 0.026 for trophic level 3 organisms, and 0.030 for trophic level 4 organisms. Whether these default values are representative of an average lipid value(s) that would be appropriately representative of Washington is confounded by the same sources of uncertainty as discussed above for BCFs.

Dissolved organic carbon (DOC) and particulate organic carbon (POC) affect accumulation: Chemical sorption to POC and DOC in the water column can substantially reduce the fraction of the chemical in water that can actually be absorbed by aquatic organisms (Gobas 2001). Because of this BCFs and BAFs are frequently expressed in terms of the freely dissolved chemical concentration. EPA's 2000 guidance and the new BAFs in EPA's 2015 criteria documents are based on use of the freely dissolved concentration. The EPA 2000 methodology depends on median DOC (2.9 mg/L) and POC (0.5 mg/L) concentrations developed from a national dataset to develop national BAFs. DOC and POC concentrations can vary widely among waterbodies. DOC and POC data from Washington waters show a wide range of values (0.2 to 81.6 mg/L DOC and 0.028 to 1.78 mg/L POC; see Table 7) that differ among marine and estuarine waters, streams, and lakes and reservoirs

Table 7 shows dissolved organic carbon (DOC) and particulate organic carbon (POC) data from surface water sampling in Washington waters. Data is from Ecology's Environmental Management System (EIM) Database, accessed November 18, 2015.

Table 7: DOC and POC data from Washington surface water

Parameter	Statistic	Freshwater streams	Freshwater lakes and reservoirs	Marine and estuarine waters
DOC (mg/L)	min	0.2	0.5	0.611
	max	81.6	22.2	64.9
	median	2.1	2.6	1.805
	mean	3.230	2.514	3.718
	n	6871	1193	204
POC (mg/L)	min			0.028
	max			1.78
	median			0.0545
	mean			0.123
	n			32

EPA encourages states to use local DOC and POC information for water quality standards (EPA 2000):

> *"Although national default values of POC and DOC concentrations are used by EPA to set national 304(a) criteria as described by this document, EPA encourages States and authorized Tribes to use local or regional data on POC and DOC when adopting criteria into their water quality standards. EPA encourages States and Tribes to consider local or regional data on POC and DOC because local or regional conditions may result in differences in POC or DOC concentrations compared with the values used as national defaults."*

Because Washington waters have a wide range of DOC and POC concentrations, the national BAFs that were calculated using national default POCs and DOCs likely are not reflective of BAFs in many of Washington's waters. Site-specific DOC and POC can also affect BCFs, and, how or if these parameters are accounted for in BCF development also introduces uncertainty around the applicability of a single chemical-specific BCF across different waterbodies in Washington. The 1980 BCFs are based on total concentrations (not freely dissolved fractions), and do not incorporate DOC and /or POC into the equations).

There are many site-specific sources of variability in accumulation factors that affect their applicability to specific waterbodies: EPA (2009) describes sources of variability in BAFs:

> *"The bioaccumulation methodology used in the 2000 Human Health Methodology encourages developing site-specific BAFs because EPA recognizes that BAFs vary not*

only between chemicals and trophic levels, but also among different ecosystems and waterbodies; that is, among sites. The bioaccumulation potential of a chemical can be affected by various site-specific physical, biological, and chemical factors:

- *water temperature and dissolved oxygen concentration;*
- *sediment-water disequilibria;*
- *organism health, physiology and growth rate;*
- *food chain structure;*
- *food quality; and*
- *organic carbon composition.*

National average BAF value for a given chemical and trophic level may not provide the most accurate estimate of bioaccumulation for certain waterbodies in the United States. At a given location, the BAF for a chemical may be higher or lower than the national BAF, depending on the nature and extent of site-specific influences."

These site-specific sources of variability could also apply to many measured and calculated BCFs.

Historic and current use of BCFs and BAFs in HHC development: Both BCFs and BAFs have been, and currently are, used in criteria development. Recent actions where both have been applied include:

- EPA used BCFs and trophic level weighted BAFs (based on EPA 2000 methodology) in its June 2015 final revisions to the Clean Water Act 304(a) national recommended criteria (EPA 2015).
- EPA used BCFs and trophic level 4 BAFs in its proposed September 2015 revision to the NTR for Washington (EPA 2015).
- Oregon used EPA's BCFs in its 2011 adoption of HHC that were subsequently approved by EPA.
- Several states surrounding the Great Lakes have used BAFs in EPA-approved criteria development.
- EPA used the older EPA BCF values in 2000 to promulgate Clean Water Act HHC for states in federal regulation (40CFR131.38; FR Vol. 65, No. 97, May 18, 2000, pages 31710-31719).

Different approaches to BAF development have been used for Clean Water Act criteria: EPA has used different approaches to develop BAFs, and depends on a mix of BAFs and BCFs for current (2015) criteria calculations:

- EPA's final Great Lake's Guidance (Final Water Quality Guidance for the Great Lakes System, Federal Register: March 23, 1995 (Volume 60, Number 56, Page 15365-15425) requires use of BAFs, and presents a hierarchy of methods to develop BAFs based on chemical-specific factors.

- In May 2014 EPA published 94 draft Clean Water Act 304(a) nationally recommended HHC that included use of model-derived BAFs. These BAFs were developed using the BCF BAF module of EPA's EPI Suite™ of models. This module was developed using species from the Great Lakes (USEPA 2014).
- EPA used BCFs and trophic level weighted BAFs (based on EPA 2000 methodology) in its June 2015 final revisions to the Clean Water Act 304(a) national recommended criteria (EPA 2015).
- EPA used BCFs and trophic level 4 BAFs in its proposed September 2015 revision to the NTR for Washington (EPA 2015).

Process used to develop new 304(a) guidance documents and concerns about BAF development: 40CFR131.11 recommends that states consider EPA's Clean Water Act 304(a) guidelines when adopting criteria. As part of that consideration states evaluate the basis of and the process used to develop the criteria guideline documents. States need confidence in the EPA guidelines in order to use them as the basis of state regulations, and depend on the criteria guideline documents to provide a clear and adequately extensive content that supports both review and replication of the EPA results and recommendations. In the case of the new BAFs and BCFs in the 2015 304(a) guideline documents, although many can be replicated with the provided information and using EPA's guidance, we have been unable to evaluate and replicate all of the new BAF/BCF values (e.g., anthracene).

EPA published guidance on development of BAFs in 2000, 2003, and 2009. In EPA's 2014 proposed guideline documents EPA used the EPI Suite™ of models to calculate BAFs. In Ecology's comments on EPA's draft 2014 NRWQC Ecology asked for more details about EPA's use of EPI Suite™ to calculate bioaccumulation factors (BAFs), and expressed reservations about the use of BAFs in criteria development. As a result of public comment EPA changed its BAF approach for the final recommended criteria development documents and based its new BAFs on its 2000 HHC methodology. This change of direction was briefly addressed in EPA's response to comments, but after reviewing the finalized 304(a) guidance documents, the approach used to develop the new 2015 BAFs resulted in as much uncertainty as Ecology had over the initial use of the EPI Suite™ models.

Each of EPA's finalized chemical-specific 304(a) guidance documents contains a specific section on BAF development that uses identical language to describe the 2000 guidance. However, out of approximately 2 pages devoted to BAF development in each chemical-specific document, only approximately 3-5 unique sentences are actually present in each document to address chemical-specific information. In some cases EPA cites multiple sources for inputs to its BAF development, but the sources contain values that do not appear to clearly lead to replication of all of EPA's results. Steps to adjust or combine inputs are not clearly explained to users of the documents. Replicating the steps and the inputs EPA took to develop many of the BAFs/BCFs is not possible with the information provided in the individual criteria documents.

On January 14, 2016, EPA posted at its HHC web site:

(http://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table) supplemental information to support the calculation of the new BAFs and BCFs used in EPA's new 2015 304(a) criteria guidance documents:

- *National Bioaccumulation Factors – Supplemental Information Document (January 2016)*
- *National Bioaccumulation Factors – Supplemental Information Table (excel) (1 pg., 523 K) (MS Excel Spreadsheet) (January 2016).*

EPA's release of this information, as Ecology was preparing the final proposed rule including determination of costs and benefits in accordance with the state's Administrative Procedures Act, did not allow Ecology time to be able to review the new information prior to development of the proposed rule and supporting documentation. Ecology considered this new information on BAFs provided by EPA as it developed the final rule, including consideration of any comments received on the use of BCFs versus BAFs.

Additional circumstances that add to concern about use of the new 2015 BAFs are:

- In EPA's *Water Quality Criterion for the Protection of Human Health: Methylmercury* (USEPA 2001) substantial coverage is given to the development of BAFs and the rationale for *not* developing national trophic level-specific BAFs for this chemical. In the methylmercury implementation document (EPA 2009), detailed information on alternatives for different BAF development pathways is provided. These documents underwent extensive peer and public review, and because only one chemical was being addressed, a detailed focus on the information and approaches to BAF development was part of the process. EPA's recent 2015 304(a) guidance documents include new chemical-specific BAFs for 73 pollutants and new BCFs for 19 pollutants (the new criteria for cyanide uses the older 1980 BCF, as per 68 FR No. 250, Wednesday, December 31, 2003, 75507-75515), and, as mentioned previously, included virtually no chemical specific information on the inputs used in BAF/BCF derivation. The disparity in the process used to develop new BAFs/BCFs for these pollutants, when compared with the transparency and thoughtful approach used in the methylmercury BAF development, caused concerns about using the new BAFs without additional data and information.
- EPA recently (EPA, 2015) published a new draft 304(a) aquatic life criteria document for cadmium. This document includes 2 pages of discussion on cadmium-specific BAF/BCF information, and 11 pages of tables with cadmium-specific BAF/BCF data. The document does not cite EPA 2000 as a method development approach for BAFs for aquatic life criteria, yet we would expect EPA to depend on its guidance in evaluation of cadmium accumulation for different trophic levels. The draft cadmium document does not directly use a BAF or BCF estimate to calculate the draft criteria, yet the BAF/BCF write-up provides substantial clarity and information. This more informative approach was used in the older chemical-specific criteria guidance documents but appears to have been dropped in the new 2015 HHC 304(a) guidance documents. This brevity of information is likely to affect states for many years to come as they attempt to evaluate

the EPA 304(a) guideline documents, which states will be inclined to do because the 40CFR131.11 recommends it.

- The development of the 2015 304(a) guideline documents appears rushed (drafts proposed in May 2014, finals published in June 2015), and EPA did not take the time for a thoughtful external review of individual BAFs, as was done for the methylmercury criteria document.
- Upon release by EPA of the new 2015 NRWQC, states were not provided with sufficient background information on the new BAFs, so Ecology was not in a position to understand if the 2015 BAF recommendations were appropriate to move forward with under Washington State's Administrative Procedures Act rule process as it was developing the proposed new HHC rule.
- Since the proposed rule was published additional information has come to Ecology's attention that reinforces Ecology's concern with the new 2015 304(a) criteria documents and the equation inputs used in those documents. In particular, EPA published and posted a criteria document for the new, and non-priority pollutant, bis(2-chlkoro-1-methylethyl)ether, as a priority pollutant. EPA then proposed criteria for this chemical in draft regulations for Washington and Maine, asserting in the federal publications that the new criteria were for priority pollutants only. This situation reinforces the skepticism that Ecology has regarding the thoroughness of the process used to develop the new 2015 EPA criteria, and reinforces the concern over the single public review of the new 2015 criteria documents, particularly with regard to the bioaccumulation and bioconcentration factors used in calculating those criteria.
- Concern with the new HHC was expressed to EPA in Ecology's public comment on EPA's draft 304(a) criteria (8/6/2014 letter from Melissa Gildersleeve, Ecology, to EPA Water Docket), on EPA's draft regulation for Washington (12/21/15 letter from Maia Bellon, Ecology, to Gina McCarthy, EPA) and in this Decision Document. A significant part of the rationale has to do with the inapplicability of the new BAFs to Washington and the inadequacy of the public process EPA used in developing them. Ecology continues to assert that the BAFs used in the EPA's final 304(a) criteria should have been considered second draft BAFs because they differed so significantly from the first draft that was commented on by the public, and should have been published in the federal register for a second round of public review before finalization. Ecology continues to be concerned with EPA's apparent urgency in finalizing the 304(a) criteria without a second public review to be able to consider the modified BAF approach, which Ecology believes would have been a better approach and resulted in a more durable product. Ecology's comment letter to EPA on their draft proposed regulation and this Decision Document explains why the BAFs used in that proposal are inappropriate for Washington at this time.

- Florida, which recently released a draft HHC rule, also declined to use the EPA national BAFs and, in order to use BAFs appropriately, found it necessary to develop Florida-specific BAFs. That type of intensive effort in Washington would have necessitated another draft rule to be developed and published, which would have significantly delayed adoption of HHC in Washington.

Protectiveness of the calculated criteria and use of BAFs or BCFs: The criteria equations balance many different factors, such as "more protective" (e.g., uncertainty factors up to the thousands for reference doses, linear-multistage-based CSFs, in Washington's proposal a FCR that includes all fish and shellfish from all sources) and "less-protective" (e.g., not accounting for additive or synergistic effects of chemicals), that are used to develop criteria protective of people who consume fish and shellfish. No one input to the equations alone defines the degree of protection provided by the numeric criterion values (see previous discussion on Risk Level above). Choice of the newer BAF-based approach over the older BCF-based approach does not guarantee higher or lower criteria concentrations. In some cases the newer EPA BAFs are lower than the older EPA BCFs (e.g., acrolein has a BCF of 215 and a newer BAF of 1.0) and in some cases higher (e.g., dieldrin has a BCF = 4,670 and newer trophic level BAFs of TL2 = 14,000, TL3 = 210,000, TL4 = 410,000BAF). In general, for those chemicals that have new BAFs, the new BAFs are higher values than the BCFs for more hydrophobic lipophilic compounds. However, the accumulation factors for some of the chemicals of greatest concern in Washington have not changed. For example, older BCFs for total PCBs, arsenic, and dioxin are still the basis of EPA's national recommended criteria (EPA 2015) and of the proposed criteria in EPA's draft regulation for Washington (EPA 2015). As mentioned previously, the methylmercury tissue residue criterion does not include either a BAF or a BCF, and instead accumulation is addressed as part of the implementation approaches that states will determine as they adopt and implement methylmercury criteria.

Choosing a BCF or a BAF for criteria development: Both BCFs and BAFs as currently developed have uncertainty in their applicability and development. However, only two practical alternatives exist to reflect accumulation of toxics by aquatic organisms:

1. 1980 BCF-based approach (as used in the NTR – note that these BCFs are a combination of measured and modeled BCFs and some BAFs, plus two additional newly calculated BCF values based on EPA 1980 guidance; and
2. 2015 BAF-based approach:
    - the trophic level weighted BAFs and BCFs (the majority are BAFs) used to calculate EPA's 2015 NRWQC, or,
    - the trophic level 4 BAFs and BCFs (the majority are BAFs) used in EPA's 2015 proposed new regulation (proposed 40CFR131.45).

Ecology is eliminating the second 2015 BAF approach described previously (trophic level 4 BAFs and BCFs used in EPA's 2015 proposed new regulation) because the use of trophic level 4 BAFs, based mainly on consideration of salmon and steelhead consumption, is not reflective of the consumption patterns shown in the FCR surveys that were used to develop the proposed

Washington FCR of 175 g/day: Washington-specific information on consumption indicates that different groups of people harvest both fish and shellfish, both recreationally and for subsistence (Ecology, 2013). The FCR of 175 g/day includes "all fish and shellfish," including all salmon, restaurant, locally caught, imported, and from other sources, thus includes trophic levels 2-4.

A BAF-only pathway is not readily available because EPA-developed BAFs for all HHC chemicals are not available for Ecology and the public to consider. Other approaches (e.g., developing Washington-specific development of BAFs or BCFs) would greatly increase the data and analysis needed to support the rulemaking and would cause further delays.

Decision for proposed rule: Ecology is making a risk management decision that this proposed rule use a BCF-based approach (as per EPA, 1980, and as used in the NTR) for criteria calculation for the following reasons:

- BCFs are more closely related to the specific environmental media (water) that is regulated under the Clean Water Act.
- The BCFs do not include as many inputs and predictions that are based on national water, sediment, and biota datasets, while the BAFs are dependent on these inputs. The national datasets supporting the BAFs are not necessarily reflective of Washington waters.
- The BCF-based approach includes far fewer input values. Because of this, the BCFs have far fewer sources of directly introduced uncertainty.
- BCFs are acceptable science for purposes of Clean Water Act criteria development. EPA currently uses a combination of BAFs and BCFs to calculate its NRWQC, and used a combination of BAFs and BCFs for its 2015 proposed new regulation for Washington. Therefore, both BAFs and BCFs could represent acceptable science choices for Clean Water Act purposes.

Based on Ecology's decision to use BCFs, new BCFs were calculated using EPA 1980 guidance. EPA (2015) published BAF-based criteria for two additional priority pollutants (1,1,1-trichloroethane and 3-methyl-4-chlorophenol). These pollutants do not have EPA-calculated BCFs available. Ecology-calculated BCFs for these pollutants using the EPA 1980 guidance to provide consistency among the suite of BCF values used in this rulemaking. Ecology queried the EPA EcoTox database for measured BCFs. Calculations follow:

1,1,1-Trichloroethane. A query of the EPA EcoTox database (accessed 10/16/15) resulted in a single measured BCF of 9 L/kg (BCF from: Barrows et al 1978). A measured lipid content for similar bluegills is 4.8% (Johnson 1980, as cited in EPA 1980). BCF calculations, as per EPA 1980 guidance, are shown below:

$$Weighted\ average\ BCF\ for\ average\ diet = Measured\ BCF\ x\ \frac{Weighted\ average\ percent\ lipids\ for\ average\ diet}{Species\ specific\ lipid\ content}$$

$$BCF = 5.6\ L/kg$$

3-Methyl-4-chlorophenol. A query of EPA's EcoTox database (accessed 10/16/15) showed no results for measured BCFs for this pollutant. A BCF based on Kow (EPA 1980) was calculated. Log Kow = 3.1 (EPA 2015) was used in the calculation.

$$Log\ BCF = (0.85\ Log\ Kow) - 0.70$$
$$Log\ BCF = (0.85\ x\ 3.1) - 0.70$$
$$\log\ \ BCF = 1.935$$
$$BCF = 1258$$

9. Lifespan and duration of exposure:

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

Ecology proposes to specifically acknowledge the longer-term durations of exposure that are implicit in the criteria in the proposed rule.

Background: EPA 2000 guidance for HHC development assumes a lifetime exposure of 70 years, and a duration of daily exposures over 70 years. Use of the 70-year lifespan and a duration of daily exposures over 70 years is implicit in the HHC equations. These paired assumptions result in no overall numeric change in the equation's results. However, a change in either one of these could change the calculated results of the equation. A 10-year increase or decrease in lifespan would have little effect on the calculated criteria concentrations. Changing the duration of exposure to less than the total lifespan would increase criterion concentrations, but the magnitude of increase would depend on the ratio between lifespan and duration of exposure. For instance, use of a 30-year duration of exposure (as used in some clean-up risk assessments) with a 70-year life span would increase the criteria concentrations substantially. Because the goal of the criteria is to provide for protection of people throughout their lifetime with an assumption that people could obtain all their fish from Washington waters during that period, reducing the level of protection of the criteria concentrations by assuming a shorter duration of exposure was not considered for these criteria development.

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

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

all. Thus, appropriate durations depend on the individual noncarcinogenic pollutants and the endpoints or adverse effects being considered."

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

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

Page 8-11, guidance on exposure durations for noncarcinogenic health effects:

"Three exposure durations that will need separate consideration for the possibility of adverse noncarcinogenic health effects are chronic, subchronic, and shorter-term exposures. As guidance for Superfund, chronic exposures for humans range in duration from seven years to a lifetime; such long-term exposures are almost always of concern for Superfund sites (e.g., inhabitants of nearby residences, year-round users of specified drinking water sources). Subchronic human exposures typically range in duration from two weeks to seven years and are often of concern at Superfund sites. For example, children might attend a junior high school near the site for no more than two or three years. Exposures less than two weeks in duration are occasionally of concern at Superfund sites. For example, if chemicals known to be developmental toxicants are present at a site, short-term exposures of only a day or two can be of concern."

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

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

> *health threat. ECAO may be consulted for assistance in finding short-term toxicity values."*

The reference doses used to calculate the HHC are the chronic reference doses mentioned previously, as opposed to the subchronic or acute toxicity values also mentioned. Toxicity values for shorter duration exposure periods have been developed (e.g., the Agency for Toxics Substances and Disease Registry's Minimal Risk levels (MRLs) at http://www.atsdr.cdc.gov/mrls/index.asp).

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

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

10. Hazard quotient (HQ)

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

Ecology applied this implicit variable in the HHC equations.

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

Decision for new rule: Ecology applied this EPA implicit variable in the HHC noncarcinogen equations.

References

Arnot, Jon A. and Frank A.P.C. Gobas, 2004. *A food web bioaccumulation model for organic chemicals in aquatic systems*. Env. Tox. And Chem. V. 23, No. 10, pp. 2343-2355.

Arnot, Jon A. and Frank A.P.C. Gobas, 2006. *A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms*.

Environ. Rev. Vol 14 2006. Published online by the NRC Research Press: *http://research.rem.sfu.ca/papers/gobas/A%20Review%20of%20Bioconcentration%20factor%20(BCF)%20and.pdf*

Barrows, M.E., S.R. Petrocelli, K.J. Macek, and J.J. Carroll 1978. *Bioconcentration and elimination of selected water pollutants by bluegill sunfish (Lepomis macrochirus).* In: Hague R., ed. *Proceedings of the 1978 Symposium on Dynamics, Exposure, and Hazard Assessment of Toxic Chemicals*. Ann Arbor, MI, Ann Arbor Science Publishers, pp 379-392.

Ecology, 2013. Washington Department of Ecology. *Fish Consumption Rates Technical Support Document* – Chapter 6.4. Available online at: *https://fortress.wa.gov/ecy/publications/publications/1209058.pdf*

Ecology, 2013. Washington Department of Ecology, Water Quality Program. Policy Forum held February 8, 2013. “Risk Levels Used in Human Health Criteria”. Found at: *http://www.ecy.wa.gov/programs/wq/swqs/RiskLevelCarcinogens.pdf*

EPA, 1980. U.S. Environmental Protection Agency. *Appendix C – Guidelines and methodology used in the preparation of health effect assessment chapters of the consent decree water criteria documents*. FR Vol. 45, No. 231, Nov. 28, 1980.

EPA 1980. U.S. Environmental Protection Agency. *Ambient water quality criteria for mercury*. EPA 440/5-80-058

EPA, 1989. U.S. Environmental Protection Agency. *Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) Interim Final*. EPA/540/1-89/002

EPA, 1989. U.S. Environmental Protection Agency. National primary and secondary drinking water regulations. 40 CFR Parts 141, 142, and 143. FR Vol. 54, No. 97, Monday May 22, 1989. Page 22062.

EPA, 1992. U.S. Environmental Protection Agency. *Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B).* 40 CFR Part 131.36. Also known as the National Toxics Rule.

EPA, 1995. U.S. Environmental Protection Agency. *A guide to the biosolids risk assessments for the EPA Part 503 Rule*. EPA/832-B-93-005. Sept., 1995. *http://water.epa.gov/scitech/wastetech/biosolids/503rule_index.cfm*

EPA, 1999. U.S. Environmental Protection Agency. Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B), originally published in 1992, amended in 1999 for PCBs. *http://www.ecfr.gov/cgi-bin/text-idx?SID=76816a2f92256bf94a548ed3115cee23&node=40:23.0.1.1.18.4.16.6&rgn=div8*

EPA, 2000. U.S. Environmental Protection Agency. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*, (EPA-822-R-00-004), also known as the "EPA 2000 guidance": *http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_complete.pdf.*

EPA 2001. U.S. Environmental Protection Agency. *Water Quality Criterion for the*

Protection of Human Health: Methylmercury. EPA-823-R-01-001.EPA 2002. *National recommended water quality criteria: 2002 – Human health criteria calculation matrix.* EPA 822-R-02-012, November 2002.

EPA, 2002. U.S. Environmental Protection Agency. *National Recommended Water Quality Criteria: 2002. Human health criteria calculation matrix*. EPA-822-R-02-012. November 2002. at *http://water.epa.gov/scitech/swguidance/standards/upload/2002_12_30_criteria_wqctable_hh_calc_matrix.pdf*

EPA 2003. U.S. Environmental Protection Agency. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000*). *Technical Support Document Volume* 2: *Development of National Bioaccumulation Factors* (EPA-822-R-03-030).

EPA, 2007. U.S. Environmental Protection Agency. *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, Working Document, To Be Applied in Consultation with Tribal Governments on a Site-specific Basis*, Revision 00.2007 *(http://yosemite.epa.gov/R10/CLEANUP.NSF/7780249be8f251538825650f0070bd8b/e12918970debc8e488256da6005c428e/$FILE/Tribal%20Shellfish%20Framework.pdf,*

EPA. 2009. U.S. Environmental Protection Agency. *Guidance for Implementing the January 2001 Methylmercury Water Quality*

Criterion. EPA 823-R-09-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

EPA 2009. U.S. Environmental Protection Agency. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000) Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors*. EPA-822-R-09-008).

EPA, 2011. U.S. Environmental Protection Agency. *EPA Exposure Factors Handbook - 2011 edition* (EPA 600/R-090/052F), at *http://www.epa.gov/ncea/efh/pdfs/efh-complete.pdf.*

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

EPA, 2013. U.S. Environmental Protection Agency. *EPA Human Health Ambient Water Quality Criteria and Fish Consumption Rates Frequently Asked Questions*. January 18, 2013. Available online at: *http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/hhfaqs.pdf*

EPA 2014. U.S. Environmental Protection Agency. Draft national recommended human health surface water criteria for 94 toxics. 79 FR 27303, pages 27303 -27304

EPA, 2014. U.S. Environmental Protection Agency. Integrated Risk Information System (IRIS), at http://www.epa.gov/IRIS/ . *(Note: This website was referenced 4/2014 and may have changed since that date)*

EPA, 2014. U.S. Environmental Protection Agency. *Supplemental Guidance for Superfund. Risk Assessment Guidance for Superfund: Human Health Evaluation Manual*. Memo from

Dana Stalcup, USEPA, to Superfund National Policy Managers, Regions 1-10; OSWER Directive 9200.1-120). Available online at: http://www.epa.gov/oswer/riskassessment/pdf/superfund-hh-exposure/OSWER-Directive-9200-1-120-ExposureFactors.pdf

EPA 2015. U.S. Environmental Protection Agency. *Update of Human Health Ambient Water Quality Criteria: 3-Methyl-4-chlorophenol 59-50-7.* EPA 820-R-15-092.

EPA, 2015. U.S. Environmental Protection Agency. National Recommended Human Health Criteria list: *http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm (Note: This website was referenced 11/10/15 and may have changed since that date.)*

EPA 2015. U.S. Environmental Protection Agency. *Proposed Rule: Revision of certain federal water quality criteria applicable to Washington.* 80 FR No. 177, Monday, September 14, 2015. Pages 55063 – 55077)

EPA 2015. U.S. Environmental Protection Agency. . *Draft aquatic life ambient water quality criteria cadmium – 2015.* EPA-820-D-15-003, November 2015

Gobas, F.A.P.C., 2001. *Assessing bioaccumulation factors of persistent organic pollutants in aquatic food chains*. In: *Persistent organic pollutants. Environmental behavior and pathways for human exposure*. Stuart Harrad editor, Kluwer Academic Publishers.

ODEQ, 2011. Oregon Department of Environmental Quality. *Human Health Criteria Issue Paper 2008-2011*. Available online at: *http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf*

Osterberg, D.J. and G. Pelletier, 2015. *Puget Sound Regional Toxics Model: Evaluation of PCBs, PBDEs, PAHs, Copper, Lead, and Zinc.* Washington State Department of Ecology, Olympia, Washington.

Sullivan P. J., J. M. Acheson, P. L. Angermeier, T. Faast, J. Flemma, C. M. Jones, E. E. Knudsen, T. J. Minello, D. H. Secor, R. Wunderlich, and B. A. Zanetell. 2006. Report: Best Science Committee. Defining and Implementing Best Available Science for Fisheries and Environmental Science, Policy, and Management. Fisheries, Vol. 31 No. 9. September 2006. Pp. 460 465. (http://www.fws.gov/wafwo/fisheries/Publications/Fisheries3109.pdf)

Veith, G.D., D.L. DeFoe, and B.V. Bergstedt 1979. *Measuring and estimating the bioconcentration factors of chemicals in fish*. Journal Fish. Res. Board Can. 36:1040.

Veith, G.D. 1980. Memorandum to C.E. Stephan. USEPA, April 14.

Challenging Chemicals: Polychlorinated Biphenyls (PCBs)

Decision

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

A comparison of the NTR HHC with the new state criteria for PCBs is defined in the text below:

National Toxics Rule (NTR) HHC	2016New HHC
Freshwater: 0.00017 µg/L	Freshwater: 0.00017 µg/L
Marine: 0.00017 µg/L	Marine: 0.00017 µg/L

Background

Polychlorinated Biphenyls (PCBs) are a group of man-made chlorinated organic compounds. There are 209 individual PCB compounds, known as congeners. Aroclor is a commonly used trade name for specific PCB mixtures and is often referenced in PCB regulations.

PCBs in the environment are human-caused and there are no known natural sources. Used as coolants and lubricants in electrical equipment because of their insulating properties, manufacturing of PCBs was halted in the United States in 1979 (EPA, 2014) due to evidence that PCBs accumulate and persist in the environment and can cause harmful health effects. From 1929 to 1979 about 600,000 metric tons of PCBs were commercially manufactured in the US. The 1976 *Toxics Substances Control Act* (TSCA) prohibited manufacture, processing, and distribution of PCBs. Products made before 1979 that may contain PCBs include older fluorescent lighting fixtures and electrical devices.

Even though they are “banned,” PCBs are still allowed in many products manufactured and sold in the United States, including many pigments and caulking. The concentrations of PCBs in these products are regulated by the EPA under the Toxic Substances Control Act regulations.

PCBs are also regulated under additional state and federal laws, and they are not always consistent. For example, the level of PCBs that is allowed in products under TSCA is millions of times higher than what is allowed in water under the Clean Water Act. This leads to water permit holders being held responsible at the end of their pipe for PCBs that came from other products.

Back in the late 1970's the total amount seemed small and the amount allowed in each product seemed low, but now we know that it's high compared to levels that impact human health.

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

According to the ATSDR, exposure routes for PCBs include:

- Leaks from old fluorescent lighting fixtures and electrical devices and appliances, such as television sets and refrigerators, that were made 30 or more years ago and may be a source of skin exposure.
- Eating contaminated food. The main dietary sources of PCBs are fish (especially sport fish caught in contaminated lakes or rivers), meat, and dairy products.
- Breathing air near hazardous waste sites and drinking contaminated well water.
- Hazards in the workplace during repair and maintenance of PCB transformers, such as accidents, fires or spills involving transformers, fluorescent lights, and other old electrical devices; and disposal of PCB materials.

HHC for PCBs: The cancer-based HHC for PCBs that are currently effective in Washington for Clean Water Act purposes are found in the 1999 revisions to the 1992 NTR. The newly adopted criteria will be effective only after EPA reviews and approves them for Clean Water Act use. The 1992 NTR rule included HHC for individual Aroclors that were calculated using a cancer potency factor of 7.7 per mg/kg-day (EPA, 1992). EPA reassessed the cancer potency of PCBs in 1996 (EPA, 1996) and adopted an approach that distinguishes among PCB mixtures by using information on environmental mixtures and different exposure pathways. Based on this reassessment, EPA derived a new cancer potency factor of 2 per mg/kg-day. EPA revised the NTR human health criterion for PCBs in 1999 (EPA, 1999) to incorporate this new science. The newer NTR criterion is 0.00017 µg/L for the protection of human health from consumption of aquatic organisms and water, and the consumption of aquatic organisms only.

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

PCBs present regulatory challenges for Clean Water Act programs because:

- PCBs were widely used prior to the 1979 "ban".
- PCBs are widespread in the sediments and in biota.
- PCBs are long-lasting and bind readily to fats. Because of this they continue to cycle in the environment and in the food web. PCBs readily accumulate in organisms.
- PCBs are transported through the atmosphere.
- Because PCBs are transported along many pathways, and come from many sources associated with human habitation and use, they are found widely in environments that range from pristine to highly developed.
- Treatment plants are most often not designed to remove these chemicals. However, treatment plants that enhance solids removal will also remove PCBs.

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

Basis for Ecology's Decision

Ecology's new HHC for total PCBs are based on an approach that is consistent with EPA's 2000 Human Health Criteria Guidance (EPA, 2000) and that also provides a high level of protection for Washingtonians. Ecology used a state-specific risk level exclusively for PCBs. These calculated criteria concentrations are higher than the prior NTR values, and because PCBs are a chemical of concern in Washington, Ecology made a chemical-specific decision *not to increase the criteria concentrations* above the prior criteria levels, thus the proposed criteria values are the same as the NTR values of 0.00017 µg/L.

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

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

Since the bioconcentration factor for PCBs is very large, exposure through drinking water is negligible. The calculated criteria for exposure routes with and without drinking water are virtually the same, as are the calculated criteria values. The calculated total PCB criteria using this approach are 0.00029 µg/L. These calculated values are higher than the current NTR values, and because PCBs are a chemical of concern in Washington Ecology made a chemical-specific risk management decision not to increase the criteria concentrations, thus the proposed criteria values are the same as the NTR values of 0.00017 µg/L. This value is associated with a lower risk level (2.3×10^{-5}) than the calculated criteria. These values are shown below.

Additional lifetime Cancer Risk Level	Average Fish Consumption Rate (g/day)	Calculated HHC concentration (µg/L = parts per billion)
Calculated value:		
4×10^{-5} Four–in-one hundred thousand = 0.00004	175	0.00029
New criteria (= NTR Criteria)		
0.00017		
The risk level associated with the final 0.00017 ppb PCB criteria is 2.3×10^{-5}		

References

ATDSR, 2001. Agency for Toxic Substances and Disease Registry. ToxFAQs for Polychlorinated Biphenyls (PCBs). February 2001 version. Available online at: http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=140&tid=26

Ecology, 2012. Washington Department of Ecology. Water Quality Program, Current EPA Approved Water Quality Assessment website, see: *http://www.ecy.wa.gov/programs/wq/303d/currentassessmt.html). (Note: This website was referenced 4/2014 and may have changed since that date)*

Ecology, 2014. Washington Department of Ecology. Environmental Information Monitoring Database at http://www.ecy.wa.gov/eim/. *(Note: This website was referenced 4/2014 and may have changed since that date)*

Ecology, 2014. Washington Department of Ecology. Polychlorinated Biphenols (PCBs) website, see: *http://www.ecy.wa.gov/programs/swfa/pbt/pcb.html*. *(Note: This website was referenced 4/2014 and may have changed since that date)*

EPA, 1992. U.S. Environmental Protection Agency. Toxics criteria for those states not complying with Clean Water Act section 303(c)(2)(B). 40 CFR Part 131.36. Also known as the National Toxics Rule.

EPA, 1996. U.S. Environmental Protection Agency. PCBs: Cancer Dose-Response Assessment and Applications to Environmental Mixtures. September 1996. EPA/600/P–96/001F. Available online at: *http://www.epa.gov/osw/hazard/tsd/pcbs/pubs/pcb.pdf*

EPA, 1999. U.S. Environmental Protection Agency. Federal Register: Volume 64, Number 216. Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance – Revision of PCBs Criteria. Page 61181-61196. See: *http://www.epa.gov/fedrgstr/EPA-WATER/1999/November/Day-09/w25559.htm*

EPA, 2000. U.S. Environmental Protection Agency. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health, (EPA-822-R-00-004), also known as the "EPA 2000 guidance": http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_complete.pdf.

EPA, 2000. U.S. Environmental Protection Agency. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health Technical Support Document. Volume 2: Development of National Bioaccumulation Factors. Available online at: http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_tsdvol2.pdf

EPA, 2011. U.S. Environmental Protection Agency. EPA Exposure Factors Handbook - 2011 edition (EPA 600/R-090/052F), at http://www.epa.gov/ncea/efh/pdfs/efh-complete.pdf.

EPA, 2011. U.S. Environmental Protection Agency. PCB TMDL Handbook. U.S. EPA Office of Wetlands, Oceans and Watersheds. December 2011. EPA 841-R-11-006. Available online at: http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/upload/pcb_tmdl_handbook.pdf

EPA, 2013. U.S. Environmental Protection Agency. Health Effects of PCBs, EPA website on basic information about PCBs, at:*http://www.epa.gov/solidwaste/hazard/tsd/pcbs/pubs/effects.htm*. *(Note: This website was referenced 4/2014 and may have changed since that date)*

EPA, 2014. U.S. Environmental Protection Agency. Integrated Risk Information System (IRIS), at http://www.epa.gov/IRIS/ .

EPA, 2014. U.S. Environmental Protection Agency. Hazardous Waste PCBs Fact Sheet. Available online at: http://www.epa.gov/solidwaste/hazard/tsd/pcbs/about.htm *(Note: This website was referenced 4/2014 and may have changed since that date)*

ODEQ, 2011. Oregon Department of Environmental Quality. Human Health Criteria Issue Paper 2008-2011. Available online at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

ODEQ, 2013. Oregon Department of Environmental Quality. Memo: Implementation Instructions for Polychlorinated Biphenyls (PCBs) Water Quality Criteria. June 21, 2013. Available online at: http://www.deq.state.or.us/wq/standards/docs/toxics/MemoPCBs.pdf

WDOH, 2014. Washington Department of Health. Fish Consumption Advisories, see: *http://www.doh.wa.gov/CommunityandEnvironment/Food/Fish/Advisories.aspx*. *(Note: This website was referenced 4/2014 and may have changed since that date)*

Challenging Chemicals: Arsenic

Decision

Ecology adopted (1) surface water HHC for arsenic of 10 µg/L (total arsenic) and (2) required arsenic pollution minimization efforts.

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

A comparison of the NTR HHC with the new HHC for arsenic is shown in the text below:

National Toxics Rule (NTR) HHC	2016 New HHC
Freshwater: 0.018 µg/L (inorganic)	Freshwater and Marine Water: 10 µg/L (total)
Marine: 0.14 µg/L (inorganic)	

Background

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

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

Arsenic Standards in Washington State: Washington's aquatic life water quality standards for arsenic are contained in the state's water quality standards rule for aquatic life criteria (WAC 173-201A-240). Arsenic HHC are also contained in the United States Environmental Protection Agency (EPA)-promulgated NTR (EPA 1992; 40 CFR 131.36). Both HHC and aquatic life criteria are shown in Table 8 below and are expressed as micrograms per liter (µg/L), which is equivalent to parts per billion (ppb). EPA recently proposed a revision to the NTR for Washington that contains proposed criteria for inorganic arsenic of 0.0045 µg/L (freshwater) and 0.0059 µg/L (marine and estuarine waters). These proposed federal criteria are based on a cancer slope factor of 1.75 mg/kg day.

Table 8: Washington's water quality standards for arsenic prior to the new rule

National Toxics Rule (NTR)- Human Health Criteria (1992)		Washington State Water Quality Standards (WAC 173-201A) for Aquatic Life			
Freshwater-Organism + Water	Marine-Organism Only	Acute Marine	Chronic Marine	Acute Freshwater	Chronic Freshwater
0. 018 µg/L (inorganic)	0.14 µg/L (inorganic)	69 µg/L (dissolved)	36 µg/L (dissolved)	360 µg/L (dissolved)	190 µg/L (dissolved)

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

EPA is currently in the process of reviewing the toxicity information in the Integrated Risk Information System (IRIS) related to inorganic arsenic, and plans to submit its next draft to the National Research Council for future peer review (EPA, 2014).

HHC for arsenic in other states: Nationwide, nearly half of the states use the SDWA MCL value of 10 µg/L for their arsenic HHC (ODEQ, 2011, P. 19). Use of SDWA regulatory levels as HHC is not unusual for both EPA and states. EPA developed Clean Water Act §304(a) national recommended HHC (for freshwater) for asbestos in 1991 and copper in 1998 based on SDWA regulatory levels (EPA 2002). The SDWA-based asbestos criterion (7,000,000 fibers/L) is currently in EPA's NTR and was issued to several states in 1992 and was retained in the 1999 NTR revision, and the copper criterion (1,300 mg/L) was issued by EPA to California in 2000 (40 CFR 131.38 - Establishment of Numeric Criteria for Priority Toxic Pollutants for the State Of California). EPA's 2015 draft HHC regulation for Washington includes retention of the asbestos criterion in the NTR, as well as addition of the SDWA-based copper criterion.

In the west, where naturally high levels of arsenic in groundwater and geology are prevalent, six states have also adopted the SDWA MCL as their HHC for arsenic. Oregon took a different approach and adopted risk-based HHC for arsenic (see Table 9 below).

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

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

Table 9: EPA approved Human Health Criteria for arsenic in western states

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

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

The arsenic cancer slope factor (CSF): Without a reliable toxicity factor for cancer Ecology cannot calculate arsenic criteria based on cancer. EPA agrees that new cancer-based criteria for arsenic cannot be calculated at this time. In a May 6, 2016 filing with the United States District Court for the Western District of Washington, EPA stated that it will withdraw its proposed arsenic criteria for Washington because "extensive additional scientific analysis is necessary before revised criteria" for arsenic can be promulgated. *Puget Soundkeeper Alliance et. al. V. U.S.E.P.A.*, Case No. 2:16-cv-00293-JLR, EPA's Motion for Summary Judgment (May 6, 2016) at 13. As EPA explained in the Declaration of Elizabeth Southerland, Director of the Office of Science and Technology with EPA's Office of Water, "EPA did not update its CWA section 304(a) recommended criteria" for arsenic in 2015, and "EPA recognizes that there is substantial uncertainty surrounding the toxicological assessment of arsenic with respect to human health effects." Declaration of Elizabeth Southerland (May 5, 2016) at 7.

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

- The inorganic arsenic cancer potency factor has been under reassessment for many years, and a date for finalization is not finalized (EPA, 2014). Newer information from EPA indicates that the CSF for arsenic could be finalized in EPA's IRIS in 2017 (see EPA's public comment letter on this proposed rule, included in the Concise Explanatory Statement accompanying this rulemaking).
- EPA did not use the 1998 IRIS cancer potency factor in its development of the new Safe Drinking Water Act (SDWA) MCL of 10 ppb promulgated in 2001, nor did they depend on this value in their promulgation of the HHC for the state of California in 2000. In the 2000 California Toxics Rule, EPA expressed their finding of uncertainty around the effects of arsenic, and did not use the newer 1998 cancer potency factor (EPA 2000). EPA used the older cancer potency factor ((1.75 per (mg/kg)/day) derived from the drinking water unit risk (5E-5 per (μg/L)) that was used to calculate the NTR arsenic criteria in its 1998 and 2002 national recommended guidance criteria calculations, but not as the basis of new regulations in either the 2000 California Toxics Rule or the new 2001 Safe Drinking water Act MCL for arsenic.
- Using either the older cancer potency factor of 1.75 per (mg/kg)/day) derived from the drinking water unit risk that was used to calculate the NTR arsenic criteria, or, the 1998 cancer potency factor of 1.5E+0 per (mg/kg)/day), injects a high degree of uncertainty into the criteria calculation for a regulatory level, especially given that EPA has not relied on either of these as the basis of more final recent regulations.

The arsenic BCF: In addition to an uncertain cancer slope factor, the accumulation factor used in the development of EPA's current 304(a) criteria is based on total arsenic, and will need to be modified in order to accurately address accumulation of inorganic arsenic into tissues. The bioconcentration factor (BCF) of 44 L/kg used in EPA's 304(a) criteria is based on total arsenic. This value does not accurately reflect the uptake of inorganic arsenic, the most toxic form of arsenic and the form to which EPA applies it's 304(a) criteria. Most of the arsenic in fish and shellfish tissues is in the organic form, which is much less toxic than the inorganic form (EPA 1997). EPA (1997; page 10) estimated the percentage of inorganic arsenic in tissue*: "the maximum inorganic arsenic in fish and shellfish used for this estimate is 4% …The median inorganic arsenic value for the fish and shellfish data… is 0.4%. No inorganic arsenic was detected in 23 of 42 fish samples and 18 of 50 shellfish samples. Therefore, the median value reflects the higher inorganic arsenic concentrations found in shellfish and is a conservative value."* A BCF specific to inorganic arsenic is not available in EPA's criteria documents, but applying the data above to the current BCF of 44 indicates that the BCF of 44 could be adjusted downward by a large amount if inorganic arsenic only were considered. A new BCF for arsenic, as well as a new CSF, will be required for in order to calculate criteria for arsenic using the HHC equations.

The arsenic Safe Drinking Water Act (SDWA) MCL: The SDWA is based on science and feasibility. This does not invalidate use of a SDWA MCL for use in Clean Water Act programs. EPA uses SDWA values as 304(a) criteria for both asbestos and copper, and has approved use of the arsenic SDWA MCL as a Clean Water Act criterion for many states. Nothing in the Clean Water Act prohibits use of SDWA regulatory values, or of cost, in the state adoption of standards. In fact, the Clean Water Act and the Code of Federal Regulations explicitly direct states to adopt standards taking into account "use and value" of the resource. EPA's 2000 guidance (page 2-4) specifies that many factors apart from science can be taken into consideration in state risk management decisions: *"Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision."*

The EPA went through an extensive process to evaluate science and feasibility to derive and finalize the SDWA arsenic MCL, and that MCL development is based on consideration of newer science than the older CSF included in EPA's 304(a) criteria for arsenic.

Arsenic exposures through tissue: Although Ecology acknowledges the large amount of uncertainty in the CSF and the BCF, using the CSFs and BCF in comparative criteria calculations helps to illustrate why the organism ingestion exposure route is largely irrelevant when considering risk levels between 10^{-4} and 10^{-6}, and why the only relevant exposure routes for those waters with drinking water as a designated use (most freshwaters in the state) is the drinking water exposure route.

The same inputs to the organism + water criteria equation for carcinogens that EPA used in its draft rule for Washington results in the hypothetical criterion (0.0045 μg/L) with the hypothetical 10^{-6} risk level in the table below. If that criterion concentration is held constant, but the risk level is increased due to changes in the FCR, the small effect of the FCR on the criteria can be seen. Using the EPA inputs and holding all variables other than FCR and risk level constant, it takes 2,240 g/day of fish + 2.4 L/day of drinking water to raise the risk level to 10^{-5} while staying at the same hypothetical water concentration. It takes 22,900 g/day of fish + 2.4 L/day of drinking water to raise the risk level to 10^{-4} while staying at the same hypothetical water concentration.

FCR survey data from Washington indicates that no one, even high consuming individuals from the surveys of the highest consuming populations, eat this much fish and shellfish on average on a daily basis over a lifetime. These increases in FCR are possible because the BCF for arsenic is low, and most of the risk is conferred by the exposure to 2.4 L/day of drinking water. In addition, the use of a BCF that was calculated for total arsenic instead of inorganic arsenic provides a large and unaccounted for protective factor in this example. Since virtually no risk is associated with the exposure to organisms, a criterion based on drinking water protection is appropriate and protective for waters with designated uses of drinking water supply.

Table 10 : Hypothetical criterion resulting from draft EPA criteria for Arsenic

Hypothetical criteria value (µg/L)[1]	Risk level	Fish consumption rate (g/day)	Fish consumption rate (pounds /day	Body weight (kg)	Cancer slope factor[3]	Drinking water intake (L/day)	BCF for total arsenic (not inorganic) (L/kg)[4]
0.0045[2]	10^{-6}	175	0.39	80	1.75	2.4	44
0.0045	10^{-5}	2,240	4.94	80	1.75	2.4	44
0.0045	10^{-4}	22,900	50.49	80	1.75	2.4	44

Footnotes:

[1] Criteria values were held constant, only the FCR and risk levels were changed in the calculations.

[2] This is EPA's proposed criteria in its proposed regulation for Washington, which was calculated with the variables shown in this row of the table.

[3] This CSF was used for illustrative purposes only. Scientific uncertainty precludes its use in criteria development.

[4] This is the BCF for total arsenic in tissues from EPA's most recent Clean Water Act 304(a) criteria document for arsenic. Most arsenic in tissues is in the organic form (see: EPA 1997. *Arsenic and fish consumption*. EPA 822-R-97-003.) A BCF (or BAF) that expresses total or inorganic arsenic in water to inorganic arsenic in tissue would be much lower than the 44 L/kg used here. In that case the possible FCRs in the table would be even greater. Uncertainty in this value precludes its use in criteria development.

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

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

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

Basis for Ecology's decision

Ecology made two specific rule changes for arsenic:

- Surface water HHC for total arsenic at the SDWA MCL of 10 µg/L, based on a consideration of the continuing uncertainty around the long-term reassessment of the EPA IRIS cancer potency factor for arsenic, the need for a BCF specific to inorganic arsenic, EPA's Clean Water Act-approval of the of the SDWA MCL for arsenic for other states, and presence of naturally occurring arsenic in Washington. The criterion of 10 µg/L is being applied to both marine and freshwater scenarios. The MCL was developed for drinking waters. Because calculation of new criteria for arsenic is not possible with current information, Ecology also chose to apply the criterion of 10 µg/L to marine and estuarine waters in lieu of not adopting a criterion value for these waters.
- Pollution minimization requirements to reduce anthropogenic inputs of arsenic in discharges to surface waters.

Ecology has determined that use of the EPA cancer potency factor and BCF would introduce a significant amount of uncertainty if used to develop HHC for arsenic.

After review of what other states have done in setting HHC for arsenic, with subsequent approval by EPA, consideration of naturally high concentrations of arsenic in Washington, the scientific uncertainty in assessing risk from exposures to arsenic from tissue ingestion (no CSF for inorganic arsenic) and also with translating that to a water criterion value (no accumulation translator (BCF) for inorganic arsenic), and given the extensive process carried out by EPA to develop a protective MCL appropriate for drinking water exposures, Ecology has determined that use of the SDWA MCL for arsenic, coupled with pollution prevention requirements for industrial dischargers, is appropriate for Washington:

- ***Use of SDWA MCL for Arsenic:*** Use of the MCL has been approved by EPA widely across the nation. In particular, several other western states that have high levels of natural arsenic in the environment have adopted the SDWA MCL and are successfully applying it for protection of human health (Table 2). The SDWA is based on science and feasibility. This does not invalidate use of a SDWA MCL for use in Clean Water Act programs. EPA uses SDWA values as 304(a) criteria for both asbestos and copper, and has approved use of the arsenic SDWA MCL as a Clean Water Act criterion for many states. Nothing in the Clean Water Act prohibits use of SDWA regulatory values in the state adoption of standards.

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

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

References

California Regional Water Quality Control Board, San Francisco Bay Region, 2013. *San Francisco Bay Basin (Region 2) Water Quality Control Plan (Basin Plan). June 29, 2013*. 1515 Clay Street, Suite 1400 Oakland, CA 94612. Retrieved on 5/29/2014 from: http://www.waterboards.ca.gov/sanfranciscobay/water_issues/programs/planningtmdls/basinplan/web/docs/bp_ch3+tables.pdf.

CTD, 2013. Comparative Toxicogenomics Database. Arsenic: Disease Categories. *http://ctdbase.org/detail.go?type=chem&acc=D001151&view=disease*.

Ecology, 2002. Washington Department of Ecology. A Total Maximum Daily Load Evaluation for Arsenic in the Similkameen River. Publication No. 02-03-044. *https://fortress.wa.gov/ecy/publications/SummaryPages/0203044.html*.

EPA 1997. Arsenic and fish consumption. EPA 822-R-97-00

EPA, 2000. U.S. Environmental Protection Agency. 40 CFR Part 131.38 California Toxic's Rule, at *http://www.epa.gov/fedrgstr/EPA-WATER/2000/May/Day-18/w11106.pdf*.

EPA, 2001. U.S. Environmental Protection Agency. Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring Final. FR Vol. **66, No. 4, 6976,** January 22, 2001.

EPA, 2002. U.S. Environmental Protection Agency. Implementation Guidance for the Arsenic Rule: Drinking Water Regulations for Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring. EPA-816-K-02-018. *http://water.epa.gov/lawsregs/rulesregs/sdwa/arsenic/guidance.cfm* .

EPA, 2014. U.S. Environmental Protection Agency. Integrated Risk Information System (IRIS). Detailed Report, Arsenic, inorganic Assessment Milestones and Dates, at:

http://cfpub.epa.gov/ncea/iristrac/index.cfm?fuseaction=viewChemical.showChemical&sw_id=1090.

Gomez-Caminero, A., P.D. Howe, M. Hughes, E. Kenyon, D.R. Lewis, M. Moore, A. Aitio, G.C. Becking, J. Ng, 2001. Arsenic and arsenic compounds. International Programme on Chemical Safety, World Health Organization Task Group on Environmental Health Criteria for Arsenic and Arsenic Compounds. *http://apps.who.int/iris/handle/10665/42366*.

Los Angeles Regional Water Quality Control Board, 1994. *Water Quality Control Plan, Los Angeles Region. Basin Plan for the Coastal Watersheds of Los Angeles and Ventura Counties.* 101 Centre Plaza Drive, Monterey Park, CA 91754. Retrieved on 5/29/2014 from: http://www.waterboards.ca.gov/losangeles/water_issues/programs/basin_plan/basin_plan_documentation.shtml.

NAS, 1999. National Academy of Sciences, National Research Council. *Arsenic in Drinking Water*, at *http://www8.nationalacademies.org/cp/projectview.aspx?key=49483*.

North Coast Regional Water Quality Control Board, 2011. *Water Quality Control Plan for the North Coast Region. May 2011*. 5550 Skylane Blvd., Suite A, Santa Rosa, CA 95403**.** Retrieved on 5/29/2014 from: http://www.waterboards.ca.gov/northcoast/water_issues/programs/basin_plan/083105-bp/04_water_quality_objectives.pdf.

ODEQ, 2011. Oregon Department of Environmental Quality. Water Quality Standards Review and Recommendations: Arsenic. *http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf.*

Regional Water Quality Control Board, Central Coast Region, 2011. *Water Quality Control Plan for the Central Coastal Basin, June 2011*. Regional Water Quality Control Board, Central Coast Region State Water Resources Control Board California Environmental Protection Agency. 895 Aerovista Place, Suite 101San Luis Obispo, CA. 93401-7906. Retrieved on 5/29/2014 from: http://www.waterboards.ca.gov/centralcoast/publications_forms/publications/basin_plan/docs/basin_plan_2011.pdf.

Safe Drinking Water Act. Title XIV of the Public Health Service Act. Safety of Public Water Systems. (Safe Drinking Water Act)

Welch, Alan H., S.A. Watkins, D.R. Helsel, and M.J. Focazio, 2000. Arsenic in Ground-Water Resources of the United States. U.S. Geological Survey Open-File Report 063-00. http://pubs.usgs.gov/fs/2000/fs063-00/fs063-00.html#TOP.

This page intentionally left blank

Challenging Chemicals: Methylmercury

Decision

Ecology decided to defer state adoption of HHC for methylmercury at this time, and plans to schedule adoption of methylmercury criteria and develop a comprehensive implementation plan after the current rulemaking is completed and has received EPA Clean Water Act approval. This decision means that Washington's HHC for total mercury will remain in the NTR until new methylmercury criteria are adopted by the state. The decision allows time for Ecology to gather more information to make an informed decision on how the new methylmercury criteria will be implemented.

Background

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

Washington's criteria for mercury: Washington's HHC and aquatic life criteria for mercury are shown in Table 11 below. The HHC for total mercury were issued to Washington in the 1992 NTR (40 CFR 131.36). Washington's current aquatic life criteria for total mercury are contained in the state's water quality standards rule for aquatic life criteria (WAC 173-201A-240). The HHC are based on non-cancer effects to human health. The acute aquatic life criteria are based on aquatic life effects, and the chronic aquatic life criteria are based on human health protection. The chronic marine and freshwater numeric criteria and the chronic criteria provision of "edible tissue concentrations shall not be allowed to exceed 1.0 mg/kg of methylmercury" are all based on the federal Food and Drug Administration's action level of 1 parts per million (ppm) for methylmercury in commercial fish.

Table 11: Washington's current water quality standards for mercury

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

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

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

EPA draft federal criterion for methylmercury for Washington: In September 2015 EPA proposed a regulatory change that would revise the current federal human health criteria applicable to Washington's waters (the NTR; 40CFR131.36). In 1992 EPA promulgated HHC for Washington State in the NTR, and this regulation contains the state's current HHC for mercury. EPA's newest proposal for Washington contains updates for 99 priority pollutants, including an "organisms-only" criterion for methylmercury of 0.033 mg/kg in tissue. If EPA approves criteria submitted by the state, Ecology assumes the corresponding federal criteria for mercury would remain in the NTR.

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

The 2001 methylmercury criterion was the first EPA-developed HHC expressed as a fish and shellfish *tissue* value rather than as a water column value. EPA recognized that this approach differed from traditional water column criteria and might pose implementation challenges. Therefore, in April 2010, EPA issued *Guidance for Implementing the January 2001*

Methylmercury Water Quality Criterion to provide direction to states and tribes on how to use the new fish tissue-based criterion recommendation in developing water quality standards for methylmercury and in implementing those standards in total maximum daily loads (TMDLs) and National Pollutant Discharge Elimination System (NPDES) permits. This guidance would also be applicable to EPA's 2015 proposed federal NTR criterion for Washington. However, even with guidance from EPA, questions around the following exist and will require development of a Washington specific approach:

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

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

- There are many sources and pathways for mercury to enter Washington's environment (atmospheric transport from local areas and from other areas of the world, direct discharges, pharmaceuticals, food supplies, contaminated sites, etc.) - see Ecology's Mercury Chemical Action Plan information at http://www.ecy.wa.gov/mercury/.).
- Many of these mercury sources cannot be addressed using Clean Water Act laws and implementing regulations.
- There are existing levels of mercury in fish sampled throughout the state that have prompted the WDOH to issue statewide fish advisories for selected species of fish.
- Developing NPDES discharge limits for permits based on a form of mercury (methylmercury criterion) that is created after mercury enters the environment is not straightforward.

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

Basis for Ecology's decision

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

Ecology based this decision on the following factors:

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

References

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

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

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

Ecology. 2003. Washington Department of Ecology. *Washington State Mercury Chemical Action Plan.* Department of Ecology Publication No. 03-03-001

Implementation Tools: Intake Credits

Decision

Ecology added a new definition for “intake credits” and a new section to the water quality standards rule at WAC 173-201A-460 that addresses situations where facilities bring in and discharge levels of background pollutants contained in the intake water, referred to as intake credits (see Figure 7 below for implementation of the new language). Intake credits have typically been allowed for technology based effluent limits (TBELs). The new rule language is applicable to the granting of intake credits for use with water quality-based effluent limits (WQBELs). The new language clarifies the conditions where intake credits would be allowed for determining reasonable potential and WQBELs. The procedure accounts for pollutants already present in the intake water, and would only be allowed when the mass and concentration of effluent is the same or less than intake water, and there is “no net addition” of the pollutant.

Background

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

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

- The facility must not contribute any additional mass of the identified intake pollutant to its wastewater unless an equal or greater mass is removed prior to discharge.
- Intake water must come from the same body of water to which the discharge is made.
- The facility must not alter the identified intake pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not occur if the pollutants were left in-stream.
- The facility must not increase the identified intake pollutant concentration at the point of compliance as compared to the pollutant concentration in the intake water.
- The timing and location of the discharge must not cause adverse water quality impacts to occur that would not occur if the identified intake pollutant were left in-stream.

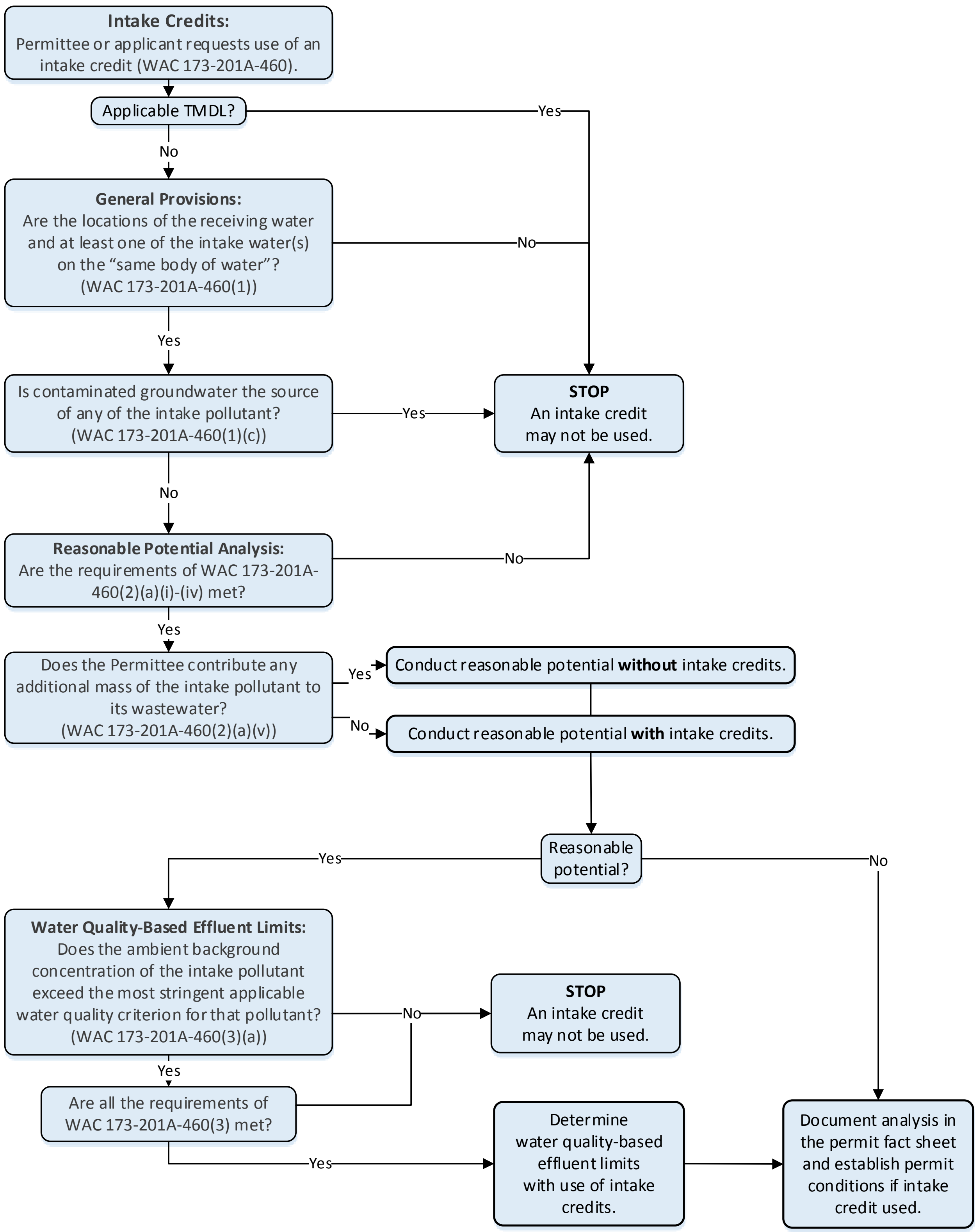


Figure 7: Flowchart for implementation of intake credit language at WAC 173-201A-460

Basis for Ecology's decision

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

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

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

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

References

EPA, 1995. Federal Register, Volume 60, Number 56, "Final Water Quality Guidance for the Great Lakes System", Appendix F, Procedure 5; Reasonable Potential to Exceed Water Quality Standards, Part D. Available online at: http://www.federalregister.gov/articles/1995/03/23/95-6671/final-water-quality-guidance-for-the-great-lakes-system.

ODEQ, 2011. Oregon Department of Environmental Quality. Oregon Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking (2008-2011). Available online at: *http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf*.

This page intentionally left blank

Implementation Tools: Compliance Schedules

Decision

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

Background

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

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

Schedules of compliance have existed in Ecology regulations at WAC 173-220-140 and WAC 173-226-180 for the NPDES permit program since 1974. These regulations require that compliance schedules set forth the shortest, reasonable period of time to achieve the specified requirements, and require that such period to be consistent with federal guidelines and requirements of the Clean Water Act. Compliance schedules become an enforceable part of the permit. If a permittee fails or refuses to comply with interim or final requirements of a compliance schedule in a permit, such noncompliance constitutes a violation of the permit. Compliance schedules were incorporated into the state water quality standards in 1992 to ensure continued use in the permitting program, and can be found at WAC 173-210A-510(4).

The use and limitations of compliance schedules for NPDES permits in Washington are described at WAC 173-220-140 and WAC 173-226-180. For purposes of water quality standards, compliance schedules may be used only where there is a finding that a permittee cannot immediately comply with a new, or newly revised, water-quality based effluent limit (WQBEL). Compliance schedules lasting longer than one year must include interim milestones, along with dates for their achievement, with no more than one year between dates. Interim milestones might relate, for example, to purchase and installation of new equipment, modification of existing facilities, construction of new facilities, and/or development of new programs. Compliance schedules also must include specific numeric or narrative effluent limits that will be met during the compliance schedule period.

Compliance schedules are not allowed for new or expanded facilities.

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

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

Basis for Ecology's Decision

The main basis for Ecology's proposal is state legislation in 2009 that recognized there are circumstances where extending a compliance schedule would be appropriate. Compliance schedules must still meet requirements in state NPDES regulations at WAC 173-220-140 and WAC 173-226-180, which includes specific timeframes within the schedule of compliance and enforceable provisions. RCW 90.48.605 focuses on instances when a TMDL exists on the receiving water, and describes a four part test that must be established:

1. The permittee is meeting its requirements under the total maximum daily load as soon as possible.
2. The actions proposed in the compliance schedule are sufficient to achieve water quality standards as soon as possible.
3. A compliance schedule is appropriate.

4. The permittee is not able to meet its waste load allocation solely by controlling and treating its own effluent.

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

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

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

In summary, the following apply as a basis for the use of the new rule language for the general allowance for compliance schedules in Washington:

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

References

Hanlon, 2007. U.S. EPA Office of Wastewater Management. May 27, 2007. Memorandum to Alexis Stauss, Director of Water Division EPA Region 9, on ''Compliance Schedules for Water Quality-Based Effluent Limitations on NPDES Permits.' Available at: *http://water.epa.gov/lawsregs/guidance/wetlands/upload/signed-hanlon-memo.pdf*.

EPA, 2012. EPA Water Quality Standards Academy - Basic Course Module 5: Compliance Schedules – Discharger Grace Periods: Webpage last updated Friday, November 23, 2012. *http://water.epa.gov/learn/training/standardsacademy/mod5/page12.cfm*.

Ecology, 2013. WA Dept. of Ecology Supplemental Material from Policy Forum #3 (Feb. 8, 2013) - Application of variances and compliance schedules to existing, new, and expanding dischargers/discharges: *http://www.ecy.wa.gov/programs/wq/swqs/SupMaterialVariancesComplianceSched.pdf*.

Implementation Tools: Variances

Decision

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

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

Background

A variance is a time-limited designated use and criterion for a specific pollutant(s) or water quality parameter(s) for a single discharger, a group of dischargers, or stretch of waters. Variances establish a set of temporary requirements that apply instead of the otherwise applicable water quality standards and related water quality criteria. A variance may be considered when the standards are expected to be attained by the end of the variance period or the attainable use cannot be reliably determined. Variances can be targeted to specific pollutants, sources, and/or stretches of waters. Variances are not allowed for new or expanded facilities.

EPA's recent revision to the federal water quality standards regulations (40CFR131) added new regulatory requirements for variances (40CFR131.14), as well as the ability to use variances for restoration activities. The new federal regulation defines a variance as

> *"131.3(o) A water quality standards variance is a time-limited designated use and criterion for a specific pollutant(s) or water quality parameter(s) that reflect the highest attainable condition during the term of the water quality standards variance."*

The US Environmental Protection Agency (EPA) has dictated that state variance procedures, as part of state water quality standards, must be consistent with the substantive requirements of 40 CFR 131.14. EPA has approved state-adopted variances in the past and has indicated that it will continue to do so if:

- Each variance is adopted into rule as part of the water quality standard.
- The state demonstrates that meeting the standard is unattainable based on one or more of the grounds outlined in 40 CFR 13 1.10(g) for removing a designated use. Note: EPA's new water quality standards regulation makes this requirement only applicable to Clean Water Act 101(1)(2) uses (the "fishable/swimmable" uses of the Clean Water Act), which is Ecology's intent also. Variances for other uses must include consideration of the "use and value" of the water. (see 40CFR131.14 for new federal requirements).
- The justification submitted by the state includes documentation that treatment more advanced than that required by sections 303(c)(2)(A) and (B) has been carefully considered, and that alternative effluent control strategies have been evaluated.
- The more stringent state criterion is maintained and is binding upon all other dischargers on the stream or stream segment.
- The discharger who is given a variance for one particular constituent is required to meet the applicable criteria for other constituents.
- The variance is granted for a specific period of time and can be renewed upon expiration.
- The discharger either must meet the standard upon the expiration of this time period or must make a new demonstration of "unattainability."
- Reasonable progress is being made toward meeting the standards.
- The variance was subjected to public notice, opportunity for comment, and public hearing. The public notice should contain a clear description of the impact of the variance upon achieving water quality standards in the affected stretch of waters.

The temporary requirements established through a variance are only effective for the life of the variance. Because a variance establishes a temporary set of requirements that apply instead of the underlying water quality criteria, EPA has specified that variances for the Clean Water Act 101(a)(2) fishable/swimmable uses are appropriate only under the same circumstances required in federal rule to undertake a Use Attainability Analysis (UAA), used to change a designated use for a water body. Also, variances can be granted when they are needed to undertake restoration activities:

> 40CFRE131.14(b)(2)(i)(A)
>
> *"…the State must demonstrate that attaining the designated use and criterion is not feasible throughout the term of the water quality standards variance because:*
>
> *(1) One of the factors listed in § 131.10(g) is met, or*
>
> *(2) Actions necessary to facilitate lake, wetland, or stream restoration through dam removal or other significant reconfiguration activities preclude attainment of the designated use and criterion while the actions are being implemented."*.

Regulations found in 40 CFR 131.10(g) establish six circumstances under which a UAA, or a variance, might be appropriate. They are:

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

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

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

Federal regulations (40CFR131.14) require that the term of the variance can only be as long as necessary to achieve the highest attainable condition.

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

Basis for Ecology's decision

Ecology adopted HHC for Washington's water quality standards. Changes to the variables that go into the HHC equation, such as an updated fish consumption rate, generally result in more protective criteria. Ecology recognizes that these new, more protective criteria may be difficult to meet in situations where technology is not yet available or feasible to remove the pollutant, or in cases where either (1) a persistent pollutant resides and is cycling within the aquatic ecosystem of the water body and cannot be removed without degrading the system, or (2) when the main sources of the pollutant are not within the scope of the state's jurisdiction to control through water quality protection. In addition, other criteria and uses may not be possible to attain in the short term and variances could be applicable to these circumstances as well. An example of this is the time needed to improve temperature in streams where the only feasible cooling method is shade via streamside tree planting and subsequent tree canopy maturation.

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

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

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

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

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

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

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

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

References

Ecology, 2013. WA Dept. of Ecology Supplemental Material from Policy Forum #3 (Feb. 8, 2013) - Application of variances and compliance schedules to existing, new, and expanding dischargers/discharges: *http://www.ecy.wa.gov/programs/wq/swqs/SupMaterialVariancesComplianceSched.pdf*.

EPA, 2013. U.S. Environmental Protection Agency. Office of Water. EPA-820-F-13-012. Discharger-specific Variances on a Broader Scale: Developing Credible Rationales for Variances that Apply to Multiple Dischargers: Frequently Asked Questions. Found online at: *http://water.epa.gov/scitech/swguidance/standards/upload/Discharger-specific-Variances-on-a-Broader-Scale-Developing-Credible-Rationales-for-Variances-that-Apply-to-Multiple-Dischargers-Frequently-Asked-Questions.pdf*.

EPA, 2014. U.S. Environmental Protection Agency. Water Quality Standards Handbook - Chapter 5: General Policies (40 CFR 131.12) - Section 5.3 Variances from Water Quality Standards. Found online at: *http://water.epa.gov/scitech/swguidance/standards/handbook/chapter05.cfm#section3*.

EPA, 2015. U.S. Environmental Protection Agency. *Water Quality Standards Regulatory Revisions; Final Rule.* 80FR162, Friday, August 21. 2015, pages 51020 – 51050.

ODEQ, 2011. Oregon Department of Environmental Quality. Oregon Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking (2008-2011). Available online at: *http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf*.

ODEQ, 2011. Oregon Department of Environmental Quality. Oregon Variance Compendium. Available online at: *http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/VarianceCompendium110124.pdf*.

IDEQ, 2009. Idaho Department of Environmental Quality. Justification for Granting of Variances from the Idaho Water Quality Standards to the Cities of Page, Mullan and Smelterville for the Discharge of Metals from their Wastewater Treatment Plant. http://www.deq.idaho.gov/media/451049-variances_justification_page_mullen_smelterville.pdf.

Implementation Clarification for Combined Sewer Overflows (CSO) Treatment Plants

Decision

Ecology added a new definition to WAC 173-201A-020 to define CSO Treatment Plants and new language to WAC 173-201A-510 *Means of Implementation*, to clarify implementation of HHC in NPDES permits for CSO Treatment Plants. This new rule language provides clarification but does not change any current practices with regard to permit requirements.

Background

The following description of CSO's is taken from EPA 2004.

"Two types of public sewer systems predominate in the United States: combined sewer systems (CSSs), and sanitary sewer systems (SSSs). CSSs were among the earliest sewer systems constructed in the United States and were built until the first part of the 20th century. As defined in the 1994 CSO Control Policy (EPA 1994a), a CSS is:

> *A wastewater collection system owned by a state or municipality (as defined by Section 502(4) of the Clean Water Act) that conveys domestic, commercial, and industrial wastewaters and storm water runoff through a single pipe system to a publicly-owned treatment works (POTW).*

During wet weather events (e.g., rainfall or snowmelt), the combined volume of wastewater and storm water runoff entering CSSs often exceeds conveyance capacity. Most CSSs are designed to discharge flows that exceed conveyance capacity directly to surface waters, such as rivers, streams, estuaries, and coastal waters. Such events are called CSOs. A CSO is defined as:

> *The discharge from a CSS at a point prior to the POTW treatment plant.*
>
> *Some CSO outfalls discharge infrequently, while others discharge every time it rains. Overflow frequency and duration varies from system to system and from outfall to outfall within a single CSS. Because CSOs contain untreated wastewater and storm water, they contribute microbial pathogens and other pollutants to surface waters. CSOs can impact the environment and human health. Specifically, CSOs can cause or contribute to water quality impairments, beach closures, shellfish bed closures, contamination of drinking water supplies, and other environmental and human health problems."*

CSOs are driven by influxes of stormwater into combined sanitary and stormwater collection systems. Because of the episodic and short-term nature of CSO discharges it is infeasible to calculate effluent limits that are based on criteria with durations of exposure up to 70 years. The federal regulations (40CFR122.44(k)) allow use of best management practices (BMP)-based limits in NPDES permits if it is infeasible to calculate numeric limits:

“§ 122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see § 123.25).

In addition to the conditions established under § 122.43(a), each NPDES permit shall include conditions meeting the following requirements when applicable.

***(k)** Best management practices (BMPs) to control or abate the discharge of pollutants when:*

***(1)** Authorized under section 304(e) of the Clean Water Act for the control of toxic pollutants and hazardous substances from ancillary industrial activities;*
***(2)** Authorized under section 402(p) of the Clean Water Act for the control of storm water discharges;*
***(3)** Numeric effluent limitations are infeasible; or*
***(4)** The practices are reasonably necessary to achieve effluent limitations and standards or to carry out the purposes and intent of the Clean Water Act.“*

In Washington CSO control strategies are implemented through methods and approaches specified in chapter 173 of the Washington Administrative Code (WAC 173), 40CFR122, and the *Water Quality Program Permit Writer’s Manual* (Ecology 2015). Chapter 173-245 WAC establishes procedures for CSO reduction. One reduction strategy available is treatment at the CSO site. Discharges from these CSO Treatment Plants are typically more frequent than once per year though still relatively infrequent and typically of short duration. Ecology adopted the additional CSO treatment plant implementation language in the water quality standards in order to provide clarity to the implementation of HHC in permits for CSO Treatment Plants.

Basis for Ecology’s decision

Ecology adopted CSO treatment plant implementation language in the water quality standards in order to provide clarity to the implementation of HHC in permits for CSO Treatment Plants. The new rule language is below:

173-201A-020 Definitions.
Combined Sewer Overflow (CSO) Treatment Plant **–** is a facility that provides At-Site treatment as provided for in chapter 173-245 WAC. A CSO Treatment plant is a specific facility identified in a department-approved CSO Reduction Plan (Long-term Control Plan) that is designed, operated and controlled by a municipal utility to capture and treat excess combined sanitary sewage and stormwater from a combined sewer system.

173-201A-510 Means of Implementation
(6) *Combined Sewer Overflow Treatment Plant*

The influent to these facilities is highly variable in frequency, volume, duration, and pollutant concentration. The primary means to be used for requiring compliance with the human health criteria shall be through the application of narrative limitations, which includes but is not limited to best management practices required in waste discharge permits, rules, orders and directives issued by the department.

References

EPA 2004. U.S. Environmental Protection Agency. *Report to Congress on the Impacts and Control of CSOs and SSOs.*

Ecology 2015. *Water Quality Program Permit Writer's Manual*. Revised January 2015,

Ecology publication no. 92-109.

This page intentionally left blank

Appendix A. Input Values to Calculate New HHC Criteria

The table below contains the input values used by Ecology to calculate the new 2016 human health criteria found in WAC 173-201A-240, as adopted on August 1, 2016. Risk levels and hazard quotients are not shown. The risk level used with the cancer slope factors was 1 x 10^{-6}, except for PCBs, which was 4 x 10^{-5}. The hazard quotient used with the reference doses was 1. For further information see the following sections in this document:

- Human Health Criteria Equations and Variables
- Challenging Chemicals: Arsenic
- Challenging Chemicals: PCBs, for the bases of the input values.

Notes:
1. RfDs in orange are in the EPA 2015 final criteria documents and have corresponding CSFs which are the basis of the EPA proposed Rule for Washington. These RfDs were not the basis of the proposed EPA rule.
2. Safe Drinking Water Act criteria bases are indicated in blue rows.

Column headings:
PP# = Priority pollutant number (Appendix A to 40 CFR Part 423)
NTR Chem # = Chemical number in the National Toxics Rule (40CFR131.36)
CAS # = Chemical Abstract Service number
RSC = Relative source contribution
RfD = Reference dose (mg/kg-day)
BW = Body weight (kg)
DWI = Drinking water intake (L/day)
FCR = Fish consumption rate (kg/day)
BCF = bioconcentration factor (L/kg)
CSF = Cancer slope factor (mg/kg-day)

PP #	NTR Chem #	Chemical Name	CAS # - 1	CAS # -2	RSC	RfD	BW	DWI	FCR	BCF	CSF
11	41	1,1,1-Trichloroethane	71556	71-55-6	1	2	80	2.4	0.175	5.6	-
15	37	1,1,2,2-Tetrachloroethane	79345	79-34-5	1	0.02	80	2.4	0.175	5	0.2
14	42	1,1,2-Trichloroethane	79005	79-00-5	1	0.004	80	2.4	0.175	4.5	0.057
29	30	1,1-Dichloroethylene	75354	75-35-4	1	0.05	80	2.4	0.175	5.6	-
8	101	1,2,4-Trichlorobenzene	120821	120-82-1	1	0.01	80	2.4	0.175	114	0.029
25	75	1,2-Dichlorobenzene	95501	95-50-1	1	0.3	80	2.4	0.175	55.6	-
10	29	1,2-Dichloroethane	107062	107-06-2	1	0.078	80	2.4	0.175	1.2	0.0033
32	31	1,2-Dichloropropane	78875	78-87-5	1	0.0893	80	2.4	0.175	4.1	0.036
37	85	1,2-Diphenylhydrazine	122667	122-66-7	1	-	80	2.4	0.175	24.9	0.8
30	40	1,2-Trans-Dichloroethylene	156605	156-60-5	1	0.02	80	2.4	0.175	1.58	-
26	76	1,3-Dichlorobenzene	541731	541-73-1	1	0.002	80	2.4	0.175	55.6	-
33	32	1,3-Dichloropropene	542756	542-75-6	1	0.025	80	2.4	0.175	1.91	0.122
27	77	1,4-Dichlorobenzene	106467	106-46-7	1	0.07	80	2.4	0.175	55.6	-
129	16	2,3,7,8-TCDD (Dioxin)	1746016	1746-01-6	1	7E-10	80	2.4	0.175	5,000	-
21	55	2,4,6-Trichlorophenol	88062	88-06-2	1	0.001	80	2.4	0.175	150	0.011
31	46	2,4-Dichlorophenol	120832	120-83-2	1	0.003	80	2.4	0.175	40.7	-
34	47	2,4-Dimethylphenol	105679	105-67-9	1	0.02	80	2.4	0.175	93.8	-
59	49	2,4-Dinitrophenol	51285	51-28-5	1	0.002	80	2.4	0.175	1.5	-
35	82	2,4-Dinitrotoluene	121142	121-14-2	1	0.002	80	2.4	0.175	3.8	0.667
20	71	2-Chloronaphthalene	91587	91-58-7	1	0.08	80	2.4	0.175	202	-
24	45	2-Chlorophenol	95578	95-57-8	1	0.005	80	2.4	0.175	134	-
60	48	2-Methyl-4,6-Dinitrophenol	534521	534-52-1	1	0.0003	80	2.4	0.175	5.5	-
28	78	3,3'-Dichlorobenzidine	91941	91-94-1	1	-	80	2.4	0.175	312	0.45
22	52	3-Methyl-4-Chlorophenol	59507	59-50-7	1	0.1	80	2.4	0.175	1258	-
94	110	4,4'-DDD	72548	72-54-8	1	0.0005	80	2.4	0.175	53,600	0.24

PP #	NTR Chem #	Chemical Name	CAS # - 1	CAS # -2	RSC	RfD	BW	DWI	FCR	BCF	CSF
93	109	4,4'-DDE	72559	72-55-9	1	0.0005	80	2.4	0.175	53,600	0.167
92	108	4,4'-DDT	50293	50-29-3	1	0.0005	80	2.4	0.175	53,600	0.34
1	56	Acenaphthene	83329	83-32-9	1	0.06	80	2.4	0.175	242	-
2	17	Acrolein	107028	107-02-8	1	0.0005	80	2.4	0.175	215	-
3	18	Acrylonitrile	107131	107-13-1	1	-	80	2.4	0.175	30	0.54
89	102	Aldrin	309002	309-00-2	1	0.00003	80	2.4	0.175	4,670	17
102	103	alpha-BHC	319846	319-84-6	1	0.008	80	2.4	0.175	130	6.3
95	112	alpha-Endosulfan	959988	959-98-8	1	0.006	80	2.4	0.175	270	-
78	58	Anthracene	120127	120-12-7	1	0.3	80	2.4	0.175	30	-
114	1	Antimony	7440360	7440-36-0	1	0.0004	80	2.4	0.175	1	-
115	2	Arsenic	7440382	7440-38-2	Based on Safe Drinking Water Act, see sections in this document: Human Health Criteria Equations and Variables, and, Challenging Chemicals: Arsenic						
116	15	Asbestos	1332214	1332-21-4	Based on Safe Drinking Water Act, as per EPA 304(a) criteria documents.						
4	19	Benzene	71432	71-43-2	1	0.0005	80	2.4	0.175	5.2	0.055
5	59	Benzidine	92875	92-87-5	1	0.003	80	2.4	0.175	87.5	230
72	60	Benzo(a)Anthracene	56553	56-55-3	1	-	80	2.4	0.175	30	0.73
73	61	Benzo(a)Pyrene	50328	50-32-8	1	-	80	2.4	0.175	30	7.3
74	62	Benzo(b)Fluoranthene	205992	205-99-2	1	-	80	2.4	0.175	30	0.73
75	64	Benzo(k)Fluoranthene	207089	207-08-9	1	-	80	2.4	0.175	30	0.073
103	104	beta-BHC	319857	319-85-7	1	-	80	2.4	0.175	130	1.8
96	113	beta-Endosulfan	33213659	33213-65-9	1	0.006	80	2.4	0.175	270	-
18	66	Bis(2-Chloroethyl)Ether	111444	111-44-4	1	-	80	2.4	0.175	6.9	1.1
66	68	Bis(2-Ethylhexyl) Phthalate	117817	117-81-7	1	0.06	80	2.4	0.175	130	0.014
47	20	Bromoform	75252	75-25-2	1	0.03	80	2.4	0.175	3.75	0.0045
67	70	Butylbenzyl Phthalate	85687	85-68-7	1	1.3	80	2.4	0.175	414	0.0019
6	21	Carbon Tetrachloride	56235	56-23-5	1	0.004	80	2.4	0.175	18.75	0.07

PP #	NTR Chem #	Chemical Name	CAS # - 1	CAS # -2	RSC	RfD	BW	DWI	FCR	BCF	CSF
91	107	Chlordane	57749	57-74-9	1	0.0005	80	2.4	0.175	14,100	0.35
7	22	Chlorobenzene	108907	108-90-7	1	0.02	80	2.4	0.175	10.3	-
51	23	Chlorodibromomethane	124481	124-48-1	1	0.02	80	2.4	0.175	3.75	0.04
23	26	Chloroform	67663	67-66-3	1	0.01	80	2.4	0.175	3.75	-
76	73	Chrysene	218019	218-01-9	1	-	80	2.4	0.175	30	0.0073
120	6	Copper	7440508	7440-50-8	Based on Safe Drinking Water Act, as per EPA 304(a) criteria documents.						
121	14	Cyanide	57125	57-12-5	1	0.0006	80	2.4	0.175	1	-
82	74	Dibenzo (a,h) Anthracene	53703	53-70-3	1	-	80	2.4	0.175	30	7.3
48	27	Dichlorobromomethane	75274	75-27-4	1	0.003	80	2.4	0.175	3.75	0.034
90	111	Dieldrin	60571	60-57-1	1	0.00005	80	2.4	0.175	4,670	16
70	79	Diethyl Phthalate	84662	84-66-2	1	0.8	80	2.4	0.175	73	-
71	80	Dimethyl Phthalate	131113	131-11-3	1	10	80	2.4	0.175	36	-
68	81	Di-n-Butyl Phthalate	84742	84-74-2	1	0.1	80	2.4	0.175	89	-
97	114	Endosulfan Sulfate	1031078	1031-07-8	1	0.006	80	2.4	0.175	270	-
98	115	Endrin	72208	72-20-8	1	0.0003	80	2.4	0.175	3,970	-
99	116	Endrin Aldehyde	7421934	7421-93-4	1	0.0003	80	2.4	0.175	3,970	-
38	33	Ethylbenzene	100414	100-41-4	1	0.022	80	2.4	0.175	37.5	-
39	86	Fluoranthene	206440	206-44-0	1	0.04	80	2.4	0.175	1,150	-
80	87	Fluorene	86737	86-73-7	1	0.04	80	2.4	0.175	30	-
104	105	gamma-BHC (Lindane)	58899	58-89-9	1	0.0047	80	2.4	0.175	130	-
100	117	Heptachlor	76448	76-44-8	1	0.0001	80	2.4	0.175	11,200	4.1
101	118	Heptachlor Epoxide	1024573	1024-57-3	1	0.000013	80	2.4	0.175	11,200	5.5
9	88	Hexachlorobenzene	118741	118-74-1	1	0.0008	80	2.4	0.175	8,690	1.02
52	89	Hexachlorobutadiene	87683	87-68-3	1	0.0003	80	2.4	0.175	2.78	0.04
53	90	Hexachloro-cyclopentadiene	77474	77-47-4	1	0.006	80	2.4	0.175	4.34	-
12	91	Hexachloroethane	67721	67-72-1	1	0.0007	80	2.4	0.175	86.9	0.04

PP #	NTR Chem #	Chemical Name	CAS # - 1	CAS # -2	RSC	RfD	BW	DWI	FCR	BCF	CSF
83	92	Indeno (1,2,3-cd) Pyrene	193395	193-39-5	1	-	80	2.4	0.175	30	0.73
54	93	Isophorone	78591	78-59-1	1	0.2	80	2.4	0.175	4.38	0.00095
46	34	Methyl Bromide	74839	74-83-9	1	0.02	80	2.4	0.175	3.75	-
44	36	Methylene Chloride	75092	75-09-2	1	0.006	80	2.4	0.175	0.9	0.002
	8b	Methylmercury	22967926	22967-92-6	1	0.0001	80	2.4	0.175	NA	-
124	9	Nickel	7440020	7440-02-0	1	0.02	80	2.4	0.175	47	-
56	95	Nitrobenzene	98953	98-95-3	1	0.002	80	2.4	0.175	2.89	-
61	96	N-Nitrosodimethylamine	62759	62-75-9	1	-	80	2.4	0.175	0.026	51
63	97	N-Nitrosodi-n-Propylamine	621647	621-64-7	1	-	80	2.4	0.175	1.13	7
62	98	N-Nitrosodiphenylamine	86306	86-30-6	1	-	80	2.4	0.175	136	0.0049
64	53	Pentachlorophenol	87865	87-86-5	1	0.005	80	2.4	0.175	11	0.4
65	54	Phenol	108952	108-95-2	1	0.6	80	2.4	0.175	1.4	-
106-112	119	Polychlorinated Biphenyls (PCBs)	n	1336-36-3	1	-	80	2.4	0.175	31,200	2
84	100	Pyrene	129000	129-00-0	1	0.03	80	2.4	0.175	30	-
125	10	Selenium	7782492	7782-49-2	1	0.005	80	2.4	0.175	4.8	-
85	38	Tetrachloroethylene	127184	127-18-4	1	0.006	80	2.4	0.175	30.6	0.0021
127	12	Thallium	7440280	7440-28-0	1	0.000068	80	2.4	0.175	116	-
86	39	Toluene	108883	108-88-3	1	0.0097	80	2.4	0.175	10.7	-
113	120	Toxaphene	8001352	8001-35-2	1	0.00035	80	2.4	0.175	13,100	1.1
87	43	Trichloroethylene	79016	79-01-6	1	0.005	80	2.4	0.175	10.6	0.05
88	44	Vinyl Chloride	75014	75-01-4	1	0.003	80	2.4	0.175	1.17	1.5
128	13	Zinc	7440666	7440-66-6	1	0.3	80	2.4	0.175	47	-