Erin Herlihy

Attached please find a comment letter plus additional supporting documents submitted on behalf of Association of Washington Business.

COMMENTS ON BEHALF OF

ASSOCIATION OF WASHINGTON BUSINESS, NORTHWEST PULP & PAPER ASSOCIATION, AMERICAN FOREST & PAPER ASSOCIATION, GREATER SPOKANE, INC., FOOD NORTHWEST, AND WESTERN WOOD PRESERVERS INSTITUTE

ON THE STATE OF WASHINGTON PROPOSED HUMAN HEALTH WATER QUALITY CRITERIA

CR 102 – WSR 24-19-075 (September 17, 2024)

October 25, 2024

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Association of Washington Business, Northwest Pulp & Paper Association, American Forest & Paper Association, Greater Spokane Inc., Food Northwest, and Western Wood Preservers Institute submit the following comments on the Department of Ecology (Ecology) proposed revision to certain human health water quality criteria in the state water quality standards. WSR 24-19-075 (September 17, 2024).

Because the proposed action would simply substitute federal human health water quality criteria (HHWQC) for the existing criteria contained in Washington state regulations, the commentators incorporate by reference their May 31, 2022, comment letter on EPA proposed HHWQC for Washington. Attachment D. As set forth in the May 2022 comment letter, the EPA HHWQC are not based on any legitimate legal authority, sound science, and EPA policies for deriving HHWQC. The EPA ruling also failed to properly defer to the risk management determinations that are the prerogative of the state of Washington as reflected in the current language of WAC 173-201A-240, Table 240, footnotes B and E. EPA also failed to properly assess and document the likely cost of the federal standards. The commentators request that Ecology respond to the comments in that letter in addition to the comments set forth below. These comments are supported by the attachments identified in the table of contents as well as the documents contained in the Supporting Documents Files submitted with these comments. Documents in the Supporting Documents File are identified by page number within parentheses in footnote citations. We request that this comment letter, the 2022 comments letter, attachments, and Supporting Documents File be included in the rulemaking docket.

Introduction

Maintaining and improving water quality in the state of Washington is our shared goal. We support sustainable water quality standards that result in cleaner water, preserve aquatic life, and protect human health. To be effective in reaching these goals, the adopted standards must be based on accurate and complete data, recognized scientific principles, and prudent risk management calculations. Most of all, water quality standards must reflect the important balance between protection and attainability to justify significant public and private investments necessary to meet the standards.

In announcing the 2016 human health water quality criteria codified in WAC 173-201A-240, Washington State officials voiced confidence in the thorough process Ecology followed in developing the state HHWQC and the resulting protections the standards afford the people of Washington. For example, in a November 15, 2016, statement, then-director Maia Bellon publicly expressed disappointment with EPA's rejection of the state HHWQC proposal:

> *We're disappointed that Washington state's approach wasn't accepted in its entirety. We worked hard to craft new water quality standards that were balanced and made real progress – improving environmental protection and human health while helping businesses and local governments comply.*

We were always clear in our goal –to meet EPA's requirements and tailor our proposal to work for Washington state. We believe we did that with the clean water standards we adopted…[1].

As members of Washington's regulated community, we have consistently maintained our commitment to improving water quality. We recognized that while these standards were some of the most protective standards adopted by any state in the nation, they reflected an effort to satisfy Clean Water Act requirements while providing a path to compliance, challenging though it was.

By contrast, Ecology is now undertaking a politically motivated repeal of state criteria and adoption of the EPA criteria as state criteria. Ecology provides no substantive rationale or explanation to support its proposed action, which reveals that the singular purpose of this effort is to provide a strategic advantage to EPA in defending the federal standards in federal court.[2] Or as Ecology euphemistically characterizes its purpose, "to provide durability and regulatory certainty for pollution limits that were set" by EPA. This is an illegitimate basis for rulemaking. And the significant implications of the rule render unlawful Ecology's attempt to skirt the requirements of the Washington Administrative Procedure Act. The proposed rule meets the definition for a "significant legislative rule" under section 34.05.328(5)(c)(iii), and as such this rulemaking cannot evade the procedural requirements for significant legislative rules.[3] Moreover, if the EPA criteria were to be vacated or remanded, there would be no legal basis for this proceeding under section 34.05.310(4)(c).[4]It is important to recognize the unintended consequences of the proposed rule.

The criteria that Ecology proposes to adopt have foreseeable consequences that Ecology, like EPA before it, has simply failed to consider. Two years after EPA's final rule, and eight years after Ecology's 2016 rule was finalized, Ecology has undertaken no assessment of the costs and benefits of its proposed criteria *today*. It is erroneous to simply assume it is reasonable to codify federal standards in state law (and thus add the State's endorsement of those standards) without considering the standards in light of current circumstances. Such a consideration would entail evaluation of alternative approaches and the costs and benefits associated with Ecology's chosen criteria. Ecology's proposal makes no effort to undertake these essential elements of reasonable rulemaking. If it did so, Ecology would discover that its proposed criteria impose impossible standards and onerous costs on regulated parties and the Washington's population at large. Faced with the inability to meet an unattainable standard and the resulting permit uncertainty, employers are less likely to invest in newer water treatment technologies or other upgrades to modernize and expand their operations, with the result that many will choose to leave the State, putting at risk important family-wage jobs, including union jobs and those bringing critical economic activity to rural areas.

Similarly, local governments across Washington State will be required to invest untold millions, possibly billions, of dollars in new technology even though these investments will not result in compliance with the EPA standards Ecology proposes to adopt. Those costs will be

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[1] Ecology, "Ecology Director Maia Bellon responds to EPA's announcement on Washington's water quality standards Department of Ecology News Release," (November 15, 2016) (07960-07961).
[2] Association of Washington Business, et al. v. EPA, et al., D.D.C. No. 23-cv-3605.
[3] RCW 34.05.328(5)(c)(iii) (2024).
[4] RCW 34.05.310(4)(c) (2024).

passed on to the citizens of the State in the form of higher utility and tax rates at a time when many are already facing economic challenges. This added burden would compound the skyrocketing cost of living for Washingtonians due to record inflation driving up the costs of housing, food, fuel, and other essentials. These burdens will fall heaviest on the citizens of our State who can least afford another increase in their costs of living. These are the implications of the proposed rule; law and sound public policy dictate that Ecology not proceed with the proposed rule without a clearly documented implementation plan and environmental justice assessment.

In contrast to the thorough and inclusive process employed by Ecology to develop its standards, EPA's rule was not based on a comprehensive assessment of all relevant factors. EPA was arbitrary and capricious in selecting only some of the elements and factors that the state specifically chose, after years of in-depth discussions, for its overall risk management decisions. For instance, EPA should not have disregarded Ecology's risk factor, relative source contribution, and bioconcentration determinations while accepting Ecology's 175 g/day fish consumption rate, as all were inter-related components of the State's risk management decision. EPA did not adequately justify its decisions to reject Ecology's consideration of these factors which drive the federal HHWQC Ecology now proposes to adopt. Ecology cannot lawfully repeal the state standards and adopt the EPA standards without conducting its own analysis of these issues as this action is a significant legislative rule. [5]

Ecology could correct EPA's errors by adopting new criteria that are based on legitimate State risk management decisions. Instead, Ecology replicates EPA's mistakes. It would be a mistake for the State to assume the federal standards are the floor to any future state standards without first conducting additional analysis.

EPA has never provided any guidance on how its PCB criterion can be implemented. Ecology cannot proceed without filling that gap. Ecology is acting in derogation of the state Administrative Procedures Act by proceeding with this rulemaking without disclosing to the public how it intends to implement the EPA standards adopted as state standards.

The commentators respectfully request that Ecology reconsider and abandon this rulemaking.

Comment No. 1: Ecology has already incorporated EPA's HHWQC by reference, so this rulemaking is unnecessary.

Ecology states in the subject CR 102 that this rulemaking is exempt from significant legislative rulemaking requirements because it is merely incorporating federal standards by reference. Ecology did not take this approach in a recent rulemaking to issue Aquatic Life Toxic Criteria adopted certified on September 11, 2024. In that rulemaking Ecology added to Table 240 in WAC 173-201A-240 footnote H, which provides: "Human health criteria applicable for Clean Water Act purposes in the state of Washington are contained in 40 C.F.R. 131.45 and effective as of December 19, 2022 (87 FR 69183)." Ecology added footnote H to each of the human health

[5] RCW 34.05.328(5)(c)(iii) (2024).

criteria that was disapproved and replaced by the EPA rule. Ecology has failed to explain why this rulemaking is necessary where the state water quality standards already acknowledge EPA criteria by reference.

Ecology's opaque reference to "durability and regulatory certainty" suggests that Ecology's true motivation may be to attempt to moot a pending federal case challenging EPA's water quality standards. If that is Ecology's purpose, it is improper. Ecology has attempted no reasoned explanation for preferring the federal criteria to Ecology's own 2016 criteria.

Comment No. 2: Ecology is engaging in substantive rulemaking subject to significant legislative rulemaking requirements by proposing to repeal its 2016 HHQWC rule.

Many of the commentators participated in Ecology's rulemaking process that resulted in the 2016 HHWQC. That effort included hours of public meetings, advisory committee meetings, scientific review, and a thorough analysis of the elements required under significant legislative rulemaking requirements. Ecology's 2016 standard retains regulatory significance, because they are the last EPA-approved State standards, and they would remain in effect if EPA's 2022 rule were to be vacated in pending litigation. Ecology cannot withdraw the 2016 state rule and adopt EPA HHWQC without going through the same process to properly articulate and document Ecology's rationale and allow for meaningful, and legally required, public participation.

In 2016, Ecology made a risk management decision to derive human health criteria for carcinogens based on a risk factor of 1×10^{-6} for all parameters except Polychlorinated Biphenyls (PCBs) which was set at a specific level of 4×10^{-5}. *See* WAC 173-201A-240, Table 240, footnotes B and E. It is the prerogative of the State to make these risk management decisions. Ecology's proposed rulemaking to supplant its prior risk management decision with EPA's uniform risk factor of 1×10^{-6} is a substantive change to the state water quality standards and goes beyond incorporating or adopting a federal standard by reference. This action is subject to significant legislative rulemaking requirements.

Under section 34.05.328(5)(c)(iii), a "significant legislative rule" is defined as follows.

> A "significant legislative rule" is a rule other than a procedural or interpretive rule that (A) adopts substantive provisions of law pursuant to delegated legislative authority, the violation of which subjects a violator of such rule to a penalty or sanction; (B) establishes, alters, or revokes any qualification or standard for the issuance, suspension, or revocation of a license or permit; or (C) adopts a new, or makes significant amendments to, a policy or regulatory program. [6]

Given that the rule adopts substantive provisions of law, revokes and then establishes standards that would be used for permits and reflects new and significant amendments to Ecology's water quality standards, the proposed rule is a significant legislative rule. The State's last official regulatory word on human health criteria was the 2016 rule. Here, Ecology purports to remove those standards and adopt new ones without any explanation of the reasons for changing its view about each of the inputs and resulting criteria from the conclusions it reached

[6] RCW 34.05.328(5)(c)(iii) (2024).

in 2016. It is not enough to say the State is compelled to adopt EPA's standards without change—that is not correct. The State could adopt different standards and submit them for EPA approval, and EPA must approve them if they are based on sound science and adequately protect the designated uses, based on the record, even if they differ from the federal rule.

Moreover, the EPA criteria are subject to ongoing litigation, and if the EPA criteria were to be vacated or remanded, there would be no legal basis for this proceeding under RCW 34.05.310(4)(c).

Comment No. 3: The proposed criteria are based on an unreasonable fish consumption rate.

The EPA criteria that Ecology proposes to adopt as a State standard are based on a fish consumption rate (FCR) of 175 g/day—far in excess of EPA's default national FCR of 22 g/day and higher even than EPA's recommended 142 g/day rate for subsistence fishers. *See* EPA, *"Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" ("2000 Methodology")*, 2000 Methodology at 1-5. The 175 g/day FCR rests on unreasonable assumptions based on a cherry-picked and outdated survey of tribal members in the Columbia River Basin. A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin 69 (Columbia River Inter-Tribal Fish Commission 1994), tinyurl.com/53c9x9ar. The study reported on "rates of consumption represent fish obtained *from all sources*," including grocery stores—in other words, fish not even exposed to Washington waters and thus unaffected by the proposed criteria. *Id.* (emphasis added). And the FCR fails to account for the fact that anadromous fish species that spend most of their lives in ocean waters far from the shore (e.g., many species of salmon) have lower degrees of exposure to pollutants in inland waters than fish and shellfish found exclusively inland.

Ecology should set state standards based on contemporary and accurate data about fish consumption from Washington waters and should take into variations in where fish species live and the variation in fish consumption over a lifetime. *See* National Health and Nutrition Examination Survey 21–22 (Apr. 2014) (adjusting risk to account for the reality that people do not eat the same amount of fish every day over a lifetime).[7]

Commentators incorporate by reference comments submitted in response to EPA's 2021 proposed rule. *See* Attachment D at 26-52.

Comment No. 4: The proposed criteria are unmeasurable, unattainable, and therefore unreasonable.

The 7 ppq PCB criterion is so small that modern technology cannot even reliably detect or measure the pollutant at that concentration. EPA's most recently approved, state-of-the-art method for measuring PCBs to determine compliance with an NPDES permit "has an average analytical quantitation limit for each PCB congener of approximately 2,000 [ppq], which is a substantial improvement over the current regulatory method," but "well above" EPA's criterion. 87 Fed. Reg. at 69,195–96 (describing Method 1628). The "current regulatory method" can

[7] https://www.epa.gov/sites/default/files/2015-01/documents/fish-consumption-rates 2014.pdf

reliably quantify PCB concentrations only at 500,000 ppq and greater. See 40 C.F.R. § 136.3. Even extremely sensitive analytical methods (which are not approved by EPA to measure NPDES compliance) come nowhere close to reliably measuring 7 ppq—at best, at 1,000 ppq (Method 8082A) or 100 ppq (Method 1668C).

Even if the measurement methods were up to the task, 7 ppq is not achievable. As the City of Spokane explained, "[t]he City does not believe 7 ppq will ever be realistically achieved in the Spokane River or in other water bodies across the State" because "PCBs continue to be introduced into the environment under the Toxic Substances Control Act" at a concentration limit "7 billion times less restrictive than the proposed WQS." Spokane Letter 2 (emphasis added). And in a public presentation to stakeholders, Washington's Department of Ecology has effectively recognized the same: no existing technology can achieve 7 ppq PCBs. Workshop on PCB Variances for Spokane River Dischargers 83 (Nov. 14, 2019), https://www.ezview.wa.gov/Portals/_1962/Documents/SpokaneRiverCleanWater/VarianceWorkshop_All.pdf.

The available empirical evidence confirms the same conclusion. A 2013 study by the Association of Washington Business determined that the "best performing" municipal treatment facility in Washington using a microfiltration membrane could reduce PCBs to an approximate range of between 190 and 630 ppq. EPA-HQ-OW-2015-0174-0380, at 12. When AWB updated the study in 2022, it again concluded that "[t]he lowest levels achieved based on the literature review were ... two orders-of-magnitude greater than the proposed [criterion]" of 7 ppq.

It is unreasonable for Ecology to adopt a water quality standard that it knows is impossible to attain. Setting an unattainable standard misleads the public, leaves the regulated community without any foreseeable route to compliance, and prevents industry and municipalities from undertaking the long-term planning that it essential to responsible operation.

Commentators incorporate by reference comments submitted in response to EPA's 2021 proposed rule. *See* Attachment D at 56-60.

Comment No. 5: Ecology may not finalize an Environmental Justice Assessment or conduct SEPA review without undertaking a cost-benefit analysis and an implementation plan.

Ecology has failed to conduct the requisite cost-benefit analysis required by RCW 34.05.328 (10(d) and (3) of the State APA. A responsible consideration of the rule's costs would reveal a significant burden on the regulated community that is not justified by any corresponding public benefit. This is particularly the case for the PCB criterion that Ecology proposes to adopt as a state standard. Most wastewater treatment plants and receiving waters in Washington exceed the PCB criterion. There is no evidence that any current technology exists that can achieve the EPA PCB criterion. The level of treatment required as a result of this rule is likely to result in substantial new construction of costly wastewater treatment facilities and significant increases in wastewater utility costs and corresponding utility rates and The commentators have previously submitted information on the high cost of treatment to attain the EPA human health criteria, *see, e.g.,* Attachment C, yet neither EPA nor Ecology has quantified and justified the costs of the criteria that Ecology proposes to adopt.

Likewise, neither EPA nor Ecology has provided an implementation plan for the proposed criteria. Ecology cannot reasonably adopt this standard without an implementation plan that allows it to mitigate the cost and impact of additional treatment on burdened communities. Ecology cannot evaluate environmental justice without an assessment of where the necessary treatment facilities would be located and the impact of building new wastewater treatment plants on the affected communities. For example, the criteria Ecology proposes to adopt may limit the ability of wastewater treatment plants to accept additional influent. In that event, communities may not be able to meet their obligations under the Growth Management Act and may face adverse effects on the availability of affordable housing and their ability to address homelessness. It is also probable that advanced treatment will require additional treatment plant footprints, additional energy consumption, and additional use of chemicals. Ecology has not evaluated the potential impact on greenhouse gas emissions or community health from the addition of new treatment facilities.

Ecology is also constrained in conducting review under the State Environmental Policy Act (SEPA) without an implementation plan. The SEPA checklist published with the proposed rule is illusory without an implementation plan. Ecology has no basis for determining the absence of significant environmental and human health impact without some understanding of how it will be implemented and the resulting costs and benefits.

Commentators incorporate by reference comments submitted in response to EPA's 2021 proposed rule. *See* Attachment D at 64-71.

ARCADIS

Northwest Pulp and Paper Association

Summary of Health Risk Assessment Decisions in Environmental Regulations

May 31, 2022

ARCADIS

Summary of Health Risk Assessment Decisions in Environmental Regulations

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Acronyms and Abbreviations

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CWA	Clean Water Act
DBCP	dibromochloropropane
FFDCA	Federal Food, Drug and Cosmetic Act
g/day	grams per day
HHWQC	Human Health Water Quality Criteria
HQ	hazard quotient
LFC	lowest feasible concentration
LoREX	low release and exposure
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg/L	milligrams per liter

mg/yr	milligrams per year
MTCA	Model Toxics Control Act
NCEL	New Chemical Exposure Limit
NIOSH	National Institute of Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PCB	polychlorinated biphenyls
PEL	Permissible Exposure Limit
REL	Recommended Exposure Limit
RfD	reference dose
SDWA	Safe Drinking Water Act
THM	trihalomethane
TSCA	Toxic Substances Control Act
TWA	time weighted average
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration

ARCADIS

Summary of Health Risk Assessment Decisions in Environmental Regulations

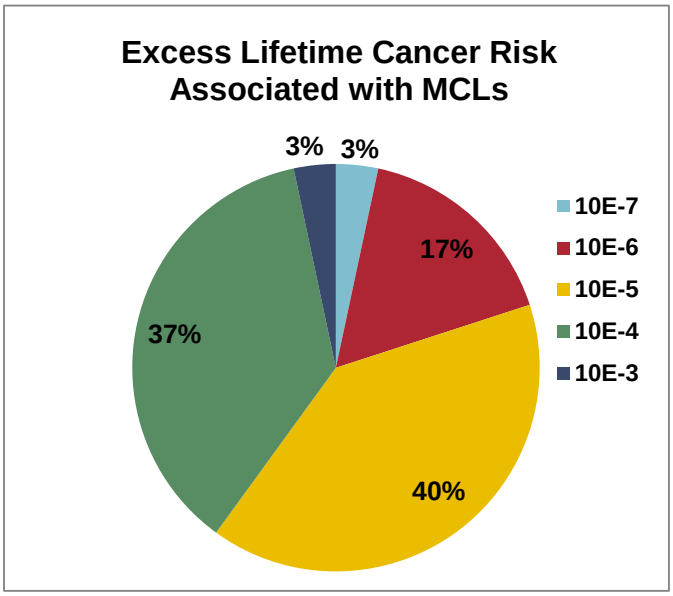
Executive Summary

This white paper provides perspective on how we protect human health through the choices reflected in environmental regulations. Limits on the concentrations of chemicals in the environment reflect a combination of science and policy. Regulators estimate the risks to human health from exposure to chemicals and then decide, as a matter of policy, what level of risk is acceptable. Those decisions are multi-faceted and reflect many smaller choices about both how to apply scientific knowledge and our values as a society. Wise choices must consider such decisions within the broader context of all the sources of risks to our health and the consequences of over-regulation.

Laying the groundwork: risk assessment concepts

Regulators estimate the potential risks to human health from exposure to chemicals in the environment by considering two factors: toxicity and exposure. The amount of a chemical to which people are exposed depends on how much of the chemical is in the air, water, soil, or food. It also depends on the amount of contact that people have with those media. The degree of contact – for example, the amount water that people drink or the amount of fish that people eat – can vary widely between people. Whether assessing the possible risks from environmental exposure or in setting limits on the acceptable concentrations in environmental media, regulators must decide what assumptions to make about the degree of exposure.

The risk of getting cancer from a lifetime of exposure to a carcinogenic chemical is expressed as a probability of developing cancer above and beyond the background risk that already exists, also known as the excess lifetime cancer risk. A $1x10^{-4}$ risk (or 1E-04) is a one in ten thousand chance of getting cancer over and above the background risk assuming a lifetime of exposure; a $1x10^{-6}$ risk (or 1E-06) is a one in a million chance. These risk levels represent the upper bound probability that an individual exposed to the chemical in the environment will develop cancer as a result of that exposure.



Putting risks into perspective

The debate over Human Health Water Quality Criteria (HHWQC) in Washington concerns in part the level of acceptable risk. Washington chose $1x10^{-6}$ as the acceptable risk level for all carcinogenic chemicals

except Polychlorinated biphenyls (PCBs)[1]. USEPA proposes to use the same acceptable risk level ($1x10^{-6}$) and apply it to PCBs as well, even though a cancer risk level of $1x10^{-5}$ is consistent with USEPA's 2000 Methodology (USEPA 2000) and the level Idaho relied on to derive the USEPA approved Idaho HHWQC (USEPA 2019). This white paper discusses three factors that bear on this debate.

1. Acceptable risk from exposure to chemicals in the environment

Various statutes and associated regulations define acceptable risks differently. Standards set under the Occupational Safety and Health Act to protect workers on the job reflect an excess lifetime cancer risk on the order of $1x10^{-3}$. The limits on the concentrations of chemicals in our drinking water at the Maximum Contaminant Levels (MCLs) allowed reflect a range of excess lifetime cancer risks as depicted in the pie chart. Regarding HHWQC, the United States Environmental Protection Agency (USEPA) says this (USEPA 2000):

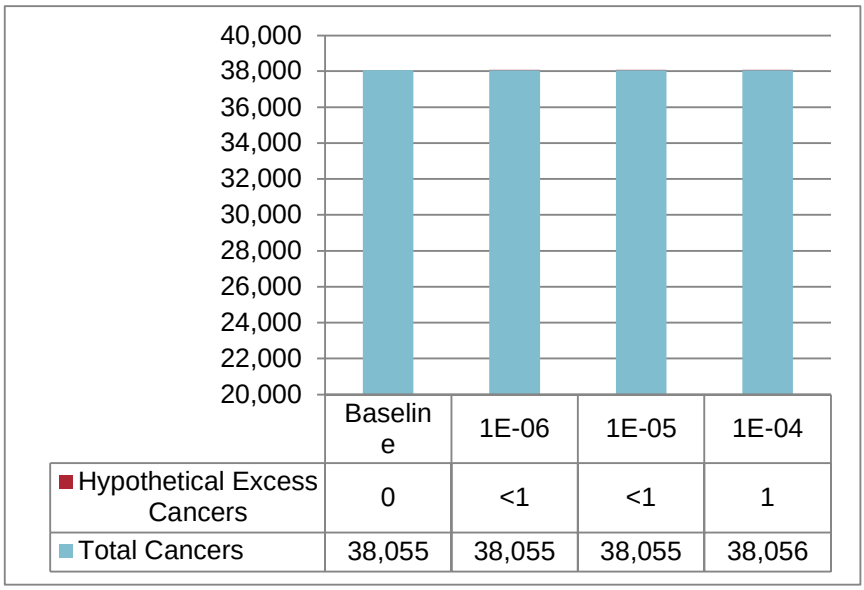
> *EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} level.*

USEPA's decision to consider the tribal populations as the general population (USEPA 2015) coupled with their current proposal to base Washington's HHWCC on 10^{-6}, results in a level of protection that is one hundred times greater than envisioned by USEPA's own guidance.

2. Comparison between risk of cancer from environmental exposure to regulated chemicals and risk of cancer from all causes.

[1] For PCBs, Washington's criteria were based on a chemical-specific cancer risk level of $2.3x10^{-5}$.

The risk of cancer from all causes far outweighs the possible risk of cancer from exposure to chemicals in the environment. The figure to the right shows how these risks translate to an estimated number of cancer occurrences per year in Washington State[2]. Compared to total cancer incidence in Washington, the increase in cancers associated with the excess lifetime cancer risks between $1x10^{-4}$ and $1x10^{-6}$ are far smaller (on the order of a thousandth of percent at an allowable excess lifetime cancer risk of $1x10^{-4}$ or less) than other causes of cancer. This finding is consistent with the comparisons of mortality risk associated with various allowable risk levels to mortality risk from various activities that are part of everyday life, as discussed below.

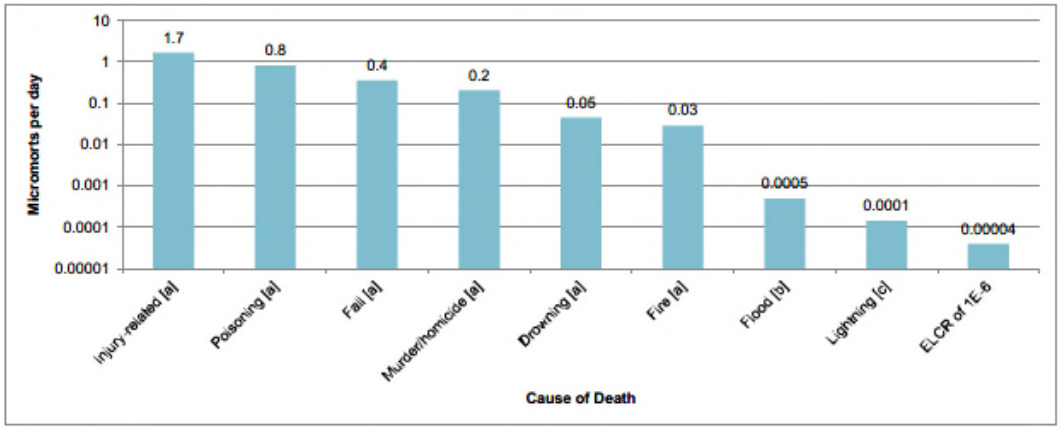


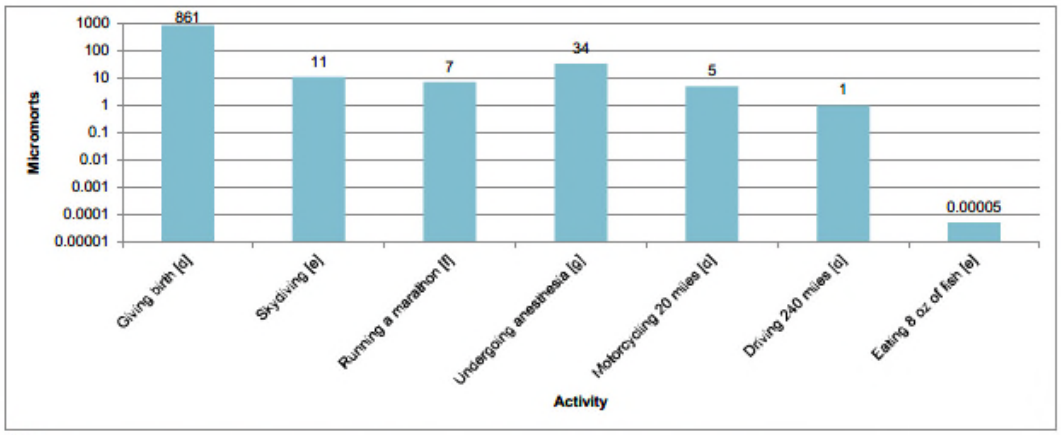
	Baseline	1E-06	1E-05	1E-04
Hypothetical Excess Cancers	0	<1	<1	1
Total Cancers	38,055	38,055	38,055	38,056

3. Comparison between risk of cancer from environmental exposure and everyday risks

We face risks every day. When risk assessors want to be able to compare the relative risks from various activities, they sometimes describe those risks in terms of “micromorts”. A micromort is an activity that typically occurs over time or distance which presents a risk of $1x10^{-6}$ (one in one million). As illustrated below, we routinely accept – whether we realize it or not – risks that far exceed an excess lifetime cancer risk of $1x10^{-4}$ to $1x10^{-6}$. The average American faced an unintentional injury-related mortality risk of approximately 610 micromorts per year in 2020, or 1.7 micromorts per day. In the U.S. population of 329 million people, the unit of 1.3 micromorts per day means that about 559 people die each day from an unintentional injury. This means that every day, every American has a risk of slightly greater than $1x10^{-6}$ of dying from unintentional injury. This every day, accepted risk provides context for discussions about protecting the general population and highly exposed subgroups.

[2] Note that in order to make the hypothetical excess cancers visible on the bar graph, the Y axis was set to start at 20,000 rather than 0.





Notes:

[a] NCHS Vital Statistics System for numbers of deaths. Bureau of Census for population estimates via WISQARS (2020)

[b] NOAA (2020a)

[c] NOAA (2020b)

(d) Hoyert (2020)

(e) United States Parachute Association (2020)

[f] Blastland and Spiegelhalter (2014)

(g) Guohua et al. (2009)

[e] Assuming organism-only AWQC are based on a fish consumption rate of 175 grams per day and risk level of $1x10^{-6}$.

Assumptions underlying risk characterization

Risk assessors must make many assumptions to estimate the possible risks from exposure to chemicals in the environment. These include assumptions about the degree of exposure. Assumptions about the amount of fish Washingtonians eat each day are particularly critical to the discussion about HHWQC though many other assumptions are important as well.

Outdated basis for the fish consumption rate of 175 g/day.

The proposed criteria for carcinogenic and non-carcinogenic chemicals assume that citizens in Washington State, specifically Native Americans, consume 175 grams per day (g/day) of fish. This fish consumption rate was derived from Columbia River Inter-Tribal Fish Commission (CRITFC) fish consumption rate survey (CRITFC 1994) using survey methods that have been shown to not represent the true, long-term fish consumption rate as now defined by USEPA and referred to as the usual fish consumption rate (UFCR) by USEPA (2014A), The State of Washington has reviewed and summarized a range of fish consumption rates developed using both the older survey methods and the newer National Cancer Institute (NCI) methodology (Tooze et al., 2006; Tooze et al., 2010) used by USEPA (2014A) and others to derive UFCRs representative of long-term fish consumption. The NCI method is currently believed to be the state-of-the-art approach for conducting dietary intake surveys, including consumption of fish. Per USEPA (2014A), "*the NCI Method is preferred because it accounts for days without consumption; distinguishes within-person from between-person variation; allows for the correlation between the probability of consumption and the consumption-day amount; and can use covariate data to better predict usual intake*". Idaho considered these survey results in developing its new and revised state HHWQC (Idaho 2016). These more recent estimates derived by the newer NCI methodology show that the fish consumption rate of 175 g/day used in the proposed HHWQC for carcinogenic and non-carcinogenic chemicals is based on an outdated survey methodology that overstates the long-term fish consumption rate of the general population and tribal populations (as shown below) and is no longer an appropriate method to use to derive HHWQC.

Population	Method	50%	Mean	75%	90%	95%	99%
Nez Perce[1]	Food Frequency Questionnaire	70.5	123	---	270	437	796
Nez Perce[1]	NCI	49.5	75.0	---	173	232	---
Shoshone Bannock[1]	Food Frequency Questionnaire	74.6	158	---	392	603	1058
Shoshone Bannock[1]	NCI	14.9	34.9	---	94.5	141	---
General Population[2]	Short-term consumption survey data	37.9	56	78.8	128	168	---
General Population[2]	NCI	12.7	18.8	24.8	43.3	56.6	--=

[1] Polissar et al. (2016).

[2] National Survey: NHANES 2003–2006, Adult Respondents, values as reported in Ecology (2013)

Compounded conservatism

Water quality criteria based on a high-end fish consumption rate (e.g., 175 g/day) and an excess lifetime cancer risk of $1x10^{-6}$ present a risk that is far more protective than the acceptable range as defined by USEPA (2000) for both the general population and highly exposed subpopulations, such as Native Americans. Why? Because conservative assumptions add up. If a decision maker chooses a conservative value for every variable in a risk calculation, the results will be far more protective than intended. Consider the hypothetical example of a risk assessment that is based on three independent and log-normally distributed parameters. In the case of a fish consumption calculation, those parameters might be the amount of fish eaten each day, the source of the fish, and the number of years over the course of a lifetime that people live in a certain place and eat fish from a local source. Each value represents the 95th percentile, or in other words that 9,500 out of 10,000 people have a lower exposure: they eat less fish, do not only eat fish from local waters, or do not eat local fish for their entire life, for example. Combining those three variables would result in a risk estimate that would fall at the 99.78th percentile of the resulting distribution. The risk to 9,978 out of 10,000 people would be lower than the allowable risk level used to establish the standard. So, if $1x10^{-6}$ was selected as the allowable risk level for a criterion based on those assumptions, 9,978 people would have a risk less than $1x10^{-6}$ and only 22 would have a risk greater than $1x10^{-6}$. Decisions made on the basis of this hypothetical calculation, which compounds conservative factors, are far more protective than

intended if the goal was to protect the average member of the population (or the 90th percentile or even the 95th percentile of the population) at the selected allowable risk level. Additionally, USEPA's proposed criteria go beyond the type of compounded conservatism of exposure assumptions described above and designate Native Americans as the general population and then apply acceptable risk levels previously used for the general population to the Native American subpopulation. The effect of this designation is to add an additional level of conservatism such that the general population and high-end consumers such as Native Americans, are protected at levels far greater than required by USEPA guidance cited above (2000).

This may look like an academic calculation. Some readers may think that overestimating risks is a good thing because it allows us to be extra-cautious, and that regulatory decisions based on risk estimates should be as conservative and protective as possible. But the consequences of such choices also need to be considered. There's a cost to reducing the levels of chemicals in the environment to meet more-stringent limits, a cost that may be measured in dollars, energy usage and therefore carbon dioxide (CO2) emissions exacerbating climate change, or the risk of injury to workers who have the job of reducing the levels of those chemicals. Chemicals may be used to treat wastewater to meet lower standards, for example, and the sludge that results has to be trucked to a landfill or incinerated. Generating the power used to operate the wastewater treatment plant uses natural resources and creates air emissions. Each of these aspects of the life cycle of wastewater treatment operations, and their related risks, should be weighed against the value of regulatory decisions based on the combination of several conservative assumptions, referred to as compounded conservatism. In addition, although more difficult to qualify, communicating overestimated risks to the public can lead to unnecessary psychological stress in community members that can contribute to real (as opposed to predicted) adverse human health effects (USEPA 2003).

Compounding conservative values for multiple variables (including a high fish consumption rate, long duration of residence, and upper percentile drinking water rate) to estimate risks with a low target excess lifetime cancer risk will have an unintended consequence. It will result in HHWQC that are far more protective of the vast majority of the population than reflected by the target excess lifetime cancer risk. That additional degree of protection must be weighed against the risks and environmental impacts, as well as increased public utility treatment costs borne by ratepayers and financial implications on private industry, that would result from the additional treatment needed to meet such criteria.

Health Benefits of fish consumption

Risk managers should also consider how the risks incurred from eating fish compare to the benefits gained. Researchers and public health officials have been aware for several decades that consumption of fish has associated with it many benefits (specifically the reduced risk of mortality from coronary heart disease). Recent expert reviews and regulatory agency recommendations continue to urge that people regularly consume fish. In fact, it is recommended that the general population eat 1 to 2 fish meals per week and that

pregnant women eat 2 to 4 meals per week because of the benefits to the infants they are carrying (EFSA 2014). Such benefits almost always outweigh the possible risks of chemical exposure.

1. Risk assessment concepts

This section provides some background information relevant to the topics discussed in this white paper. It begins with a general discussion of how both cancer and non-cancer risks are evaluated by the United States Environmental Protection Agency (USEPA) (Section 1.1). It then puts those risks into perspective by describing what risk assessment conclusions mean with respect to an individual or a larger group of people, and how cancers resulting from exposure to chemicals in the environment, if they occur, compare to the general incidence of cancer (Section 1.2).

1.1 Evaluation of cancer and noncancer health endpoints

Risk generally depends on the following factors (USEPA 2012A):

- Amount of exposure, that depends on:
  - How much of a chemical is present in an environmental medium, such as soil, water, air, or fish;
  - How much contact (exposure) a person has with the environmental medium, containing the chemical; and
  - The toxicity of the chemical.

Scientists consider two types of toxic effects, cancer and noncancer, when they assess the possible risks to human health from exposure to chemicals in the environment. The ways in which most United States regulatory agencies evaluate these risks differ because of one fundamental assumption, that the human body can tolerate some low dose of a chemical that causes harm other than cancer but that no dose of a carcinogen (a chemical that may cause cancer) is entirely safe.

Chemicals that may cause cancer – or, in scientific terminology, those with a carcinogenic endpoint – are, with a very few exceptions, conservatively assumed to have some probability of causing an adverse health effect (cancer) at any dose, by typical regulatory risk assessment practice. There is no safe dose. Thus, *any* exposure to a chemical believed to cause cancer has associated with it a risk.

Scientific Notation
One in a million is the same as…
1 in 1,000,000 or
1/1,000,000, or
0.000001, or
$1x10^{-6}$, or
1E-6, or
0.0001%

Carcinogenic risk is expressed as a probability of developing cancer as a result of a given level of exposure over a lifetime (USEPA 1989) above and beyond the background risk that already exists. This additional risk of getting cancer associated with exposure to chemicals is often referred to as the excess lifetime cancer risk. The excess lifetime cancer risk is usually described in scientific notation. A $1x10^{-4}$ risk (or 1E-04) is a one in ten thousand chance of getting cancer over and above the background risk assuming a lifetime of exposure; a $1x10^{-6}$ risk (or 1E-06) is a one in a million chance. These risk levels represent the upper bound probability that an individual exposed to the chemical in the environment will develop cancer as a result of that exposure. It's important to note that the probability pertains to the risk of getting cancer, not the risk of dying from cancer. These probabilities apply only to people who are exposed to the chemicals under the conditions and to the extent that was assumed in estimating the risk. (Typically, these risk levels correspond to 70 years of exposure and represent the risk over an entire lifetime.) It is also important to recognize that these are upper-bound estimates of risk that depend on numerous assumptions. The actual risks are expected to be lower and may even be zero (USEPA 1986). Public health policy makers must choose some "acceptable" excess lifetime cancer risk (also referred to in this white paper as an allowable risk) when developing limits for chemicals in the environment.

Chemicals that cause non-cancer adverse health effects are assumed to have some threshold dose below which no adverse health effects are expected to occur. In other words, test data show that there is a safe (or allowable) dose. Scientists use the hazard quotient (HQ) to indicate the degree of risk from exposure to a noncarcinogenic chemical:

HQ = (estimated exposure or dose) / (allowable dose).

An HQ of less than or equal to one indicates that the estimated exposure is less than or equal to the allowable dose (referred to by the USEPA as a reference dose or RfD) and that no adverse health effects are expected, even over a lifetime of continuous exposure. In other words, such exposures are considered safe. An HQ of greater than one indicates that estimated exposure is greater than the RfD. An exceedance of the RfD indicates that the potential exists for an adverse health effect to occur. However, because of the multiple conservative assumptions used to estimate exposures and to derive RfDs, an HQ somewhat greater than one is generally not considered to represent a substantial public health threat. The USEPA has offered this perspective (USEPA 1996):

> *Because many reference [doses] incorporate protective assumptions designed to provide a margin of safety, a hazard quotient greater than one does not necessarily suggest a likelihood of adverse effects. A hazard quotient less than one, however, suggests that exposures are likely to be without an*

> *appreciable risk of noncancer effects during a lifetime. Furthermore, the hazard quotient cannot be translated into a probability that an adverse effects [sic] will occur, and is not likely to be proportional to risk. A hazard quotient greater than one can be best described as only indicating that a potential may exist for adverse health effects.*

The United States Department of Health and Human Services (2013) provides further perspective:

> *If the hazard quotient exceeds unity, the toxicant may produce an adverse effect but normally this will require a hazard quotient of several times unity; a hazard quotient of less than one indicates that no adverse effects are likely over a lifetime of exposure.*

In short, while an HQ less than one provides substantial certainty that exposure will not result in a risk, exposure that results in an HQ of somewhat greater than one (even up to several times one) is also unlikely to result in an adverse effect. An HQ of 1.0 was used to derive the proposed HHWQC for non-carcinogenic chemicals.

1.2 Perspective on cancer risks

The excess lifetime cancer risk that may occur as a result of exposure to a carcinogen in the environment, as described above, is the excess risk above and beyond the background risks that we all face. The Center for Disease Control and Prevention provides perspective on background risks. It estimates that in 2018, 1,708,921 new cancer cases were diagnosed in the United States and 599,265 people died of cancer. These numbers include 38,055 new diagnoses and 12,791 deaths in the state of Washington. **Table 1** summarizes the incidence of invasive cancer in the United States and in the state of Washington in 2018.

Table 1 Incidence of Cancer in 2018, from all causes

Geography	Cancer Cases Diagnosed in 2018*	Estimated Population in 2018**	Annual Cancer Incidence Rate
U.S. (national)	1,708,921	326,687,501	$5.3x10^{-3}$
Washington State	38,055	7,523,869	$5.06x10^{-3}$
Washington State (tribal population)	163	174,111	$9.3x10^{-4}$

* Center for Disease Control and Prevention 2018.

** U.S. Census Bureau 2018.

As the data in Table 1 show, a person living in the United States has about a 5/1,000 chance ($5.3x10^{-3}$), *per year*, equal to about a 3.7 in 10 chance (37%) over a 70-year lifetime (5.3 times 70 years divided by 1,000), of being diagnosed with cancer and a member of the tribal population living Washington has about a

9/10,000 chance ($9.3x10^{-4}$), per year, equal to 0.6 in 10 chance (6%) over a 70-year lifetime if being diagnosed with cancer (9.3 times 70 years divided by 10,000). In contrast, many regulatory agencies believe that an "acceptable" excess lifetime cancer risk that should be used to set limits on chemicals in the environment should correspond to a risk of 1/10,000 ($1x10^{-4}$) to 1/1,000,000 ($1x10^{-6}$) over the course of a *lifetime* and a level of $1x10^{-6}$ was selected as the "acceptable" excess lifetime cancer risk for the proposed HHWQC for carcinogens. Based on the current population of 174,111 tribal members in Washington (U.S. Census Bureau 2018), an acceptable cancer risk of $1x10^{-6}$ correlates to 0.17 total cancer in the tribal population over 70 years (USEPA's assumed lifetime). Expressing an increase in predicted lifetime cancer incidence as a fraction of a cancer is a bit unusual given that people either get cancer or don't. We don't get a fraction of a cancer. Another way to express the fraction of a cancer that might occur in Washington's tribal population assuming a $1x10^{-6}$ acceptable risk is the number of years, or generations, it would take for a single cancer to occur in the tribal population. At the current tribal population size, it would take 402 years for a single excess cancer to occur as a result of exposure to a substance given USEPA's proposed HHWQC. Assuming each generation is 70 years, it would take 5.7 generations before a single cancer would be expected in the tribal population at an acceptable risk level of $1x10^{-6}$. In that same time period, given the current cancer rates in the tribal population summarized above (Table 1), about 65,000 cancers would have occurred from other causes. The single excess cancer is immeasurable when compared to the background incidence of cancers.

Table 2 shows how the annual risk of cancer from all causes, based on the 2018 data shown in Table 1, compares to the annual cancer risk that would result from exposure to compounds in the environment that met environmental standards based on a lifetime cancer risk of $1x10^{-4}$ to $1x10^{-6}$. The cancer risk from exposures to environmental pollutants at or below their environmental standards is a tiny fraction (0.028% to 0.00028%) of the background cancer risk we all face. Further, in proposing to consider tribal populations as the general population and recommending a cancer risk level of $1x10^{-6}$ rather than $1x10^{-4}$ when deriving the HHWQC, the effect is that the true general population has a risk of between $1x10^{-7}$ and $1x10^{-8}$. Therefore, the annual risk of cancer associated with environmental pollutants is even lower than what is presented below in Table 1.

Table 2 Incidence of Cancer in 2018 Compared to Acceptable Risk under Environmental Regulations

Geography	Annual Cancer Incidence Rate based on 2018 Data	Annual Risk of Cancer associated with Lifetime Excess Lifetime Cancer Risk $1x10^{-4}$	Annual Risk of Cancer associated with Lifetime Excess Lifetime Cancer Risk $1x10^{-6}$
United States (national)	$5.2x10^{-3}$ (0.52%)	$1.4x10^{-6}$ (0.00014%)	$1.4x10^{-8}$ (0.0000014%)
Washington State	$5.1x10^{-3}$ (0.51%)	$1.4x10^{-6}$ (0.00014%)	$1.4x10^{-8}$ (0.0000014%)

2. Risk assessment choices in federal regulatory programs

We've been assessing the risks from exposure to chemicals in the United States for just over half a century. In 1958, scientists knew of just four human carcinogens; by 1978, they knew of 37 human carcinogens and over 500 animal carcinogens (Wilson 1978). The National Toxicology Program (NTP) currently lists 256 agents, substances, mixtures, and exposure circumstances that *are* known or reasonably anticipated *to* cause cancer in humans (NTP 2021). Environmental legislation that developed in the United States in parallel to the study of what could cause cancer reflected both our scientific understanding of the hazards of chemical exposure and the socioeconomic factors of the times. Much of the legislation requiring assessment of risks of exposure to chemicals in the environment originated between 1972 and 1980[3].

This perspective is important when considering the risk assessment choices expressed in federal regulatory programs. Congress and regulators had to articulate their thinking about risk and what levels of risk were acceptable over a relatively short period of time. We had little time to test and debate ideas, as a society, about how what levels of risk are acceptable to us. It is useful, then, to take the "big picture" view of acceptable risk as we discuss risk-based water quality criteria in Washington State.

Various federal laws and regulations define 'acceptable risk' in different ways. These definitions typically fall into one or more of the general categories shown in **Table 3** (Schroeder 1990).

Table 3 Ways of Reflecting Risk Considerations in Environmental Laws

Type of standard	Variation	Premise
Health based standards	Zero risk	Risk should be reduced to zero or to some other level that is acceptable to society
	Significant risk	
Balancing standards	Cost-benefit	Possible risks must be balanced against the economic benefits of using a chemical or the costs of controlling risks
Technology based standards	Feasibility analysis	Limits are set based on the levels achievable by the best available treatment technology that the regulated industry can afford to install.

[3] Includes: Clean Water Act (1972), Clean Air Act (1972), Safe Drinking Water Act (1974), Resource Conservation and Recovery Act (1976), Comprehensive Environmental Response, Compensation, and Liability Act (1980).

As a result of the different ways of thinking about acceptable risk and the factors that must be taken into account when regulating exposure to chemicals, regulators have defined goals for limiting cancer risks in different ways in various regulatory programs. **Table 4** summarizes benchmark criteria. Those criteria and some of the striking differences between programs are described below.

Table 4 Benchmarks for "Acceptable" Risk

Law / Regulation	Focus	Risk Standard	Criterion for Carcinogens
Clean Water Act	Surface water	Adverse health impacts	$1x10^{-4}$ to $1x10^{-6}$
Safe Drinking Water Act	Public drinking water	Any adverse effect	Goal: 0 Enforceable standard: $1x10^{-4}$ to $1x10^{-7}$
Toxic Substances Control Act	Chemicals manufactured or imported into the United States	Unreasonable risk	$1x10^{-4}$ (inferred, absent clear policy)
Occupational Safety and Health Act	Worker protection	Significant risk over 45-year working life	$1x10^{-3}$
Comprehensive Environmental Response, Compensation, and Liability Act, or Superfund	Uncontrolled hazardous waste sites	No significant risk	$1x10^{-4}$ to $1x10^{-6}$

2.1 The beginning of "minimal risk" discussions: the Delaney Clause

Delaney Clause – 1958
- Health based standards ✓
- Balancing standards
- Technology based standards

The debate over what level of exposure to a carcinogen could be considered safe began in the United States when people became concerned about pesticide residues in processed foods. This debate produced the 1958 Food Additives Amendment (section 409) to the 1954 Federal Food, Drug and Cosmetic Act (FFDCA), which said:

> *…no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal…*

This "zero risk" clause, named for Congressman James Delaney, was a landmark decision in the regulation of compounds that might cause cancer. The Delaney Clause sounds simple enough, but soon ran into practical limitations: How low of a dose do we need to test to assure ourselves that a chemical does not

cause cancer? And how, given the limits of analytical chemistry, do we know when a chemical that can induce cancer is present in a food product?

The United States Food and Drug Administration (USFDA) faced this challenge in regulations proposed in 1973 (USFDA 1973), saying:

> *If the results of the test for carcinogenicity establish that the compound or its metabolites will induce cancer in test animals, the required sensitivity of the regulatory assay method will be determined based on the Mantel-Bryan procedure ….*
>
> *Absolute safety can never be conclusively demonstrated experimentally. The level defined by the Mantel-Bryan procedure is an arbitrary but conservative level of maximum exposure resulting in a minimal probability of risk to an individual (e.g., 1/100,000,000), under those exposure conditions of the basic animal studies.*

In describing the benchmark (1/100,000,000 or 10^{-8}) provided as an example of minimal probability of risk to an individual, the USFDA cited a groundbreaking paper by Mantel and Bryan (1961) that said:

> *We may, for example, assume that a risk of 1/100 million is so low as to constitute "virtual safety." Other arbitrary definitions of "virtual safety" may be employed as conditions require.*

Many of the comments on the regulation proposed in 1973 pertained to how the proposed regulation dealt with the risk of cancer and the 1/100,000,000 benchmark. After considering those comments the USFDA promulgated a final regulation in 1977. In doing so it re-defined the benchmark risk level. The preamble to the final rule explains that tests for carcinogens must be able to measure the concentration corresponding to the 1/1,000,000 (or 10^{-6}) risk level, which the USFDA described as an "insignificant public health concern". (USFDA 1977)

In this rulemaking, the USFDA was careful to point out that it was not making an explicit judgment on an acceptable level of risk, simply seeking to set a practical benchmark that could be used to design animal experiments:

> *[10^{-6}] does not represent a level of residues "approved" for introduction into the human diet. The purpose of these regulations is to establish criteria for the evaluation of assays for the measurement of carcinogenic animal drugs. These criteria must include some lowest level of reliable measurement that an assay is required to meet. In defining a level of potential residues that can be considered "safe", therefore, the Commissioner is establishing a criterion of assay measurement that, if it can be met for a compound, will ensure that any undetected residues resulting from the compound's use will not increase the risk of human cancer.*

Despite this caution, many people took this regulatory action as a precedent for defining an "acceptable" level of risk as $1x10^{-6}$. In fact, the Delaney Clause was replaced in 1996 by legislation that specifies 10^{-6} as an acceptable level of risk[4] (Moran 1977).

2.2 Clean Water Act

Under the Clean Water Act (CWA), States and authorized Native American tribes set water quality standards for the surface water bodies under their jurisdiction. A water quality standard has two parts: the designated uses of a body of water, and the criteria (or concentration limits for specific chemical compounds) necessary to protect those uses. The USEPA develops Human Health Water Quality Criteria (HHWQC) that States and Native American tribes can use to set those concentration limits (USEPA 2000). In general (USEPA 2000),

CWA – 1972	
Health based standards	ü
Balancing standards	
Technology based standards	

> *Water quality criteria are derived to establish ambient concentrations of pollutants which, if not exceeded, will protect the general population from adverse health impacts from those pollutants due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities.*

For compounds that may cause cancer in people exposed to surface water, those criteria must correspond to some level of risk that is thought to be acceptable.

The USEPA's 1980 HHWQC National Guidelines simply represented a range of risks. In other words, the guidance presented a range of chemical concentrations corresponding to incremental cancer risks of 10^{-7} to 10^{-5}. Revised guidelines published in 2000 corresponded to the 10^{-6} risk level, with this explanation (USEPA 2000):

> *With [HHWQC] derived for carcinogens based on a linear low-dose extrapolation, the Agency will publish recommended criteria values at a 10^{-6} risk level. States and authorized Tribes can always*

[4] The Delaney Clause is no longer in effect. The Food Quality Protection Act of 1996 changed the standard for the residues of carcinogens in foods from the "zero risk" criterion implicit in the Delaney Clause to a standard of "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." The law allows for chemical residues if the risk of causing cancer in less than one-in-a-million people over the course of a typical life-span. The USEPA must consider the benefits of pesticides in supporting an adequate, wholesome, and economical food supply in determining an acceptable level of risk.

> *choose a more stringent risk level, such as 10^{-7}. EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10^{-4} level.*

The Agency elaborated on this policy with respect to more highly exposed people, saying:

> *EPA understands that highly exposed populations may be widely distributed geographically throughout a given State or Tribal area. EPA recommends that priority be given to identifying and adequately protecting the most highly exposed population. Thus, if the State or Tribe determines that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, and by the national … criteria in particular, EPA recommends that the State or Tribe adopt more stringent criteria using alternative exposure assumptions….*
>
> *EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen.*
>
> *…changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are relative, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6}, those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level).*[5]

[5] In 2014, USEPA updated the default fish consumption rate to 22 g/day which represents the 90th percentile consumption rate of fish and shellfish from inland and nearshore waters for the U.S. adult population 21 years of age and older, based on NHANES data from 2003 to 2010 (USEPA 2014). This change does not impact the meaning of this statement.

In other words, the USEPA generally sets HHWQC at the 10^{-5} to 10^{-6} risk level, but allows states and tribes flexibility in setting enforceable criteria. In regions where some groups may eat more fish than is typical and by doing so perhaps increase their exposure to chemicals in fish, the Agency advises that the criterion set for the general population should not result in a risk to those who eat more fish that is greater than 10^{-4}. USEPA's proposal to set HHWQC at the 10^{-6} risk level for tribal populations who may eat more fish than is typical for the general population is not consistent with USEPA policy. The general population with more typical consumption rates is effectively being protected at a level lower (i.e., more stringent) than what was intended by the CWA. As discussed earlier, there are costs and consequences that must also be considered when setting substantially more stringent standards then intended or required by statute or EPA policy.

USEPA concluded that Washington's state-adopted HHWQC for PCBs does not meet the requirements of the CWA. The HHWQC for PCBs was derived using the fish ingestion rate of 175 g/day and corresponds to a cancer risk level of $2.3x10^{-5}$. When the state-adopted HHWQC for PCBs is combined with a higher ingestion rate of 797 g/day (the amount eaten by members of the Suquamish tribe at the 95th percentile, who eat the largest amounts of fish of all the people in Washington State (Washington State Department of Ecology 2013), the resulting risk is $1x10^{-4}$ (calculated as 797 x 2.3E-5 / 175). Therefore, even the most highly exposed populations would be protected in a manner consistent with the CWA. USEPA is incorrect in its conclusion that Washington's state-adopted HHWQC for PCBs does not meet the requirements of the CWA.

2.3 Safe Drinking Water Act

The USEPA sets two kinds of criteria for chemicals in public water supplies, Maximum Contaminant Level Goals (MCLGs) and Maximum Contaminant Levels (MCLs). Here's how the Agency describes the process of determining those criteria (USEPA 2013A):

> *If there is evidence that a chemical may cause cancer, and there is no dose below which the chemical is considered safe, the MCLG is set at zero. If a chemical is carcinogenic and a safe dose can be determined, the MCLG is set at a level above zero that is safe….*
>
> *Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is a Maximum Contaminant Level (MCL), the maximum permissible level of a contaminant in water which is delivered to any user of a public water system. …The MCL is set as close to the MCLG as feasible….. EPA may adjust the MCL for a particular class or group of systems to a level that maximizes health risk reduction benefits at a cost that is justified by the benefits.*

The USEPA also determines non-enforceable Drinking Water Specific Risk Level Concentrations. It has described the Drinking Water Specific Risk Level Concentration as being based on the $1x10^{-4}$ excess lifetime cancer risk (USEPA 2012B). In some cases, as illustrated in **Table 5**, adjustments to the MCL have resulted in a concentration limit that corresponds to a higher risk. In other cases, the MCL for a chemical is lower than the concentration corresponding to the 10^{-4} risk level and therefore represents a lower risk level.

SDWA – 1972	
Health based standards	ü
Balancing standards	ü
Technology based standards	ü

Table 5 Comparison of Drinking Water MCLs and Cancer Risk Levels for Potential Carcinogens

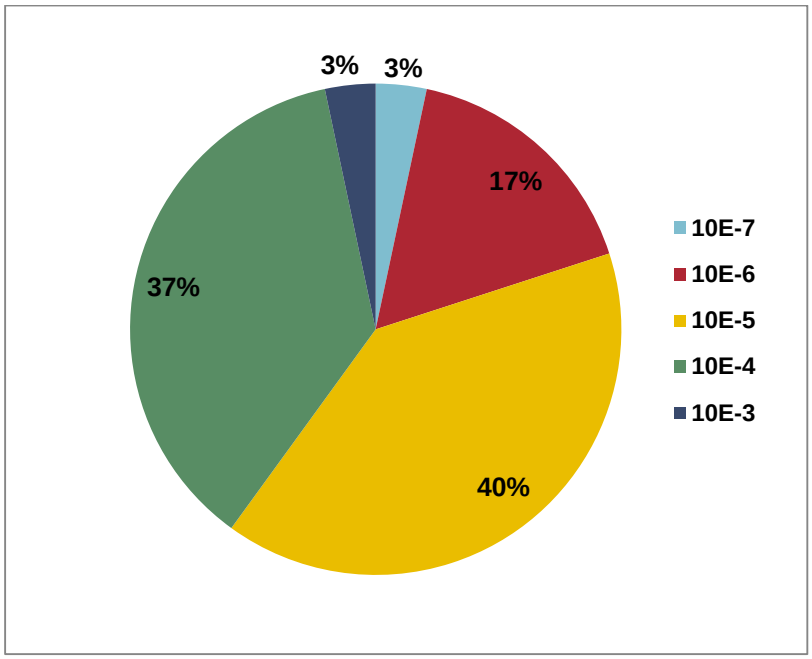
Compound	MCL* (mg/L)	Concentration (mg/L) at 10^{-4} Cancer Risk*	Approximate Risk Level of MCL
Alachlor	0.002	0.04	$5x10^{-6}$
Arsenic	0.01	0.002	$5x10^{-4}$
Benzene	0.005	1 to 10	$5x10^{-7}$ to $5x10^{-6}$
Benzo(a)pyrene	0.0002	0.0005	$4x10^{-5}$
Bromodichloromethane (THM**)	0.081	0.1	$8x10^{-5}$
Bromate	0.01	0.005	$2x10^{-4}$
Bromoform (THM**)	0.081	0.8	10^{-5}
Carbon tetrachloride	0.005	0.05	10^{-5}
Chlordane	0.002	0.01	$2x10^{-5}$
Di(2-ethylhexyl)adipate	0.4	3	10^{-5}
Di(2-ethylhexyl)phthalate	0.006	0.3	$2x10^{-6}$
Dibromochloromethane (THM**)	0.082	0.08	10^{-4}
Dibromochloropropane (DBCP)	0.0002	0.003	$7x10^{-6}$
Dichloroacetic acid+	0.063	0.07	10^{-4}
Dichloroethane (1,2-)	0.005	0.04	10^{-5}
Dichloroethylene (1,1-)	0.007	0.006	10^{-4}
Dichloromethane	0.005	0.5	10^{-6}
Dichloropropane (1,2-)	0.005	0.06	10^{-5}
Epichlorohydrin	TT++	0.3	$7x10^{-7}$
Ethylene dibromide	0.00005	0.002	$2.5x10^{-6}$
Heptachlor	0.0004	0.0008	$5x10^{-5}$
Heptachlor epoxide	0.0002	0.0004	$5x10^{-5}$
Hexachlorobenzene	0.001	0.002	$5x10^{-5}$
Pentachlorophenol	0.001	0.009	10^{-5}
Polychlorinated biphenyls (PCBs)	0.005	0.01	$5x10^{-5}$

Compound	MCL* (mg/L)	Concentration (mg/L) at 10^{-4} Cancer Risk*	Approximate Risk Level of MCL
2,3,7,8-TCDD (dioxin)	$3x10^{-8}$	$2x10^{-8}$	10^{-4}
Toxaphene	0.003	0.003	10^{-4}
Trichloroethane (1,1,2-)	0.005	0.06	$8x10^{-6}$
Trichloroethylene	0.005	0.3	10^{-6}
Vinyl chloride	0.002	0.002	10^{-4}

* USEPA 2018.
** Total trihalomethane (THM) concentration should not exceed 0.08 mg/L.
+ The total for five haloacetic acids is 0.063.
++ When epichlorohydrin is used in drinking water systems, the combination (or product) of dose and monomer level shall not exceed that equivalent to an epichlorohydrin-based polymer containing 0.01% monomer dosed at 20 mg/L. (0.01/100 * 20 mg/L = 0.002 mg/L)

As these examples show and as illustrated in **Figure 1**, the excess lifetime cancer risks associated with a single drinking water contaminant present in a water supply at its MCL may fall within a range of several orders of magnitude. Thirty-seven percent of MCLs correspond to an estimated lifetime risk of $1x10^{-4}$ to $1x10^{-3}$; 40% of MCLs represent a potential risk of cancer after a lifetime of exposure of $1x10^{-5}$ to $1x10^{-4}$. While the USEPA may consider the benchmark excess lifetime cancer risk of 10^{-4} in setting a standard, the requirement to set the MCL as close to the MCLG as feasible or to adjust the MCL to a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits" may result in a MCL that represents a very different risk level for that compound. And the combined risks of exposure to multiple chemicals, if they are present in the water supply, may increase the potential risk further.

Figure 1 Approximate Risk Levels associated with MCLs in Drinking Water



2.4 Occupational Safety and Health Act

The United States Occupational Safety and Health Administration (OSHA) develops standards to protect workers under the Occupational Safety and Health Act of 1970. OSHA first promulgated standards in 1974 to regulate the industrial use of 13 chemicals identified as potential occupational carcinogens. Those standards did not set limits on exposure, simply mandated the use of engineering controls, work practices, and personal protective equipment to limit exposure.

OSHA has since promulgated standards for certain carcinogens, including the regulations at 1910 Subpart Z, Toxic and Hazardous Substances. Those standards reflect a landmark decision by the Supreme Court known as the “Benzene Decision”, more formally known as *Industrial Union Department v. American Petroleum Institute, 448 U.S. 607*, in 1980, At issue was whether setting worker protection standards for carcinogens such as benzene at the lowest technologically feasible level that would not impair the viability of the industries regulated conformed to the statutory requirement that such standards be "reasonably necessary or appropriate to provide safe and healthful employment". The decision read, in part,

> *… "safe" is not the equivalent of "risk-free." A workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm…. [T]he requirement that a "significant" risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first*

> *instance, what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as "unsafe."*

The Supreme Court essentially stated that a risk of fatality of 1×10^{-3} in an occupational setting was unacceptable. OSHA applied this benchmark to excess lifetime cancer risk. (Again, it is worth noting that not all cancers are fatal: an excess lifetime cancer risk of 1×10^{-3} corresponds to a far lower risk of cancer-related death.) For example, when OSHA set the Permissible Exposure Limit (PEL) for methylene chloride as a time weighted average (TWA) concentration, it offered an explanation that indicated how it thought about acceptable risk and acknowledged the level of risk associated with the standard being replaced (OSHA 1997):

> *OSHA's final estimate of excess cancer risks at the current PEL of 500 [parts per million] ppm (8-hour TWA) is 126 per 1000. The risk at the new PEL of 25 ppm is 3.62 per 1000. The risk at 25 ppm is similar to the risk estimated in OSHA's preliminary quantitative risk assessment based on applied dose of [methylene chloride] on a mg/kg/day basis (2.3 per 1000 workers) and clearly supports a PEL of 25 ppm. Risks greater than or equal to 10(-3) are clearly significant and the Agency deems them unacceptably high. However, OSHA did not collect the data necessary to document the feasibility of a PEL below 25 ppm across all affected industry sectors, and so the Agency has set the PEL at 25 ppm in the final rule.*
>
> *Further guidance for the Agency in evaluating significant risk and narrowing the million-fold range provided in the "Benzene decision" is provided by an examination of occupational risk rates, legislative intent, and the academic literature on "acceptable risk" issues. For example, in the high risk occupations of mining and quarrying, the average risk of death from an occupational injury or an acute occupationally-related illness over a lifetime of employment (45 years) is 15.1 per 1,000 workers. The typical occupational risk of deaths for all manufacturing industries is 1.98 per 1,000. Typical lifetime occupational risk of death in an occupation of relatively low risk, like retail trade, is 0.82 per 1,000. (These rates are averages derived from 1984-1986 Bureau of Labor Statistics data for employers with 11 or more employees, adjusted to 45 years of employment, for 50 weeks per year).*

The National Institute of Occupational Safety and Health, or NIOSH, is the research and development counterpart to OSHA. Part of the organization's mission is to develop recommendations for health and

safety standards. Their work provides guidance on limits for occupational exposures that supplements and informs OSHA rulemaking.

In 1976, NIOSH published its first guidelines on carcinogens in the workplace. Those guidelines called for "no detectable exposure levels for proven carcinogenic substances" (NIOSH 2016). NIOSH set Recommended Exposure Limits (RELs) for most carcinogens at the "lowest feasible concentration (LFC)." In 1995, NIOSH revised its policy (NIOSH 2010):

> *NIOSH recommended exposure limits (RELs) will be based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques. To the extent feasible, NIOSH will project not only a no-effect exposure, but also exposure levels at which there may be residual risks.*
>
> *The effect of this new policy will be the development, whenever possible, of quantitative RELs that are based on human and/or animal data, as well as on the consideration of technological feasibility for controlling workplace exposures to the REL.*

The 1995 NIOSH policy recommended exposure limits for potentially carcinogenic chemicals at concentrations corresponding to an excess risk of 1 in 1,000 workers exposed to the substance for a 45-year working lifetime (NIOSH 1995). Both the 2011 Current Intelligence Bulletin for titanium dioxide and the 2013 Criteria Document for hexavalent chromium compounds used 1 in 1,000 as the risk level for carcinogenic effects in setting RELs [NIOSH 2011, 2013].

In 2016, NIOSH issued another new carcinogen policy. In a document titled *NIOSH Current Intelligence Bulletin 68: NIOSH Chemical Carcinogen Policy* (NIOSH 2016), NIOSH states that they will no longer use the term REL for occupational carcinogens and instead will use the term “risk management limit for carcinogen” (RML-CA) to acknowledge there is no safe exposure. NIOSH 2016 further states the following:

> *NIOSH will set the RML-CA for an occupational carcinogen at the estimated 95% lower confidence limit on the concentration (e.g., dose) corresponding to 1 in 10,000 (10-4) excess lifetime risk, when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10-3). This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess*

> *risks greater than 10-4. will set the RML-CA for an occupational carcinogen at the estimated 95% lower confidence limit on the concentration (e.g., dose) corresponding to 1 in 10,000 (10-4) excess lifetime risk, when analytically possible to measure.*

In summary, the levels of risk considered to be acceptable for workers have varied over time at OSHA and at NIOSH. In the latest evolution of policy, an excess risk of 1/10,000 ($1x10^{-4}$) over a working lifetime of 45 years of exposure has been adopted as the basis for workplace standards, although some standards, former and current, have exceeded that limit. By comparison to the other definitions of acceptable risk described in this white paper, this risk equates to an annual risk of $2x10^{-6}$ or an excess lifetime cancer risk (70 years) of approximately $2x10^{-4}$.

2.5 Toxic Substances Control Act

The Toxic Substances Control Act, abbreviated TSCA, regulates most chemical substances manufactured or imported into the United States. Under this law the USEPA can require reporting, record-keeping and testing of chemical substances, and may impose restrictions on their manufacture or use. The law defines the conditions under which the USEPA can take action. If an "unreasonable risk of injury to health or the environment" from a chemical substance has been proven, for example, the Agency can require risk-abatement action such as labeling chemical substances, regulating uses, restrictions on disposal, and prohibiting or limiting manufacture. But neither the law nor the regulations that implement the law define "unreasonable risk" clearly.

The USEPA has not published explicit guidance on how it reaches a finding of "unreasonable risk" but has described it generally as follows (USEPA 2013B):

> *EPA's determination that manufacture, processing, use, distribution in commerce, or disposal of an individual substance which has been the subject of a notice under section 5 of the TSCA may present an unreasonable risk of injury to human health or the environment is based on consideration of (i) the size of the risks identified by EPA; (ii) limitations on risk that would result from specific safeguards (generally, exposure and release controls) sought based on Agency review and (iii) the benefits to industry and the public expected to be provided by new chemical substances intended to be manufactured after Agency review. In considering risk, EPA considers factors including environmental effects, distribution, and fate of the chemical substance in the environment, disposal methods, waste water treatment, use of protective equipment and engineering controls, use patterns, and market potential of the chemical substance.*

TSCA – 1976	
Health based standards	✓
Balancing standards	✓
Technology based standards	✓

What does this mean with respect to the acceptable level of cancer risk for workers manufacturing a new chemical or consumers who might be exposed to it? The USEPA has not published a clear statement on acceptable risk under TSCA, but the cases described below shed some light on the question[6]. The first is a publication by an Agency official early in the TSCA program regarding the determination of acceptable risks under TSCA, and the second, the USEPA's explanation of how it derives limits for worker exposure to new chemicals under TSCA.

In 1983, a USEPA official indicated that the objective is to reduce risks to an "insignificant" level but that the USEPA did "not employ any predetermined statistical risk level since this will vary depending on a variety of factors." (Todhunter 1983). In other words, at that time "unreasonable risk" did not correspond to a benchmark level or range (such as 10^{-4} to 10^{-6}). The USEPA has not apparently published anything since that time to suggest that a benchmark level exists under TSCA, with one exception.

The Agency sometimes sets New Chemical Exposure Limits (NCELs) for new chemicals regulated under TSCA. An NCEL is the concentration that a worker who makes or uses a chemical can be exposed to safely. To derive an NCEL for a potential carcinogen, the USEPA reportedly begins with the policy that a cancer risk of 10^{-4} is acceptable (USEPA 1995). But in some cases the Agency finds that the calculated NCEL may be difficult to attain or monitor. In such cases the risks to workers may be higher than 10^{-4} (Sellers 2015).

2.6 Superfund

CERCLA/ SARA – 1980 / 1986	
Health based standards	✓
Balancing standards	
Technology based standards	

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as Superfund, defines the significant risks at uncontrolled hazardous waste sites that must be cleaned up. The regulations at 40 CFR 300.430(e)(2)(i)(A) specify that remediation goals shall consider the following:

> *For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6}*

[6] This discussion is adapted from: Sellers, K., 2015. *Product Stewardship, Life Cycle Analysis, and the Environment*. (Taylor & Francis/ CRC Press)

using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals ….

2.7 Inconsistent results

The different benchmarks for acceptable risks have led to some striking inconsistencies in the ways in which some chemicals are regulated in the United States. Consider the example below, which contrasts risk management decisions under TSCA and the Safe Drinking Water Act (SDWA).

While the USEPA has not published a direct statement under TSCA on what level of risk is acceptable, it is interesting to compare risk-related benchmarks under TSCA to those under the SDWA[7].

When the exposure to a new chemical will be quite limited – or more specifically 'low release and exposure' (LoREX) – the manufacturer or importer can be exempt from TSCA regulations. Regulations at 40 CFR 723.50(2) specify the criteria for the LoREX exemption. They include the case where no exposure in drinking water would exceed a 1 milligram per year (mg/yr) estimated average dosage. While this exemption does not define serious human health effects or significant environmental effects to a degree that helps to explain the concept of "unacceptable risk" under TSCA, it does provide a point of reference: the risks from exposure to any compound at 1 mg/yr in drinking water are anticipated to be acceptable.

The USEPA has also considered the possible risk from chemicals in drinking water under the SDWA. A risk assessor working under USEPA guidelines has typically assumed that an adult drinks 2.4 liters of water per day (USEPA 2014B). An adult drinking 2 liters of water per day for an entire year could drink water containing up to 0.0014 milligrams per liter (mg/L) of a chemical before reaching the LoREX criterion of 1 mg/yr of exposure:

2 liters water / day * 365 days/year * 1 year * 0.0014 milligrams / liter * = 1 mg/yr

The MCLs for 10 chemical (nonradionuclide) substances are below 0.0014 mg/L (USEPA 2013C). Put another way, for 13% of the chemicals regulated under the SDWA (that is, 10/76) the USEPA has found that exposure to 1 mg/yr in drinking water – which is considered to be a negligible exposure under the TSCA New Chemicals program – was acceptable. If such chemicals were brought onto the market now, they could be exempted from regulation under TSCA.

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[7] This discussion is adapted from: Sellers, K., 2015. *Product Stewardship, Life Cycle Analysis, and the Environment*. (Taylor & Francis/ CRC Press)

2.8 Summary

The level of risk considered to be acceptable varies widely between different federal regulatory programs. The risks we experience at work or by drinking from a public water supply can be on the order of $1x10^{-4}$ or even higher. Under other programs, such as the cleanup of hazardous waste sites, a risk level of $1x10^{-6}$ is the point of departure for determining the goals for cleanup, though as long as excess lifetime cancer risk is equal to or less than $1x10^{-4}$ a site generally does not require cleanup. Perhaps most relevant to this discussion are the risk goals set under the Clean Water Act. Federal water quality criteria are typically based on a risk of $1x10^{-6}$; the USEPA has noted that criteria based on a 1/100,000 risk are acceptable for the general population as long as groups of people who may be more highly exposed (such as subsistence anglers) would encounter a risk less than or equal to $1x10^{-4}$. USEPA's proposal to set HHWQC at the 10^{-6} risk level for more highly exposed tribal populations is not consistent with USEPA policy.

3. Estimating risks: importance of underlying assumptions

The preceding paragraphs described the variation in one important assumption, the level of acceptable risk. That value may vary from 10^{-7} to more than 10^{-3}, depending upon the regulatory program and the context of the decision. Risk assessors must make other assumptions to estimate the possible risks from exposure to chemicals in the environment. These include assumptions about the degree of exposure. To illustrate the range of assumptions that can be factored into calculations of risks, Section 3.1 describes fish consumption estimates. Section 3.2 describes the effects of compounding a series of assumptions, if the assessor selects the most conservative value for each.

3.1 A closer look at one critical assumption: fish consumption

Calculations of the risk from eating fish containing chemicals in the environment typically reflect a simple assumption about the amount of fish eaten by each person per day or per year. But such values represent some complicated variables. Different people eat different amounts of fish. Those fish may come from different places, some very far from the area being considered in the risk assessment. The ways in which fish are cooked can decrease the amount of chemicals in the fish. The assumptions that are made to account for these variables and simplify the calculations can have a big effect on the calculated risk.

95th Percentile Values

The 95th percentile value for a variable like fish consumption means that 95 out of 100 people eat less fish than that amount.

The amount of fish a person eats every day depends in part on geographic region, age, gender, and body size (USEPA 2021), as well as cultural or taste preferences. Estimates of fish consumption can also vary based on the way in which the fish consumption rate is estimated. While a detailed discussion of all of those factors and their effect on estimated fish consumption rates is beyond the scope of this white paper, it is crucial to recognize that in that last 10 years USEPA (USEPA 2014A), Washington (Ecology 2013), Idaho

(2019) and others have determined that methods used to estimate fish consumption rates prior to about 2010, are not appropriate to estimate long-term fish consumption rates (USEPA (2014A) refers to fish consumption rates representative of long-term behavior as "Usual Fish Consumption Rates" (UFCRs).

The USEPA 2011 Exposure Factors Handbook (USEPA, 2011, p. 10–16) qualified the older fish dietary estimates as follows:

> *…it should be noted that the distribution of average daily intake rates generated using short-term data (e.g., 2-day) does not necessarily reflect the long-term distribution of average daily intake rates. The distributions generated from short-term and long-term data will differ to the extent that each individual's intake varies from day to day…..*
>
> *…Short-term consumption data may not accurately reflect long-term eating patterns and may under-represent infrequent consumers of a given fish species. This is particularly true for the tails (extremes) of the distribution of food intake.*

Usual fish consumption rates are derived using the National Cancer Institute (NCI) method (see Table 6) and per USEPA (2014A) "*the NCI Method is preferred because it accounts for days without consumption; distinguishes within-person from between-person variation; allows for the correlation between the probability of consumption and the consumption-day amount; and can use covariate data to better predict usual intake.* Fish consumption rates estimated using the older methods, such as the 175 g/day rate used in the current and proposed HHWQC, overstate long-term fish consumption and are no longer recommended or used by USEPA. USEPA (2014A) outlines how newer NCI statistical and dietary survey methodologies can be used to derive more credible usual fish consumption rates; however, they are ignoring their own guidance in selecting the fish consumption rate of 175 g/day for the derivation of the proposal HHWQC.

As shown in the table below when the NHANES fish dietary data for the national general population were reevaluated using the newer NCI statistical methodology (Polissar et al., 2012) the 90th percentile fish consumption rate decreased from 128 g/day to a more statistically representative value of 43.3 g/day. A reevaluation of the fish ingestion rates using the NCI method also results in a more statistically representative value that is lower than the fish consumption rate derived using the older statistical method (the 90th percentile for the Nez Perce Tribe decreased 35% from 270 g/day to 173 g/day, while the 90th percentile for the Shoshone Bannock Tribe decreased 76% from 603 grams/day to 141 g/day.

Table 6 A Comparison of Fish Consumption Rates (All Fish) using Different Statistical Survey Methods

Population	Method	50%	Mean	75%	90%	95%	99%
Nez Perce Tribe[1]	Food Frequency Questionnaire	70.5	123	---	270	437	796
Nez Perce Tribe[1]	NCI	49.5	75.0	---	173	232	---
Shoshone Bannock Tribe[1]	Food Frequency Questionnaire	74.6	158	---	392	603	1058
Shoshone Bannock Tribe[1]	NCI	14.9	34.9	---	94.5	141	---
General Population[2]	Short-term consumption survey data	37.9	56	78.8	128	168	---
General Population[2]	NCI	12.7	18.8	24.8	43.3	56.6	---

[1] Polissar et al. (2016). Statistics are for species of CWA relevance (freshwater, near coastal and estuarine species) for the Nez Perce and Shoshone-Bannock Tribes

[2] National Survey: NHANES 2003–2006, Adult Respondents, values as reported in Ecology (2013)

The conclusions of Polissar et al. (2016), A Fish Consumption Survey of the Nez Perce Tribe, state the following:

> *In summary, the NCI method's rates based on the 24-hour recall interviews are likely to be closer to the actual rates than the rates from the FFQ (Food Frequency Questionnaire) analysis, due to the lighter demand on memory required by the 24-hour recall approach*

Keeping the above caution about historic FCRs in mind, fish consumption rates do vary between populations. Consider the values listed in **Table 7** (Washington State Department of Ecology 2013) for illustration.

Table 7 Variations in fish consumption rates

Population	Key Variable	Fish	Mean fish ingestion (g/day)	95% Percentile (g/day)
Washington's Model Toxics Control Act (MTCA) Cleanup Regulation	Default fish consumption rate	All	54	
General population, Washington State, consumers only	NCI estimation method	All	19	57
Columbia River Tribes	All sources of fish	All	63	194
Tulalip Tribes	All sources of fish	All	82	268
Squaxin Island Tribe	All sources of fish	All	84	280
Suquamish Tribe	All sources of fish	All	214	797
Recreational Fishers, Washington State	Freshwater	All	6.0 to 22	42 to 67

How do we account for such varying rates of fish consumption in estimating risk and setting protective environmental standards? One way is to incorporate the range of values into risk calculations in a method known as probabilistic risk assessment. Another way is to pick a value for fish consumption that protects the majority of the population at the target excess lifetime cancer risk to set a criterion, and then to make sure that the standard represents a reasonable level of risk for more highly exposed groups of people. **Tables 8a and 8b** illustrate the results of a series of hypothetical calculations. It shows how the calculated risk varies with the amount of fish eaten, as described below.

Table 8a Excess Lifetime Cancer Risk (using an acceptable level of 1E-06) versus Fish Consumption Rates

	MTCA Default	Washington State, mean	Washington State, 95th Percentile	Current and Proposed HHWQC	Suquamish Tribe, 95th percentile
Fish consumption rate (g/day)	54	19[a]	57[a]	175	797
Excess Lifetime Cancer Risk	1E-06	4E-07	1E-06	3E-06	1E-05
	3E-06	1E-06	3E-06	9E-06	4E-05
	9E-07	3E-07	1E-06	3E-06	1E-05
	3E-07	1E-07	3E-07	1E-06	5E-06
	7E-08	2E-08	7E-08	2E-07	1E-06

[a] These fish consumption rates are UFCRs (i.e., they represent long-term consumption rates. The other consumption rates shown in the table overstate long-term consumption because they are derived using outdated fish consumption survey methods.

Table 8b Excess Lifetime Cancer Risk (using an acceptable level of 1E-05) versus Fish Consumption Rates

	MTCA Default	Washington State, mean	Washington State, 95th Percentile	Current and Proposed HHWQC	Suquamish Tribe, 95th percentile
Fish consumption rate (g/day)	54	19[a]	57[a]	175	797
Excess Lifetime Cancer Risk	1E-05	4E-06	1E-05	3E-05	1E-04
	3E-05	1E-05	3E-05	9E-05	4E-04
	9E-06	3E-06	1E-05	3E-05	1E-04
	3E-06	1E-06	3E-06	1E-05	5E-05
	7E-07	2E-07	7E-07	2E-06	1E-05

[a] These fish consumption rates are UFCRs (i.e., they represent long-term consumption rates. The other consumption rates shown in the table overstate long-term consumption because they are derived using outdated fish consumption survey methods.

Five fish consumption rates are shown. These five daily consumption rates cover the range of rates shown previously in Table 7. Included in Table 8a and 8b are the amounts eaten by fish consumers throughout Washington as represented by the MTCA default value, fish consumers throughout Washington as represented by the mean and 95th percentile UFCRs, and the value of fish consumption included in the current Washington HHWQC, equal to the consumption rate USEPA proposes to use in the updated criteria. The tables also include the amount eaten by members of the Suquamish tribe at the 95th percentile, who eat the largest amounts of fish of all the people in Washington State (Washington State Department of Ecology 2013).

The rows labelled excess lifetime cancer risk in Table 8a show how the calculated risk varies with the amount of fish eaten. In each row, the shaded box shows the group that was "assigned" a $1x10^{-6}$ (or 1E-06) risk, equal to the acceptable risk level in Washington's current and USEPA's proposed HHWQC. For example, calculations summarized in the first excess lifetime cancer risk row started with the assumption that the risk to people eating 54 g/day of fish (Washington State MTCA default value) should be no more than $1x10^{-6}$ or 1E-06. The risk to the group that eats the most fish (Suquamish Tribe, 95th percentile) would then be $1x10^{-5}$ or 1E-05, well within the range of acceptable risk set forth in USEPA guidance (USEPA 2010), if all of the other variables in the calculation remained the same. Similarly, the second to last row in the table shows that if one uses the acceptable risk level of $1x10^{-6}$ (or 1E-06) combined with the FCR in the current and proposed HHWQC, the most highly exposed people in the Suquamish Tribe (95th percentile) would be protected at 5 $x10^{-6}$, far below the $1x10^{-4}$ indicated in USEPA guidance and the 95th percentile of the general population would be protected at a $3x10^{-7}$ level, about three times lower than the most stringent acceptable risk level identified in USEPA guidance (USEPA 2010).

Table 8b follows the same pattern as Table 8a except for using an acceptable risk level of $1x10^{-5}$ (instead of $1x10^{-6}$). A $1x10^{-5}$ acceptable risk is consistent with USEPA guidance for the general population (USEPA 2010) and state-wide HHWQC using an acceptable risk level of $1x10^{-5}$ have been approved by USEPA. In each row, the shaded box shows the group that was "assigned" a $1x10^{-5}$ (or 1E-05) risk. In this case, combining an acceptable risk of $1x10^{-5}$ and a consumption rate of 54 g/day of fish (Washington State MTCA default value) results in a potential risk of no more than $1x10^{-4}$ for the group that eats the most fish (Suquamish Tribe, 95th percentile) if all of the other variables in the calculation remained the same, consistent with USEPA guidance. Similarly, the second to last row in the table shows that if one uses the acceptable risk level of $1x10^{-5}$ (or 1E-05) combined with the FCR in the current and proposed HHWQC, the most highly exposed people in the Suquamish Tribe (95th percentile) would be protected at 5 $x10^{-5}$, consistent with USEPA guidance. The 95th percentile of the general population would be protected at a $3x10^{-6}$ level, within the range of acceptable risk for the general population identified in USEPA guidance (USEPA 2010).

In 2016, Washington proposed a HHWQC for PCBs that is protective of potential non-cancer effects and corresponds to a cancer risk level of $2.3x10^{-5}$ (or 2.3E-5). This proposed HHWQC was derived using the fish ingestion rate of 175 g/day. As shown in Table 8b, when a fish ingestion rate of 175 g/day that corresponds to a risk of about 3E-5 is increased to a fish ingestion rate of 797 g/day, the resulting risk is 1E-4. Therefore, even the most highly exposed populations would be protected in a manner consistent with the CWA if the cancer risk level for PCBs is set at $2.3x10^{-5}$. USEPA is incorrect in its conclusion that Washington's state-adopted HHWQC for PCBs does not meet the requirements of the CWA.

What do these calculations mean with respect to public policy? Water quality criteria based on the consumption rate in the current Washington and proposed USEPA criteria combined with an excess lifetime cancer risk of 1x10-5 (1E-05) present a risk that, even to the most highly exposed populations, is within the acceptable range as defined by USEPA (2000) and is also within the range of acceptable risk set by USEPA for the general population. Criteria derived using a fish consumption rate of 175 g/day and an acceptable risk level of 1x10-6 lead to levels of protection for both the general and highly exposed populations that are inconsistent with USEPA guidance. Either the allowable risk level in the current and proposed criteria needs to be increased or the fish consumption rate needs to be decreased such that the people of Washington State are protected from unreasonable risk at levels consistent with existing USEPA guidance.

3.2 Compounded conservatism

Conservative assumptions add up. If a decision maker chooses a conservative value for every variable in a risk calculation, the results will be far more protective than intended. Consider the hypothetical example of a risk assessment that is based on three independent and log-normally distributed parameters (Burmaster and Harris 1993). In the case of a fish consumption calculation, those parameters might be the amount of fish eaten each day, body weight, and the number of years over the course of a lifetime that people live in a

certain place and eat fish from a local source. Each value represents the 95th percentile, or in other words that 9,500 out of 10,000 people have a lower exposure: they eat less fish, or do not eat fish from a stream for as many years, for example. Combining those three variables would result in a risk estimate that would fall at the 99.78th percentile of the resulting distribution. The risk to 9,978 out of 10,000 people would be lower than the allowable risk level used to establish the standard. Decisions made on the basis of this hypothetical calculation, which compounds conservative factors, would be far more protective than originally planned by the decision makers who intended to protect the average member of the population (or the 90th percentile or even the 95th percentile of the general population) at the selected allowable risk level.

The above example reflects the traditional interpretation of compounded conservatism. Namely the selection of conservative assumptions for multiple parameters used to estimate exposure and risk. USEPA's proposed HHWQC for Washington add another layer of conservatism outside of the selection of conservative exposure assumptions. In the proposed HHWQC USEPA has designated Native Americans as the general population and assigned to Native Americans an acceptable risk level of 1x10^{-6}, an acceptable risk level, as well as 1x10^{-5}, that USEPA's guidance indicates is for the general population. However, Native Americans are not the general population, comprising 2.3 percent of the Washington population (U.S Census Bureau, 2018). Native Americans are clearly a subpopulation, albeit with higher rates of fish consumption than the general population. Historic USEPA HHWQC guidance (USEPA 2000) recognizes the possible existence of such high-consuming subpopulations and indicates the potential risk to such subpopulations should not exceed 1x10^{-4}. By designating Native Americans as the general population and assigning the most stringent general population acceptable risk level to Native Americans, the general Washington population and Native Americans are protected at levels far lower than envisioned by existing USEPA guidance.

This may look like an academic calculation and exercise. Some readers may think that overestimating risks is a good thing because it allows us to be extra-cautious, and that regulatory decisions based on risk estimates should be as conservative and protective as possible. But the consequences of such choices also need to be considered. There's a cost to reducing the levels of chemicals in the environment to meet more-stringent limits, a cost that may be measured in dollars, energy usage, or the risk of injury to workers who have the job of reducing the levels of those chemicals. Chemicals may be used to treat wastewater to meet lower standards, for example, and the sludge that results has to be trucked to a landfill or incinerated. Generating the power used to operate the wastewater treatment plant uses natural resources and creates air emissions. Each of these aspects of the life cycle of wastewater treatment operations, and their related risks, should be weighed against the value of regulatory decisions based on compounded conservatism.

Compounding the use of a high fish consumption rate, long duration of residence, upper percentile drinking water rate, and other high-end assumptions to estimate risks combined with changing the acceptable risk policy to designate a potentially high-consuming subpopulation Native Americans as the general population), with a low target excess lifetime cancer risk historically applied to the general population will result in water

quality standards that are far more protective of the vast majority of the population than reflected by the target excess lifetime cancer risk. That additional degree of protection must be weighed against the risks and environmental impacts that would result from the additional treatment needed to meet such a standard.

4. Environmental Justice considerations

Environmental justice is, in the words of USEPA (2014C),

> *… the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. …. It will be achieved when everyone enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn, and work.*

But how do we know what's fair treatment? The USEPA (2006) has developed guidelines relevant to risk-based decision-making. After defining the problem to be solved and collecting relevant information, we are to assess the potential for "adverse" environmental and human health effects or impacts, and to assess the potential for "disproportionately high and adverse" effects or impacts before deciding on a course of action.

Within the context of setting HHWQC within the State of Washington and the discussion in this white paper, the adverse human health effect of particular concern is cancer. At issue is whether the higher rates of fish consumption by Native Americans could lead to a disproportionate and unfair risk. The proposed HHWQC reflect two key assumptions: that Native Americans in Washington State consume 175 g/day of fish, and that the maximum acceptable risk to the subpopulation of Native Americans should be $1x10^{-6}$, a risk level typically applied to the general population. These two assumptions are each conservative and they need not be compounded to achieve environmental justice.

As demonstrated in Table 8b, a standard based on the premise that those eating an average amount of fish each day would be protected to $1x10^{-5}$ risk level would assure that even the most highly exposed population, represented by the 95th percentile of the Suquamish Tribe, would encounter a risk of $1x10^{-4}$. Such a risk would not be "disproportionately high and adverse". As indicated in Section 2.2,

> *EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10^{-4} level.*

Further, the 10^{-4} risk level is embedded in many other standards, including drinking water; our standards for protecting workers on the job reflect the judgment that a 10^{-3} risk is acceptable. As a society, we accept that level of risk as reasonable.

Increasing the assumed amount of fish consumption or capping the acceptable level of risk is not necessary to develop standards that correspond to risks within acceptable bounds. Nor is it necessary to achieve environmental justice.

5. Putting environmental risks in perspective: everyday risks

Consider how a $1x10^{-6}$ lifetime risk of developing cancer compares to risks we face in our daily lives. For ease of discussion, we can refer to mortality risks in terms of micromorts[8], units representing a one in one million chance of death. For example, one micromort is the risk incurred by the average person driving 240 miles in the United States. The micromort allows different kinds of risk to be compared on a similar scale. Motorcycling 20 miles or undergoing anesthesia are equivalent to 5 micromorts apiece, skydiving or running a marathon are equivalent to 7 micromorts apiece, and giving birth in the United States is equivalent to 210 micromorts (Blastland and Spiegelhalter 2014). When we compare a lifetime risk of developing cancer to such micromorts, we need to keep two important distinctions in mind. Not all cancers are fatal. And many of the micromort statistics described below represent the risk of death *each year*, not over the course of a lifetime.

In 2010, approximately 200,955 people died in the United States from unintentional injury-related deaths (e.g., poisoning, motor vehicle traffic, firearms, falls) (CDC, 2020). This means that given a total population of about 300 million people, the average American faced an unintentional injury-related mortality risk of approximately 610 micromorts per year in 2020, or 1.7 micromorts per day. In other words, about 559 people die each day from an unintentional injury. This means that *every day*, *every American* has a risk of slightly greater than $1x10^{-6}$ of dying from unintentional injury.

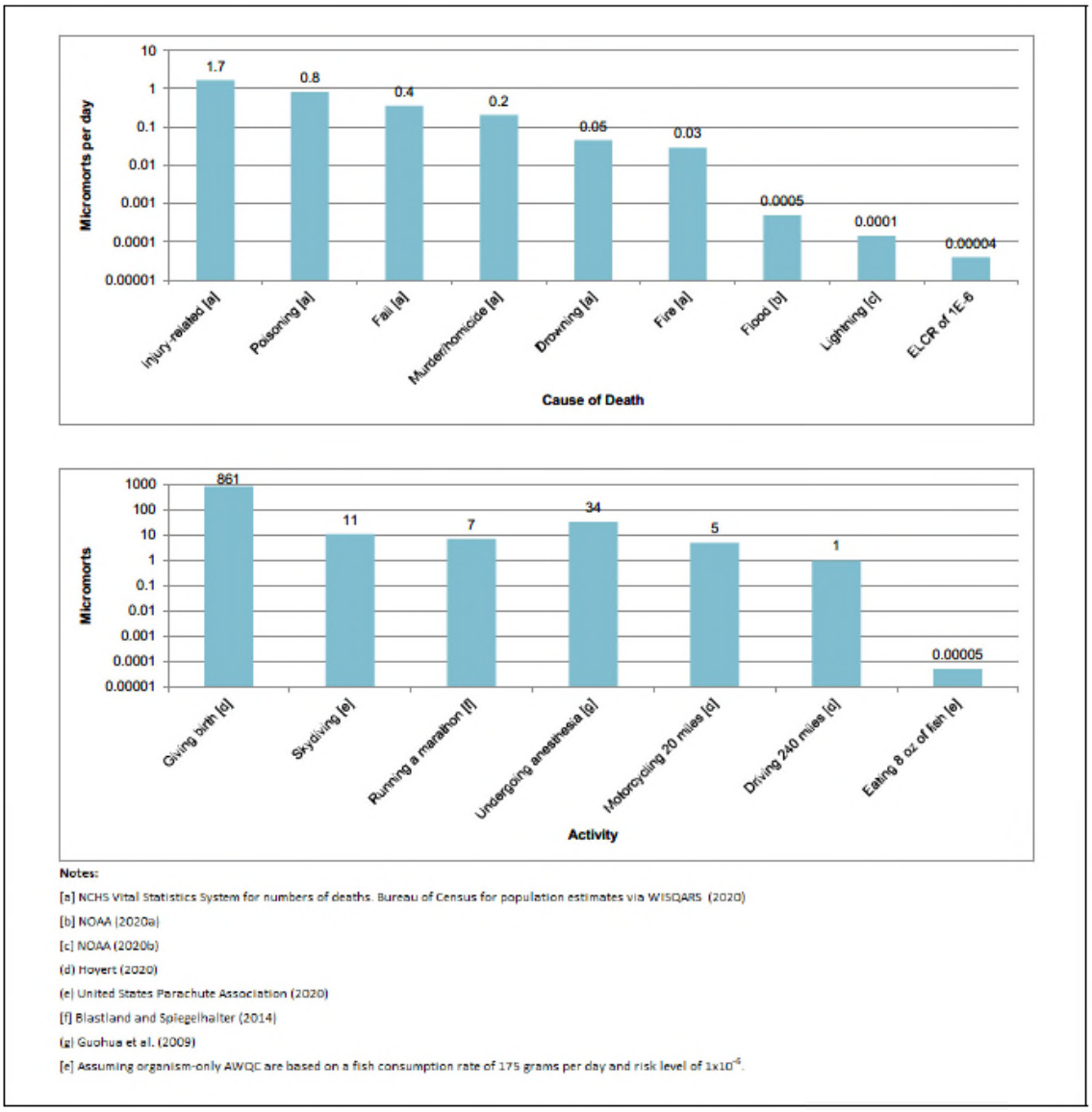
Compare this to an excess lifetime cancer risk of $1x10^{-6}$, which (if we assume a lifetime corresponds to 70 years as does USEPA (USEPA 1989, USEPA 2014B)) translates to a worse-case 0.01 micromorts per year or 0.00004 micromorts per day; this is worse case from the perspective that not all cancers are fatal and the risks estimated by risk assessments are *upper bound estimates* of risk and *do not* represent *actual* risks. Thus, USEPA's definition of "acceptable" risk is several orders of magnitude below (i.e., more stringent) the average American's daily risk of dying from an unintentional injury; it is also approximately 5,200 times lower than the 2020 risk of dying from a murder/homicide (24,576 deaths or 0.2 micromorts per day), 12 times lower than the 2020 risk of dying from a flood (59 deaths or 0.0005 micromorts per day) and 4 times lower than the 2020 risk of dying from a lightning strike (17 deaths or 0.0001 micromorts per day) in the United States (CDC, 2020, NOAA 2020a; NOAA 2020b) (**Figure 2**). This is consistent with the concept of $1x10^{-6}$

[8] A micromort is a unit of risk that represents a one-in-a-million ($1x10^{-6}$) probability of death. Risk assessors use micromorts to characterize and compare the riskiness of various day-to-day activities.

being a *de minimus* level of risk, because risks within this range are not risks that most members of the general public are concerned with and attempt to actively avoid.

Consider next that many regulatory agencies employ the USEPA-recommended $1x10^{-6}$ risk level to deriving HHWQC that relies on conservative upper-end values to estimate exposure. If one were to derive organism-only HHWQC by selecting a fish consumption rate of 175 g/day and targeting a risk level of $1x10^{-6}$, this means that a person would need to consume approximately 4,500 kilograms of locally-caught fish in his or her lifetime just to reach this *de minimus* level of risk, assuming ambient water always contains chemicals present at the resulting HHWQC. This also means that the risk associated with a single meal of fish would be $5x10^{-11}$, or 0.00005 micromorts, which for perspective should be noted is 20,000 times lower than the risk an average person faces when driving 250 miles in the United States (1 micromort) (**Figure 2**). Given that 175 g/day is an upper-end consumption rate estimate, the average member of the population would have an excess lifetime cancer risk lower than $1x10^{-6}$. For example, if we assume the average member of the population eats 8 g/day of fish, he or she would have an excess lifetime cancer risk of $5x10^{-8}$, roughly 20 times lower than the high-end consumer. If, on the other hand, one was to derive organism-only HHWQC by selecting an average fish consumption rate of 8 g/day and targeting a risk level of $1x10^{-6}$, the high-end consumer eating 175 g/day would have an excess lifetime cancer risk of $2x10^{-5}$, higher than $1x10^{-6}$ but still nearly an order of magnitude below the level USEPA (2000) recommends for highly exposed populations. Risk managers must make decisions such as these, recognizing that if highly exposed individuals are protected at $1x10^{-6}$, the average member of the population – and in fact the majority of the population itself – will have risks well below this *de minimus* level.

Figure 2 Common Risks Expressed as Micromorts



Notes:

[a] NCHS Vital Statistics System for numbers of deaths. Bureau of Census for population estimates via WISQARS (2020)

[b] NOAA (2020a)

[c] NOAA (2020b)

(d) Hoyert (2020)

(e) United States Parachute Association (2020)

[f] Blastland and Spiegelhalter (2014)

(g) Guohua et al. (2009)

[e] Assuming organism-only AWQC are based on a fish consumption rate of 175 grams per day and risk level of $1x10^{-6}$.

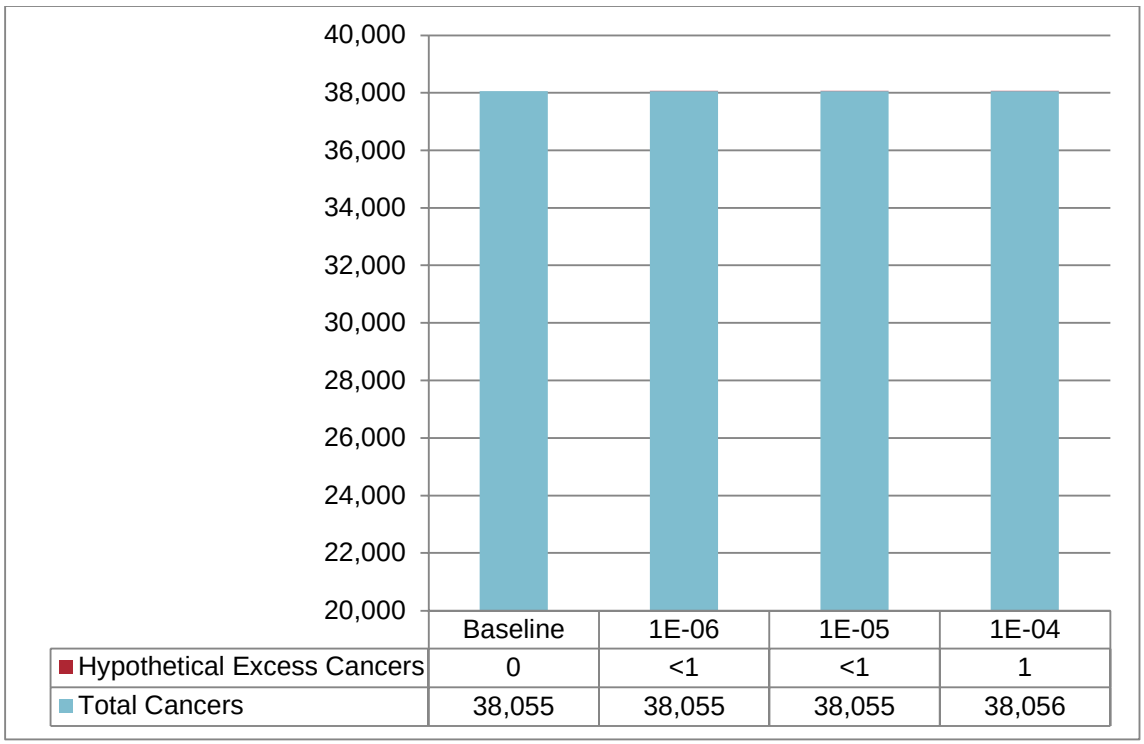
Another perspective when thinking about allowable risk is to consider the reduction or change in cancers associated with a particular allowable risk level. Allowable risk levels that result in large reductions in expected cancers clearly have a greater public health benefit than allowable risk levels that result in little change. The average excess lifetime cancer risk can be combined with the estimated size of the population of Washington (7,523,869 in 2018) and the cancer rate in Washington in 2018 (38,055 new cancers) to see

how large of a change in incidence is associated with using various allowable risk levels to set regulatory standards such as water quality criteria[9]. **Figure 3** shows that comparison.

The comparison illustrated in Figure 3 demonstrates that the annual increased incidence of cancer in the state of Washington associated with various alternative allowable cancer risks is very small when compared to the baseline incidence of cancer. This is true even at an allowable lifetime risk of $1x10^{-4}$ where 1 (and for the reasons described above, almost certainly less than 1) additional cancer may occur in the State compared to the 38,230 cased diagnosed in 2014. The change is two thousandths of a percent in overall incidence. Clearly, compared to total cancer incidence, the increases in cancers associated with the above allowable risk levels are small and are swamped by other causes of cancer. This finding is consistent with the comparisons of mortality risk associated with various allowable risk levels to mortality risk from various activities that are part of everyday life shown above.

[9] Assumptions used when deriving most criteria represent an upper percentile of the exposed population, not the average person in the population. To estimate the increased state-wide cancer incidence an average excess lifetime cancer risk needs to be used otherwise increased state-wide incidence will be overestimated. Based on the work we have completed using probabilistic approaches, criteria derived using the typical deterministic approach may overestimate the potential risk to an average member of the population by 10, 100, or more fold. Because a probabilistic evaluation of the proposed Washington criteria is beyond the scope of this paper an exact estimate of the excess lifetime cancer risk for an average Washingtonian could not be developed. However, we do know that the average Washingtonian eats about 19 grams of fish per day (Ecology 2013), not 175 as assumed by the proposed criteria. Therefore, that assumption ***by itself***, results in a nearly 10-fold overestimate of excess lifetime cancer risk for the average Washingtonian. Use of other conservative assumptions in the derivation of the proposed criteria means that the excess lifetime cancer risk for the average Washingtonian is more than 10-fold lower than the allowable excess lifetime cancer risk used to derive the proposed criteria. Based on the difference between the average fish consumption rate and the 175 g/day assumed by proposed criteria, the increased incidence of cancers associated with different excess lifetime cancer risks was estimated by multiplying the expected annual cancer incidence associated with each of the excess lifetime cancer risks by the ratio of consumption rates (19 g/d/175 g/d = 0.109). The adjusted incidence of cancers based on a conservative estimate of excess lifetime cancer risk for the average Washingtonian are shown in Figure 3.

Figure 3 Comparison between Total Cancer Incidence and the Hypothetical Excess Annual Cancer Incidence Associated with Various Allowable Risk Levels



	Baseline	1E-06	1E-05	1E-04
Hypothetical Excess Cancers	0	<1	<1	1
Total Cancers	38,055	38,055	38,055	38,056

*Total cancers estimated by adding the number of hypothetical excess cancers to the number of cancers reported for Washington in 2018 (38,055 cases (CDC 2018)).

6. Health benefits of fish consumption

Finally, risk managers should also consider how the risks incurred from eating fish compare to the benefits gained. Researchers and public health officials have been aware for several decades that consumption of fish has associated with it many benefits. Early comparisons of those benefits to the potential risks associated with exposure to possible chemicals in the environment suggested that the benefits (specifically the reduced risk of mortality from coronary heart disease) far outweighed any increased cancer risks that might be associated with the allowable risk levels used in the derivation of HHWQC (e.g., $1x10^{-6}$, $1x10^{-5}$, and $1x10^{-4}$) (Anderson and Weiner 1995, Patterson 2002, Daviglus et al. 2002, Dourson et al. 2002, Anderson et al. 2002, US Department of Agriculture 2015, Xue and Hing 2021). A great deal of research continues on the health benefits and risks of consuming fish with measurable levels of chemicals. A literature search of publications since 2005 revealed over 400 citations, including three recent reviews by expert panels or recommendations by regulatory agencies (Nesheim and Yaktine 2007, WHO 2011, EFSA 2014). All of those recent expert reviews and regulatory agency recommendations continue to urge that people regularly consume fish. In fact, in the recommendation is that the general population eat 1 to 2 meals per week and

that pregnant women eat 2 to 4 meals per week because of the benefits to the infants they are carrying (EFSA 2014). Such benefits almost always outweigh the possible risks of chemical exposure.

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A REVIEW OF METHODS FOR DERIVING HUMAN HEALTH-BASED WATER QUALITY CRITERIA WITH CONSIDERATION OF PROTECTIVENESS

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August 2012

National Council for Air and Stream Improvement

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TABLES

AN OVERVIEW OF PARAMETERS USED IN THE DERIVATION OF EPA HUMAN HEALTH AMBIENT WATER QUALITY CRITERIA

1.0 EXECUTIVE SUMMARY

Consistent with the requirements of the Clean Water Act, states are obligated to establish numeric water quality criteria for toxic substances and to periodically consider the need for revisions to those criteria. Toxics criteria are designed to protect both resident aquatic life and humans exposed via drinking water, consumption of fish, and/or dermal contact. Criteria for the protection of human health (i.e., Human Health Ambient Water Quality Criteria, or HHAWQC) are traditionally derived using EPA-recommended equations that include parameters for risk, toxicity, and exposure. The values used for these parameters are revisited and adjusted periodically in response to the availability of new science and shifts in policy.

The material presented in this paper includes an overview of the derivation procedures for HHAWQC, focusing especially on the selection of values for the parametric components in the HHAWQC derivation equations. Particular attention is given to the use of conservative (i.e., over-protective) choices for multiple parameter values and the overall effect of compounded conservatism on the resulting criteria relative to health protection targets established by state and federal agencies.

1.1 Parameters Used in HHAWQC Derivation and Frequently Used Values

The equations used to derive HHAWQC are composed of explicit parameters (i.e., those that are listed and defined), and implicit parameters (i.e., those that are embodied with the application of the explicit parameters). The equations and rationales for selection of specific parameter values were developed by EPA more than twenty years ago and while updates in parameter values have been made periodically, the basic methodology remains unchanged. **Table 1.1** lists the explicit and implicit parameters used in the HHAWQC derivation. Also shown are typical parameter values recommended by EPA. The third column in the table provides an indication regarding whether the typical value reflects a central, upper-end, or maximum in the range of values that could be chosen for each parameter. It is clear from the table that, in nearly every case, the typical values used for explicit and implicit parameters are selected from the upper end of the range of possible values.

It is well-known, and mathematically intuitive, that the practice of selecting "upper end of range" values for multiple parameters in a risk equation will lead to over-conservative estimates of risk or, in the case of HHAWQC, overly restrictive criteria. Indeed, EPA's Risk Assessment Task Force has suggested that "when several parameters are assessed, upper-end values and/or central tendency values are generally combined to generate a risk estimate that falls within the higher end of the population risk range" and "an exposure estimate that lies between the 90^{th} percentile and the maximum exposure in the exposed population [should] be constructed by using maximum or near-maximum values for one or more of the most sensitive variables, leaving others at their mean values" (EPA 2004). This concept, however, has not been embraced in the current practice for deriving HHAWQC.

Table 1.1 Parameter Values used in HHAWQC Derivation and Location in the Range of Possible Values

Parameter	Typical Value	Location in Range of Possible Values[1] (maximum possible, upper-end, or central tendency)
Explicit Parameters		
substance toxicity	substance-specific	upper-end
body weight of a person	70 kg (actual mean is 80kg)	central tendency
drinking water intake	2 L/day (86th percentile), but assumes drinking water is untreated surface water	(extreme) upper-end
fish ingestion/consumption rate	17.5 g/day (90th percentile of sport fishers)	upper-end
substance exposure from other sources	80%	upper-end
Implicit Parameters		
cooking loss	0% (no loss due to cooking)	maximum possible
duration of exposure	70 years	(extreme) upper end
exposure concentration	at HHAWQC 100% of the time	maximum possible
relative bioavailability	1	maximum possible
bioaccumulation/concentration factor of fish	substance-specific	substance-specific (not evaluated)

[1]"maximum possible" would be the most conservative (over protective) choice possible, "upper-end" a very conservative choice, and "central tendency" a typical or average value for a population. "Extreme" denotes a value that is very near maximum.

1.2 Degree of Conservatism in HHAWQC

Section 6 of this report details the degree of protectiveness, conservatism, and the combined effect of conservative parameter value choices in the derivation of HHAWQC. The information provided shows that the values commonly used for each parameter can have the effect of lowering the calculated HHAWQC by large factors. For example:

- substance toxicity values are commonly reduced by 10 to 3000 times below demonstrated toxicity thresholds as a means of ensuring protection of human health
- assumptions about chemical exposure via drinking water results in some criteria being as much as 30 times lower than needed to afford the degree of protection targeted by most states and EPA

- the assumption that a person lives in the same place and is exposed to the same level of contamination for a 70 year lifetime results in criteria that are up to 8 times more stringent than if a median exposure period were assumed
- the assumption that waters would exist at the allowable HHAWQC for 70 years is in opposition to water management policies in virtually all states and results in criteria values that are 1.5 to 6 times more stringent than would be the case if actual water quality management practices were considered

Each of the factors listed above, and several others discussed in more detail in the following sections, can combine (i.e., compound) when applied in the same calculation, such as that used for deriving HHAWQC. The result is criteria that are many times lower than would be the case if the advice of the Risk Assessment Task Force regarding use of upper range values for one or more sensitive values and leaving others at their mean values (EPA 2004) were followed.

1.3 Comparison of HHAWQC with other Regulatory Mechanisms for Human Health Protection

The summary above, and supporting sections of this report, offer observations suggesting that HHAWQC are considerably more protective (i.e., lower in concentration, or over-protective) than are necessary to achieve the health protection targets described by EPA and many state environmental agencies. Section 7 of this report considers other evidence that might confirm or refute this observation. It contains a comparison of fish tissue concentrations corresponding to EPA recommended HHAWQC with (a) existing fish tissue concentration data, (b) concentrations found in other foods, and (c) allowable concentrations (such as fish consumption advisory "trigger levels") set by other US and international health agencies.

Findings from this comparison support the observation that HHAWQC are over-protective. Specifically:

- For higher assumed fish consumption rates and based on EPA fish tissue data, virtually all surface waters in the US would exceed the HHAWQC for PCB, mercury, and likely a number of other substances. In contrast, for example, health agencies have established fish consumption advisories for PCBs on only about 15% of water bodies (Appendix C) indicating that assumptions used by EPA are more conservative than the assumptions used by state agencies to derive fish consumption advisories.
- A comparison of the daily intake of several example substances for which HHAWQC exist, showed that intakes from other foodstuffs was greater than from fish and was already exceeding the allowable intakes used to establish HHAWQC. Thus, establishment and enforcement of more stringent HHAWQC may not provide a measureable public health benefit.
- Various federal and international agencies have established concentration limits for fish as a food in commerce. Levels set by these agencies (whose goal is to insure the safety of edible fish) show that EPA HHAWQC are limiting fish tissue concentrations to levels substantially (10s to 1000s of times) below those considered to be without significant risk.

1.4 Other Observations

Other observations from this review are noted as follows.

- Target cancer risk levels between 10^{-6} and 10^{-4} have become widely accepted among the different EPA programs, including the derivation of HHAWQC. The HHAWQC methodology document states that a risk level of 10^{-4} for highly exposed populations is acceptable (EPA 2000a). This is sometimes interpreted as meaning that highly exposed

populations are not as well protected by the HHAWQC. However, as noted by Kocher (1996) "if only a small population would be at greatest risk, the expected number of excess cancers corresponding to individual risks at the *de minimis* level of 10^{-4} would still be [essentially] zero."

- The fish consumption rates used in calculating HHAWQC can have a significant impact on the resulting HHAWQC. This is because the HHAWQC are proportional to the fish consumption rates - as the rate increases, the HHAWQC decreases, and the decrease is particularly pronounced for high BAF/BCF substances. Potential exposure through the fish consumption pathway is dependent upon a number of different variables including the types of fish consumed, the sources of those fish (particularly anadromous fish such as salmon, see Appendix B), and the rates at which they are consumed, all of which vary widely among the population. The quantification of fish consumption rates is complicated by the methods used to collect consumption information, the interpretation of such data (particularly extremes in the distribution of individual consumption rates obtained from survey data), the availability of fish from regulated sources, and the habits of the targeted population of fish consumers. Without extreme diligence in data interpretation, most of these complications are likely to manifest in overestimations of fish consumption rates.

- The selection of some exposure parameters are unrealistic because, as a practical matter, other environmental management programs would ensure that such conditions did not occur (or would not persist for a person's lifetime). Assumptions concerning ambient water column concentrations (and related fish tissue concentrations) and drinking water concentrations are examples.

Finally, it is noteworthy that the values used for parameters in a health risk equation like that for deriving HHAWQC involve a combination of science and policy choices. And, while evolving science and policy may sometimes indicate that revisiting these choices is warranted, responsible evaluation of risk (and thus protection of health) is best considered in total rather than by simple alteration of a single parameter value without due consideration of the others. The information presented herein suggests that the degree of protection embodied in the current HHAWQC derivation method, using typically applied values for each parameter, exceeds by a large margin the health protection targets expressed by EPA and many states.

2.0 INTRODUCTION

Section 304(a) (1) of the Clean Water Act (CWA) requires the United States Environmental Protection Agency (EPA) to develop and publish recommended numeric ambient water quality criteria (AWQC) for limiting the impact of pollutants on human health and aquatic life. These recommended human health-based AWQC (HHAWQC) are intended to provide guidance for states and tribes to use in adopting their own water quality standards and are meant to "minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposures to substances through the ingestion of drinking water and consumption of fish obtained from surface waters" (EPA 2000a). Water quality criteria recommendations are derived by EPA using equations that express a risk analysis. The value of each parametric component of the criteria equations represents policy choices made by the Agency, though several of those choices are derived from scientific data (EPA 2011a).

In a staff policy paper from the Office of the Science Advisor, EPA discussed the bases for these policy choices (EPA, 2004). They noted that "Congress establishes legal requirements that generally describe the level of protectiveness that EPA regulations must achieve" and that individual statutes identify the risks that should be evaluated and protected against and also mandate the required levels of protection (EPA 2004). The Clean Water Act, which mandates the development of AWQC, simply

requires that AWQC must "protect the public health or welfare, enhance the quality of water and serve the purposes of this Act" and "be adequate to protect public health and the environment from any reasonably anticipated adverse effects of each pollutant." In order to meet these requirements, EPA "attempts to protect individuals who represent high-end exposures (typically around the 90th percentile and above) or those who have some underlying biological sensitivity" (but not hypersensitive individuals) (EPA 2004). EPA (2004) notes that "[p]rograms may approach the problem semi-quantitatively (e.g., selecting individual parameter values at specified percentiles of a distribution) or qualitatively (e.g., making conservative assumptions to ensure protection for most individuals), though no overall degree of protection can be explicitly stated."

While EPA is obligated to develop and publish AWQC guidance, adoption and implementation of criteria for most fresh waters in the U.S. is an activity mandated to states. Many states choose to adopt EPA's AWQC guidance values but states are free to depart from EPA's criteria guidance provided that there is a scientifically valid rationale for doing so. Departure from the EPA AWQC guidance values is commonly accomplished by altering one or more of the values used to represent the parametric components of the risk analysis equation used to derive the criteria guidance values.

This document contains a discussion of each parametric component of the risk analysis equation that is used to derive HHAWQC. As noted earlier, selection of parameter values for risk analyses is primarily a policy choice and it is typical that such choices are conservative in favor of protecting public health. The combined degree of conservatism embodied in the final AWQC guidance is not usually expressed quantitatively by EPA. The primary purpose of this document is to provide an exploration of the combined conservatism that may be embodied in AWQC calculated using typically chosen values for the explicit parametric components of the HHAWQC equation and use of implicit assumptions also embodied in the criteria derivation.

3.0 EQUATIONS USED FOR THE DERIVATION OF HHAWQC

In calculating HHAWQC, EPA differentiates between carcinogenic and noncarcinogenic effects. Three risk analysis equations are used, the first for noncarcinogenic effects, the second for carcinogenic effects that are assumed to have a nonlinear dose-response, and the third for carcinogenic effects that are assumed to have a linear dose-response. These are shown in Table 3.1.

Table 3.1 Equations for Deriving Human Health Water Quality Criteria

Substance Category	HHAWQC Equation	Eq. #
Noncarcinogenic effects	$RfD*RSC*(BW/(DI + (\Sigma FI_i*BAF_i)))$	**Eq. 3.1**
Carcinogenic effects (non-linear)	$(POD/UF)*RSC*(BW/(DI + (\Sigma FI_i*BAF_i)))$	**Eq. 3.2**
Carcinogenic effects (linear)	$RSD*(BW/(DI + (\Sigma FI_i*BAF_i)))$	**Eq. 3.3**

where:

HHAWQC = human health ambient water quality criterion (mg/L);

RfD = reference dose for noncancer effect (mg/kg-day);

RSC = relative source contribution factor to account for non-water sources of exposure (typically expressed as a fraction of the total exposure);

POD = point of departure for carcinogenic effects based on a nonlinear low-dose extrapolation (mg/kg-day), usually a LOAEL, NOAEL, or LED_{10};

UF = uncertainty factor for carcinogenic effects based on a nonlinear low-dose extrapolation (unitless);

RSD = Risk-specific dose for carcinogenic effects based on a linear low-dose extrapolation (mg/kg-day) and on the selected target risk level;

BW = human body weight (kg);

DI = drinking water intake (L/day);

FI_i = fish intake at trophic level (TL) i (i = 2, 3, and 4); this is the fish consumption rate (kg/d); and

BAF_i = bioaccumulation factor at trophic level i, lipid normalized (L/kg)

The first portion of each equation in Table 3.1 contains parameters that represent a measure of the toxicity of a substance and are unique to each equation. The latter portion of each equation is common for the three substance categories and describes assumed human exposure to a substance. Implicit, and not obvious, with the practice of using these equations are other assumptions concerning exposure (i.e., a duration of exposure equal to a full lifetime, an average ambient water concentration equal to the HHAWQC, and bioavailability of chemicals from fish and water equal to that observed in the toxicity experiment). Finally, and also not obvious, is that an assumed incremental risk of illness is also part of the overall algorithms. Taken collectively, these explicit and implicit elements yield a risk analysis in the form of an acceptable water column concentration for a substance.

Although the parameters in the risk equations used for deriving a HHAWQC are most accurately represented by a range or distribution of values, it has been typical for EPA to select a single value for each parameter. EPA has recognized that there are elements of both variability and uncertainty in each parametric value but has generally not implemented specific procedures to account for variability and uncertainty. However in some cases, EPA has intentionally chosen parametric values that are conservative (i.e., over-, rather than under-, protective of human health) with respect to the general population.

The sections below discuss the parametric components of the toxicity portion (Section 4) and the exposure portion (Section 5) of each equation in Table 3.1. Section 6 includes discussion of variability and uncertainty in parameter values and, where evident, conservatism embodied in typical choices made for parameter values. Also in Section 6, consideration is given to the combined effect on conservatism of typical parameter value choices in HHAWQC derivation.

4.0 TOXICITY PARAMETERS USED FOR DERIVATION OF HHAWQC

Each of the three equations used to develop HHAWQC contains a factor that represents the toxicity of the substance of concern. Equation 3.1 (Table 3.1), which is used for non-carcinogenic effects, employs the reference dose (RfD), the derivation of which incorporates various uncertainty factors (UFs) and sometimes an additional modifying factor (MF). Equation 3.2 (Table 3.1), which is used for carcinogenic effects that have a nonlinear dose-response curve (i.e., there exists some level of exposure below which no carcinogenic response is expected to occur), employs a factor calculated by dividing the "point of departure" (POD) by UFs. Equation 3.3 (Table 3.1), which is used for substances that are assumed to have a linear dose-response (i.e., some probability of a carcinogenic response is presumed to exist at any level of exposure), employs a Risk-Specific Dose (RSD). It is EPA's policy to assume that all carcinogenic effects can be described using a linear dose response

unless non-linearity has been clearly demonstrated. Typically, if a compound is considered to have both carcinogenic and non-carcinogenic health effects, HHAWQC are calculated for both the cancer and noncancer endpoints and the lower of the two concentrations is selected as the HHAWQC. The derivation of these components is described in the "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (EPA 2000a) (hereafter referred to as the "HHAWQC methodology document") and its Technical Support Document Volume 1: Risk Assessment" (EPA 2000b).

4.1 Reference Dose (RfD)

A reference dose (RfD) is defined as "an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime" (EPA 2000b).

The development of an RfD begins with a review of all available toxicological data. Relevant studies are evaluated for quality and a "critical effect" is identified. The critical effect is defined as "the first adverse effect, or its known precursor, that occurs to the most sensitive species as the dose rate of an agent increases" (EPA 2002a). The underlying assumption is that if the RfD is derived to prevent the critical effect from occurring, then no other effects of concern will occur (EPA 2002a).

The next step is the identification of a POD based on the study in which the selected critical effect has been identified. The POD may be derived from a No Observed Adverse Effect Level (NOAEL), a Lowest Observed Adverse Effect Level (LOAEL) or Benchmark Dose Lower Confidence Level (BMDL). The NOAEL is defined by USEPA as "the highest exposure level at which there are no biologically significant increases in the frequency or severity of an adverse effect between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered adverse or precursors of adverse effects."[1] If a NOAEL cannot be identified, a LOAEL may be used instead. The LOAEL is defined by USEPA as "the lowest exposure level at which there are biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group."[2]

When study data are suitable, the Benchmark Dose BMD approach is sometimes used as an alternative to the NOAEL/LOAEL approach. The BMD is the dose at which the critical effect occurs at a rate 5-10% above the rate observed in the control group (other rates could possibly be used, but 5% or 10% are most common). The BMDL, which is typically the lower 95% confidence limit of the BMD, is used as the POD when the BMD approach is used.

Once the POD is identified, the RfD is derived according to equation 4.1:

$$RfD = POD/(UF_i * MF) \qquad \textbf{Eq. 4.1}$$

where:

RfD = reference dose for noncancer effect (mg/kg-day);

POD = NOAEL, LOAEL, or BMDL (mg/kg-day);

UF_i = uncertainty factors for various circumstances (see Table 4.1) (unitless) ; and

MF = modifying factor (unitless)

[1] Taken from USEPA's online IRIS glossary (http://www.epa.gov/iris/help_gloss.htm#n)
[2] Taken from USEPA's online IRIS glossary (http://www.epa.gov/iris/help_gloss.htm#n)

Uncertainty factors are used to reduce the dose in order to account for areas of scientific uncertainty in the supporting toxicity databases (EPA 2000b). The standard UFs are 1, 3, and 10. A modifying factor further adjusts the dose in order to provide for additional uncertainty not explicitly included in the UFs, such as the completeness of the overall database (EPA 2000b). The MF is a matter of professional judgment and ranges between 0 and 10, with the standard values being 0.3, 1, 3, and 10 and the default value being 1 (EPA 2000b). Table 4.1 defines the various UFs.

Table 4.1 Uncertainty Factors (adapted from EPA 2000b)

Uncertainty Factor	Description
Intraspecies variation (UF_H)	Accounts for uncertainty associated with variations in sensitivity among members of the same species (e.g., differences in age, disease status, susceptibility to disease due to genetic differences)
Interspecies variation (UF_A)	Accounts for uncertainty involved in extrapolating from animal data to humans; used when the POD is derived from an animal study
Subchronic-to-chronic (UF_S)	Accounts for uncertainty involved in extrapolating from studies with a less-than-chronic[1] duration of exposure; used when the POD is derived from a study in which exposures did not occur over a significant fraction of the animal's or the individual's lifetime
LOAEL-to-NOAEL (UF_L)	Accounts for uncertainty associated with the use of a POD derived from a LOAEL rather than a NOAEL or BMDL
Incomplete database (UF_D)	Accounts for uncertainty associated with the use of an incomplete database to derive the POD, for example, the lack of a study of reproductive toxicity

[1] Chronic Exposure: Repeated exposure for more than approximately 10% of the life span in humans (more than approximately 90 days to 2 years in typically used laboratory animal species).

In application, the various UFs and any MF are multiplied to obtain the final factor by which the POD is to be divided. In general, EPA follows a policy that a final factor greater than 3000 indicates that the existing toxicity database is inadequate to support the derivation of an RfD. In this case, no RfD is calculated (EPA 2002a).

Although instructions for calculating an RfD are provided in the documentation for HHAWQC, in actual practice, the RfD is typically obtained from EPA's IRIS database (http://www.epa.gov/iris/).

4.2 Cancer Effects: Nonlinear Low-Dose Extrapolation

In deriving a HHAWQC, a nonlinear low-dose extrapolation may be used for carcinogenic effects when there are sufficient data available to understand the mode of action (MOA) and conclude that it is nonlinear at low doses (EPA 2005). In practical application, this is interpreted to mean that a threshold of exposure exists below which no carcinogenic response will occur.

For nonlinear carcinogenic effects, the factor representing toxicity in Equation 3.2 is calculated by dividing the POD by UFs. The recommended POD is the Lower Limit on Effective $Dose_{10}$, or LED_{10}, which is determined by calculating the lower 95 percent confidence limit on a dose associated with an estimated 10 percent increased tumor or tumor precursor response (EPA 2000b). A NOAEL or LOAEL value from a precursor response may also be used in some cases (EPA 2000b). When animal data are used to determine the POD, the selected dose is converted to a human equivalent dose using a default interspecies dose adjustment factor or a toxicokinetic model. However, as noted above, it is EPA's policy to assume that all carcinogenic effects have a linear dose response unless non-linearity has been clearly demonstrated. Thus, the non-linear low dose extrapolation procedure is rarely used.

The HHAWQC methodology document provides no specific guidance on the selection of UFs (EPA 2000a). Instead, it defers to the "upcoming cancer risk assessment guidelines," which were subsequently released in 2005.

The 2005 Cancer Risk Assessment Guidelines took a somewhat different approach than anticipated by EPA in 2000 when the HHAWQC methodology guidelines were developed. The 2005 guidelines instead recommended that for nonlinear carcinogenic effects, "an oral reference dose…should be developed in accordance with EPA's established practice for developing such values" (EPA 2005). This does not have much practical impact on HHAWQC calculation, as comparison of equations 3.2 and 4.1 reveals that the process for calculating the factor that represents the toxicity of nonlinear carcinogenic effects in HHAWQC derivations is essentially the same as that for calculating an RfD.

Given that (1) the documentation for HHAWQC derivation does not provide complete guidance on the calculation of the POD/UF factor, and (2) the 2005 Cancer Risk Assessment Guidelines took a somewhat different approach than anticipated by the HHAWQC methodology guidelines, in actual practice, the POD/UF factor will be typically be replaced by an RfD for some noncancer endpoint (e.g., a cancer precursor event) obtained from EPA's IRIS database (http://www.epa.gov/iris/).

4.3 Cancer Effects: Linear Low-Dose Extrapolation

In deriving a HHAWQC, a linear low-dose extrapolation is used for compounds that are believed to have carcinogenic potential when the chemical has direct effects on DNA, the MOA analysis indicates that the dose-response relationship will be linear, human exposures or body burdens are already near the doses associated with key events in the carcinogenic process, or there is an absence of sufficient data to elucidate the MOA.

The RSD, which is used in Equation 3.3 (Table 3.1), is derived according to Equation 4.2:

$$\text{RSD} = \text{Target Incremental Cancer Risk}/m \qquad \textbf{Eq. 4.2}$$

where:

RSD = Risk-Specific dose (mg/kg-day);

Target Incremental Cancer Risk = Typically a value ranging from 10^{-6} to 10^{-4}; and

m = cancer potency factor $(\text{mg/kg-day})^{-1}$

The HHAWQC methodology document (EPA 2000a) states that the Agency will calculate recommended HHAWQC using at a Target Incremental Cancer Risk level of 10^{-6}. However, in deriving their own HHAWQC, states and authorized tribes may choose a risk level as low as 10^{-7} or as high as 10^{-5}, as long as the risk to more highly exposed subgroups (e.g., sport or subsistence anglers) does not exceed 10^{-4}. (The rationale for this is discussed further in Section 6.1.3.)

The cancer potency factor may be calculated by first modeling the relationship between tumor incidence and dose and then selecting a POD (generally the LED_{10}). When animal data are used to

determine the POD, the selected dose is converted to a human equivalent dose using a default interspecies dose adjustment factor or a toxicokinetic model. Finally, a straight line is drawn between the POD and the origin (zero). The slope of that line, which will be "m" in Equation 4.2, is calculated. If the LED_{10} is used as the POD, m is equal to $0.10/LED_{10}$ (EPA 2000b).

Instructions for calculating m are provided in the documentation for HHAWQC. In actual practice, however, the value of m is typically obtained from EPA's IRIS database (http://www.epa.gov/iris/). Note that EPA terminology has changed somewhat since the HHAWQC methodology document was released and what was referred to as "m" or "cancer potency factor" in the methodology document is more commonly identified as "slope factor" in the IRIS database.

5.0 EXPOSURE PARAMETERS USED FOR DERIVATION OF HHAWQC

As noted above, both explicit and implicit elements are used to yield a risk analysis in the form of an acceptable water column concentration for a substance. This section summarizes each of these elements and the manner in which they are used for deriving HHAWQC.

5.1 Relative Source Contribution (RSC)

When deriving a HHAWQC for noncarcinogenic or nonlinear carcinogenic effects, a factor is included in the equation to account for non-water sources of exposure to a substance. For example, a particular chemical may be found not only in water sources, but also in some food items or in ambient air (from which it could be inhaled). This factor is known as the Relative Source Contribution (RSC) and it acts to reduce the amount of the RfD that is apportioned to water and fish consumption. The rationale for using the RSC factor in calculating a HHAWQC is to ensure that an individual's total exposure does not exceed the threshold level (EPA 2000a).

The HHAWQC methodology document (EPA 2000a) creates an "Exposure Decision Tree" procedure to be used in the selection of an RSC. In the absence of sufficient data to support the use of the Exposure Decision Tree, EPA uses 20% as a default RSC (EPA 2000a). The methodology also sets 80% as the maximum allowable RSC and 20% as the minimum (EPA 2000a). EPA encourages states and authorized tribes to develop alternate RSC values based on local data (EPA 2000a). Although the Exposure Decision Tree approach does theoretically allow for the use of an RSC other than the 20% default, in actual practice, use of values other than the default is very rare.

Note that while the methodology (EPA 2000a) specifies that the RSC value must be between 20 and 80% and states that "EPA intends to use 20 percent of the RfD (or POD/UF), which has also been used in past water program regulations, as the default value," the current EPA HHAWQC are calculated using RSCs ranging from 20 to 100%. This is because many of the HHAWQC remain unchanged from earlier years or have been updated to reflect changes in fish consumption rates or RfD, but were not recalculated using the 2000 methodology.

The RSC factor is not used in the derivation of HHAWQC for carcinogenic effects with linear low-dose extrapolation. For these substances, the only sources considered are drinking water and fish ingestion. This is because for these substances, the HHAWQC is being determined with respect to the *incremental* lifetime risk posed by a substance's presence in water, and is not being set with regard to an individual's total risk from all sources of exposure (EPA 2000a). Thus, the HHAWQC for any substance represents the concentration of that substance in water that would be expected to increase an individual's lifetime cancer risk by no more than the target risk level, regardless of any additional lifetime cancer risk contributed by potential exposures from other sources (EPA 2000a).

5.2 Body Weight (BW)

The HHAWQC methodology document (EPA 2000a) recommends using a default body weight of 70 kg for calculating HHAWQC. This is considered to be a representative average body weight for male and female adults, combined. Adult values are used because the HHAWQC are intended to be protective over the full lifespan. The methodology also notes that 70 kg is used in the derivation of cancer slope factors and unit risks that appear in IRIS and advocates maintaining consistency between the dose-response relationship and exposure factors (EPA 2000a).

5.3 Drinking Water Intake (DI)

EPA recommends using a default drinking water intake rate of 2 L/day, which is believed to represent a majority of the population over the course of a lifetime (EPA 2000a).

The basis for the drinking water intake rate is the 1994-96 Continuing Survey of Food Intake by Individuals *(*CSFII) conducted by the U.S. Department of Agriculture (EPA 2000a). The CSFII survey collected dietary intake information from nationally representative samples of non-institutionalized persons residing in United States households (EPA 2000a). Households in these national surveys were sampled from the 50 states and the District of Columbia (EPA 2000a). Each survey collected daily consumption records for approximately 10,000 food codes across nine food groups (EPA 2000a). This included the number of fluid ounces of plain drinking water consumed and also information on the household source of plain drinking water, water used to prepare beverages, and water added during food preparation (EPA 2000a).

The results of the 1994-96 CSFII analysis indicated that the arithmetic mean, 75th, and 90th percentile values for adults 20 years and older were 1.1, 1.5, and 2.2 L/day, respectively (EPA 2000a). The 2 L/day value selected by EPA represents the 86^{th} percentile for adults (EPA 2000a).

5.4 Fish Ingestion Rate (FI)

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 2000a). 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 2000a).

EPA's first preference is that states and authorized tribes use the results from fish intake surveys of local watersheds within the state or tribal jurisdiction to establish fish intake rates that are representative of the defined populations being addressed for the particular waterbody (EPA 2000a). EPA also recommends that the fish consumption rate used to develop the HHAWQC be based only on consumption of freshwater/estuarine species (EPA 2000a). In addition, for noncarcinogens and nonlinear carcinogens, any consumption of marine species of fish should be accounted for in the calculation of the RSC (EPA 2000a). States and authorized tribes may use either high-end values (such as the 90th or 95th percentile values) or average values for the population that they plan to protect (e.g., subsistence fishers, sport fishers, or the general population) (EPA 2000a).

If surveys conducted in the geographic area of the state or tribe are not available, EPA's second preference is that states and authorized tribes consider results from existing fish intake surveys that reflect similar geography and population groups (e.g., from a neighboring state or tribe or a similar watershed type) (EPA 2000a). As with the use of fish intake surveys of local watersheds, consumption rates based on data collected from similar geographic and population groups should be based only on consumption of freshwater/estuarine species with any consumption of marine species accounted for in the calculation of the RSC (EPA 2000a).

If applicable consumption rates are not available from local, state, or regional surveys, EPA's third preference is that states and authorized tribes select intake rate assumptions for different population groups from national food consumption surveys (EPA 2000a). The HHAWQC methodology document (EPA 2000a) references a document titled "Estimated Per Capita Fish Consumption in the United States" (EPA 2000c) as the source for this information, however, there is a more recent document, "Exposure Factors Handbook: 2011 Edition" (EPA 2011b) that provides more current regional and subpopulation data and is also useful for this purpose. Again, EPA recommends that fish consumption rates be based on consumption of freshwater and estuarine species only and any consumption of marine species of fish should be accounted for in the calculation of the RSC (EPA 2000a).

As their fourth and last preference, EPA recommends the use of a default fish consumption value for the general adult population of 17.5 grams/day (EPA 2000a). This default value is used by EPA in its derivation of HHAWQC. This represents an estimate of the 90th percentile per capita consumption rate for the U.S. adult population based on the CSFII 1994-96 data (EPA 2000a). EPA believes that this default value will be protective of the majority of the general population (EPA 2000a). If a state or authorized tribe identifies specific populations of sportfishers or subsistence fishers that may represent more highly exposed individuals, EPA recommends default fish consumption rates of 17.5 grams/day and 142.4 grams/day, respectively, though in such cases a subpopulation risk level may also be appropriate (EPA 2000a) as explained in Section 6.1.3.

5.5 Bioaccumulation Factors (BAF) and Trophic Level

Bioaccumulation is the process in which aquatic organisms accumulate certain chemicals in their tissues when exposed to those chemicals through water, their diet, and other sources, such as sediments. In order to account for potential exposures to these chemicals through the consumption of fish and shellfish, EPA uses national bioaccumulation factors (BAFs) in the derivation of HHAWQC. The HHAWQC methodology document (EPA 2000a) defines BAF as the ratio (in L/kg tissue) of a concentration of a chemical in the tissues of commonly consumed aquatic organisms to its concentration in the surrounding water in situations where the organisms and their food are exposed and the ratio does not change substantially over time (i.e., the ratio which reflects bioaccumulation at or near steady-state).

The HHAWQC methodology document (EPA 2000a), the "Technical Support Document Volume 2: Development of National Bioaccumulation Factors" (EPA 2003a), and the "Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors" (EPA 2009) describe procedures for deriving national and site-specific BAFs. Separate procedures are provided for different types of chemicals (i.e., nonionic organic, ionic organic, inorganic and organometallic) (EPA 2000a). Also, EPA states that national BAFs should be derived separately for each trophic level because the concentrations of certain chemicals may increase in aquatic organisms of each successive trophic level due to increasing dietary exposures (e.g., increasing concentrations from algae, to zooplankton, to forage fish, to predatory fish) (EPA 2000a). In addition, because lipid content of aquatic organisms and the amount of organic carbon in the water column have been shown to affect bioaccumulation of nonionic organic chemicals, the national BAFs should be adjusted to reflect the lipid content of commonly consumed fish and shellfish and the freely dissolved fraction of the chemical in ambient water for these chemicals (EPA 2000a).

Even though the 2000 Methodology (EPA 2000a) and subsequent Technical Support documents (EPA 2003a, 2009) provide directions for the derivation of national BAF factors, EPA has, as yet, not calculated any BAFs for individual chemicals. Instead, when calculating national HHAWQC, EPA has replaced the factor "ΣFI_i*BAF_i" with the factor "FI*BCF," where BCF is the bioconcentration factor. A BCF is defined in the HHAWQC methodology document (2000a) as the ratio (in L/kg tissue) of the concentration of a substance in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does

not change substantially over time. Like the BAF, the BCF represents a ratio that relates the concentration of a chemical in water to its expected concentration in commonly consumed aquatic organisms, but unlike the BAF, it does not consider uptake from the diet or potential sources such as sediments. BAFs are intended to be reflective of real environmental exposures and thus also reflect factors such as bioavailability and biodegradation. Thus, BAFs can be higher or lower than BCFs.

The factor FI*BCF is a single calculation rather than the summing of multiple trophic levels. In the most recent National Recommended Water Quality Criteria: 2002, Human Health Criteria Calculation Matrix tables, the BCF values used are accompanied by a footnote that reads, "The fish tissue bioconcentration factor (BCF) from the 1980 criteria documents was retained unless otherwise noted" (EPA 2002b).

States are free to calculate their own site-specific BAFs or follow the current EPA practice of using BCFs.

5.6 Implicit Elements in the Derivation of HHAWQC

The derivation of HHAWQC incorporates assumptions about exposure that are not explicitly recognized in the formal equations shown in Table 3.1. These include bioavailability, cooking loss, exposure duration, and exposure concentration.

5.6.1 *Relative Bioavailability*

Bioavailability may be defined as the degree to which a substance contained in water, food, soil, air, or other media can be absorbed by living organisms. Bioavailability is an important component of toxicity assessment since absorption is an essential prerequisite to systemic toxicity and the degree of bioavailability is an important determinant of the ultimate exposure level. EPA's recommendations for the derivation of HHAWQC do not account for the bioavailability of substances and thus implicit is the assumption that the bioavailability of chemical substances in drinking water and fish tissue obtained from regulated waterbodies is the same as the bioavailability of those chemical substances in the studies from which the toxicity parameters (RfD, POD, cancer potency factor) were derived.

5.6.2 *Cooking Loss*

Chemical substances that may be present in fish tissue can be lost as part of the cooking process. Many substances that accumulate in fish tissues are associated with the lipid (i.e., fatty) content in the tissues. Most cooking practices result in partial loss of lipid and associated chemical substances. Other substances may be volatilized during the cooking process.

EPA's recommendations for the derivation of HHAWQC do not account for chemical loss during cooking. Thus implicit is the assumption that 100% of chemical substances present in raw fish remain in edible portions of fish tissue after cooking.

5.6.3 *Exposure Duration*

EPA's intentions for HHAWQC are to "minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposures to substances through the ingestion of drinking water and consumption of fish obtained from surface waters" (EPA 2000a). Lifetime exposure is assumed to be 70 years. Thus the derivation of HHAWQC implicitly assumes that exposure to the criteria substance occurs continuously over 70 years.

5.6.4 *Exposure Concentration*

The combination of explicit toxicity and exposure elements as typically used in the HHAWQC derivation equation act to form an implicit assumption that the average concentration of regulated

substances in water and fish tissue exist in the environment at their maximum allowed concentrations at all times over the course of a person's lifetime (presumed to be 70 years).

6.0 PROTECTIVENESS, CONSERVATISM, AND THE COMBINED EFFECT OF CONSERVATIVE PARAMETER VALUE CHOICES IN DERIVATION OF HHAWQC

The Clean Water Act, from which authority for the designation of HHAWQC is derived, specifies, in a very broad sense, the level of protectiveness that should be embodied in the HHAWQC. The Clean Water Act includes language such as "protect the public health and welfare," "protect public health… from any reasonably anticipated adverse effects of each pollutant," and "[not] pose an unacceptable risk to human health."

In its HHAWQC methodology document, EPA provides another fairly broad description of its desired level of protectiveness: "Water quality criteria are derived to establish ambient concentrations of pollutants which, if not exceeded, will protect the general population from adverse health impacts from those pollutants due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities" (EPA 2000a). They also note that HHAWQC are usually derived to protect the majority of the general population from chronic adverse health effects and that they consider their target protection goal to be satisfied if the population as a whole will be adequately protected by the human health criteria when the criteria are met in ambient water (EPA 2000a).

In order to derive HHAWQC that are "adequately protective," EPA states that they have selected default parameter values that are "a combination of median values, mean values, and percentile estimates [that target] the high end of the general population" (EPA 2000a). EPA (2000a) "believes that this is reasonably conservative and appropriate to meet the goals of the CWA…"

The term "conservatism," in the context of derivation of HHAWQC, is used to describe the use of assumptions and defaults that are likely to overstate the true risks from exposure to substances in drinking water and fish tissues. The policy choice to use such overstatements is rooted in EPA's approach to dealing with uncertainty and variability in the data upon which defaults and assumptions are based.

Uncertainty is an inherent property of scientific data and thus of the process of risk assessment and the derivation of HHAWQC. Since uncertainty is due to lack of knowledge, it can be reduced by the collection of additional data, but never eliminated completely. Variability is an inherent characteristic of a population because people vary in their levels and types of exposures and their susceptibility to potentially harmful effects of the exposures (NRC 2009). Unlike uncertainty, variability cannot be reduced but can be better characterized with improved information (NRC 2009).

In a staff paper[3] on risk assessment principles and practices, EPA (2004) discussed its approach to dealing with uncertainty and variability:

> Since uncertainty and variability are present in risk assessments, EPA usually incorporates a "high-end" hazard and/or exposure level in order to ensure an adequate margin of safety for most of the potentially exposed, susceptible population, or ecosystem. EPA's high-end levels are around 90% and above…

[3] Staff paper prepared by the Risk Assessment Task Force through the Office of the Science Advisor at EPA. The document presents an analysis of EPA's general risk assessment practices.

> …EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks. This policy position prompts risk assessments to take a more "protective" stance given the underlying uncertainty with the risk estimates generated. Another framing policy position is that EPA will examine and report on the upper end of a range of risks or exposures when we are not very certain about where the particular risk lies… Further, when several parameters are assessed, upper-end values and/or central tendency values are generally combined to generate a risk estimate that falls within the higher end of the population risk range.
>
> [The] issue regarding the appropriate degree of "conservatism" in EPA's risk assessments has been a concern from the inception of the formal risk assessment process and has been a major part of the discussion and comments surrounding risk assessment…

Given the attention focused on the issue of "the appropriate degree of conservatism," it is not surprising that many researchers have studied ways in which uncertainty and variability can be better characterized and reduced, with the ultimate goal of developing risk estimates that better achieve EPA's stated goals of neither underestimating nor grossly overestimating risk without the use of highly conservative default assumptions. The sections below summarize some of these efforts and, where data are available, attempt to quantify the level of conservatism embodied in EPA's current policy choices related to the selection of parameters for use in calculating HHAWQC.

As means of examining the implications of conservatism embodied in the HHAWQC derivation process, several examples are presented in the following sections. The example substances, which include mercury, arsenic, methyl bromide, chlordane, bis (2-ethylhexyl)-phthalate (or BEHP), and polychlorinated biphenyls (PCBs), were chosen for illustration purposes because they represent broad chemical categories (e.g., metals and organics), current and legacy substances, and substances with low and high bioconcentration factors.

6.1 Toxicity Factors

Derivation of an RfD, selection of a POD and UFs, modeling the dose-response for carcinogens, and calculating the slope factor (m) are based on science, but also involve a variety of policy decisions. These policy decisions all embody some degree of conservatism. This section addresses in greater detail the conservatism associated with the lack of consideration of bioavailability and the selection of default values for uncertainty factors and cancer risk levels.

6.1.1 *Relative Bioavailability*

As noted in Section 5, an implicit assumption in the HHAWQC derivation equation is that the bioavailability of chemical substances in drinking water and fish tissue obtained from regulated waterbodies is the same as the bioavailability of those chemical substances in the studies from which the toxicity parameters (RfD, POD, cancer potency factor) were derived. However, a RfD is often based on an animal toxicity study in which exposures occurred via drinking water and for some substances, the bioavailability from fish tissue will be different from that from drinking water. In some cases, bioavailability from foods might be reduced by, for example, the formation of indigestible complexes with other food components or conversion to ionized forms that cannot pass through biological membranes and thus cannot be absorbed. For example, arsenic in drinking water is primarily inorganic arsenic, which is absorbed well, but almost all of the arsenic in fish tissues is organic arsenic, which is not highly bioavailable. Arsenic may also form insoluble complexes with, for example, iron, aluminum, and magnesium oxides, which limits bioavailability. For these substances, any particular dose consumed in fish tissue would result in a lower absorbed dose than the same dose consumed in drinking water. Thus, a RfD based on a drinking water study would be lower than a RfD based on a dose administered in fish tissue. Use of this lower RfD will overestimate the

potential hazards associated with the ingestion of fish tissue and will yield a lower HHAWQC (see, e.g., EPA 2000b).

EPA rarely provides information on the potential impacts of bioavailability on their RfDs and does not typically calculate alternative RfDs that might be used when expected exposures are via a route that is likely to result in reduced bioavailability. For example, most inorganic contaminants, particularly divalent cations, have bioavailability values of 20 percent or less from a food matrix, but are much more available (about 80 percent or higher) from drinking water (EPA 2000b). The Technical Support Document Volume 1: Risk Assessment (EPA 2000b) for the HHAWQC methodology document (EPA 2000a) does allow for the selection of an alternative RfD in cases where there is lower bioavailability of the contaminant when ingested in fish than when ingested in water and the existing RfD is based on a study in which the contaminant was administered through drinking water. However, in actual practice, this has not been done.

6.1.2 *Uncertainty Factors*

The UF methodology, which has its origins in the concept of "safety factors," has been the subject of discussion among scientists in many forums over the years. One of the most common issues of discussion is the scientific basis for the default factor of 10. It is generally accepted that selection of the first safety factors was based on qualitative judgment (Nair et al. 1995). Subsequently, however, attempts were made to justify the use of 10-fold factors based on data collected to characterize the uncertainty and variability associated with parameters such as intra- and interspecies differences.

One commonly accepted justification for the selection of 10 as the standard default uncertainty factor is that for any given chemical, the dose at which the endpoint of concern will be observed in the population of concern (e.g., the most sensitive subpopulation of humans) will be less than 10 times higher than the dose at which the endpoint of concern will be observed in the population that serves as a surrogate (e.g., average humans) for the purposes of deriving an RfD (Dourson et al. 1996).

The degree of conservatism embodied in the use of default factors of 10 has been examined by researchers who have summarized published data and determined the actual distributions of these ratios. Dourson et al. (1996) noted that "there is growing sentiment that …routine application [of 10-fold UFs] often results in overly conservative risk assessments."

For example, Nessel et al. (1995) were interested in the scientific basis for the application of an uncertainty factor of 10 when using a sub-chronic study instead of a chronic study to derive the RfD. The underlying assumption is that for any given chemical, the NOAELs and LOAELs of sub-chronic studies will be within a factor of 10 of the NOAELs and LOAELs of chronic studies. So, Nessel et al. (1995) compared NOAELs and LOAELs from 23 different sub-chronic oral toxicity studies to the NOAELs and LOAELs of chronic studies that were identical except for the study duration. The mean and median $NOAEL_{subchronic}/NOAEL_{chronic}$ ratios were 2.4 and 2.0, respectively. Twenty-two of the 23 studies had NOAEL ratios of 5 or less; only one had a ratio of 10. The LOAEL ratios' mean and median were also 2.4 and 2.0, with all 23 studies having $LOAEL_{subchronic}/LOAEL_{chronic}$ ratio of 5 or less. So, based on this study, an uncertainty factor of 5 is sufficient to account for differences between sub-chronic and chronic studies in 98% of studies. Kadry et al. (1995) reported similar findings as did the review conducted by Dourson et al. (1996).

Similarly, differences between LOAELs and NOAELs are typically less than 10 fold. Ninety-six percent of all LOAEL-to-NOAEL ratios in one study were 5 or less and 91% were 6 or less in another (summarized by Dourson et al. 1996). Kadry et al. (1995) reported similar findings.

The decision to use conservative default UFs has particular significance on the overall conservatism of the RfD that is derived using the UFs. Gaylor and Kodell (2000) examined this issue and quantified the increasing degree of conservatism as the number of default UFs applied increases.

When ratios are calculated for UFs as described in the two previous paragraphs, the distributions of these ratios are lognormal, with the value of 10 typically representing the 95th percentile (Swartout et al. 1998). Gaylor and Kodel (2000) calculated the uncertainty factors that would be required to maintain an overall 95th percentile level when multiple default uncertainty factors are applied. They found that for the use of any two UFs, for which the current default total UF would be 100, the UF required to maintain the 95th percentile level ranged from 46 to 85. For the use of any three UFs, for which the current default total UF would be 1000, the UF required to maintain the 95th percentile level ranged from 190 to 340. Swartout et al. (1998) conducted a similar analysis using a different technique and reported similar findings, concluding that default UFs of 100, 1000, and 3000, for application of two, three, and four UFs, respectively, can be replaced with UFs of 51, 234, and 1040, while maintaining the 95th percentile level.

If a composite UF calculated to maintain the desired 95th percentile level is used instead of the default values of 100, 1000, and 3000, the resultant RfD and subsequently calculated HHAWQC could be as much as 5x higher. For example, if the RfD for methyl bromide was calculated using an UF of 340 (the top of the range calculated by Gaylor and Kodel (2000)) instead of 1000, the RfD would be 0.0041 mg/kg/day rather than the existing value of 0.0014 mg/kg/day. This would yield a HHAWQC of 139 µg/L rather than 47 µg/L.

6.1.3 *Cancer Risk Levels*

EPA chose to use the one-in-one-million (10^{-6}) risk level as the default value when calculating HHAWQC because it believes this risk level "reflects an appropriate risk for the general population" (EPA 2000a). However, EPA (2000a) also notes that risk levels of 10^{-5} for the general population and 10^{-4} for highly exposed populations are acceptable.

The frequent use of the 10^{-6} risk level to represent "an appropriate risk for the general population" appears to be simply a policy choice with no solid scientific basis. In a paper[4] presented at the 84th Annual Meeting of the Air & Waste Management Association in 1991, Kelly reported that:

> …despite its widespread use: no agencies we contacted could provide documentation on the origins of 10^{-6}; its origin was determined to be a completely arbitrary figure adopted by the FDA as an "essentially zero" level of risk for residues of animal drugs; there was virtually no public debate on the appropriateness of this level despite requests by the FDA; this legislation stated that 10^{-6} was specifically not intended to be used as a definition of acceptable risk; 10^{-6} is almost exclusively applied to contaminants perceived to be of great risk (hazardous waste sites, pesticides); and 10^{-6} as a single criterion of "acceptable risk" is not and has never been in any EPA legislation or guidance documents.

The decision of which cancer risk level to use in any particular circumstance is, for the most part, something that has evolved over many years through policy positions put forth in various EPA reports and legislation, but the idea that cancer risk levels between 10^{-6} and 10^{-4} are acceptable have become widely accepted among the different EPA programs. For example, the 1990 Clean Air Act Amendments endorse a 1989 EPA assessment for benzene in which EPA identified 1 in 10 thousand (10^{-4}) as being an "acceptable" risk level and 1 in a million (10^{-6}) as representing "an ample margin of safety." An EPA Region 8 superfund site discussion[5] stated that:

> In general, the USEPA considers excess cancer risks that are below about 1 chance in 1,000,000 (1×10^{-6} or 1E-06) to be so small as to be negligible, and risks above 1E-04 to be

[4] Available online at http://www.deltatoxicology.com/pdf/10-6.pdf
[5] http://www.epa.gov/region8/r8risk/hh_risk.html

> sufficiently large that some sort of remediation is desirable. Excess cancer risks that range between 1E-06 and 1E-04 are generally considered to be acceptable, although this is evaluated on a case-by-case basis and EPA may determine that risks lower than 1E-04 are not sufficiently protective and warrant remedial action.

Jones-Otazo et al. (2005) compared screening level risk assessment practices among different regulatory agencies and found that most have adopted acceptable risk levels in the same range as EPA. The European Union (EU) and World Health Organization (WHO) both identify risks in the range of 10^{-6} to 10^{-4} as acceptable, while Health Canada uses 10^{-5} as their acceptable risk level (Jones-Otazo et al. 2005). With respect to cancer risks associated with pollutants in drinking water, WHO uses a 10^{-5} risk level: "In this and previous editions of the Guidelines [for Drinking Water Quality], an upper-bound excess lifetime risk of cancer of 10^{-5} has been used, while accepting that this is a conservative position and almost certainly overestimates the true risk" (WHO 2008).

Population Risk - One factor that has a significant effect on the magnitude of acceptable risk is the size of the affected population. Exposure of a population of 1 million to a carcinogen at the risk level of 1 in a million theoretically results in one additional case of cancer among those 1 million people over the course of 70 years. If the size of the population of concern is decreased to 100,000 instead of 1 million, the theoretical additional cases of cancer among those 100,000 individuals decreases to only 0.1 case over the course of 70 years. Population risk is an important consideration in selecting a fish intake rate for use in developing AWQC because as the size of the exposed population decreases, the population risks also decrease when the same target risk level is used. The higher the FI rate selected for a particular population, the smaller the population to which that rate applies. For example, if the FI rate selected is a 95th percentile rate, it is assumed that it is protective of all but 5 percent of the exposed population or 50,000 of the 1 million people provided in the example above. Thus, if the same target risk level of 1E-06 is used with this reduced population, the resulting population risk is 0.05 excess cancers within a population of 1 million people. In other words, in order to reach the target risk of 1 excess cancer, it would be necessary for a population of 20 million people to have lifetime exposures equivalent to the estimated exposure conditions. This topic is discussed in much greater detail in Appendix A, Section 4.0 Population Risk.

This concept is particularly relevant to HHAWQC derivation because very small populations of fish consumers with high intake rates are frequently identified as being of special concern during the HHAWQC derivation process. The HHAWQC methodology document states that a risk level of 10^{-4} for highly exposed populations is acceptable (EPA 2000a). This is sometimes interpreted as meaning that highly exposed populations are not as well protected by the HHAWQC. However, as noted by Kocher (1996) in a discussion of cancer risks at hazardous waste sites, "if only a small population would be at greatest risk, the expected number of excess cancers corresponding to individual risks at the *de minimis* level of 10^{-4} would still be [essentially] zero." Travis et al. (1987) reviewed 132 federal regulatory decisions and concluded that in actual practice, for small population risks, the *de minimis* lifetime risk was considered to be 10^{-4}.

Given that the 10^{-4} risk level has been identified as an acceptable/*de minimis* risk level for highly exposed populations, it may be useful to consider exactly what that risk level represents in terms of FI. If the default FI of 17.5 g/day represents a 10^{-6} target risk level, then a highly exposed population that eats as much as 1750 g/day will still be protected at a 10^{-4} risk level.

6.2 Explicit and Implicit Exposure Factors

The specific exposure factors that EPA uses in the derivation of HHAWQC include human body weight, drinking water consumption rates, and fish ingestion rates. In the HHAWQC methodology document, EPA states that the selection of specific exposure factors is "based on both science policy decisions that consider the best available data, as well as risk management judgments regarding the

overall protection afforded by the choice in the derivation of AWQC" (EPA 2000a). This section addresses the levels of conservatism represented by the default values selected by EPA for individual explicit and implicit exposure factors.

6.2.1 *RSC*

The RSC determines what portion of the RfD will be allocated to the consumption of water and fish from regulated waterbodies. For example, if the RfD for a particular substance is 1 mg/kg/day and the RSC is 20%, then the HHAWQC must be set such that exposures to that substance via water and fish can be no more than 0.2 mg/kg/day. Thus, the lower the RSC, the lower the HHAWQC that will be derived.

Although EPA (2000a) does provide a decision tree methodology for calculating chemical- or site-specific RSCs, the lowest allowable value, 20%, is specified as the default RSC by EPA in its calculations of HHAWQC. EPA explains this in the HHAWQC methodology document (EPA 2000a) with the statement that "[the default value of 20%] is likely to be used infrequently with the Exposure Decision Tree approach, given that the information [required to calculate a chemical-specific RSC]…should be available in most cases. However, EPA intends to use 20 percent…" This statement clearly indicates that for most chemicals, an RSC greater than 20% is appropriate, but EPA has chosen to use the most conservative 20% default value. Use of an RSC of 20% when data indicate that a larger percentage is more appropriate can result in as much as a 4-fold reduction in the HHAWQC.

The California Office of Environmental Health Hazard Assessment (OEHHA) concluded that the default use of an RSC of 20% is "unreasonably conservative for most chemicals" (Howd et al. 2004). For 22 of the 57 chemicals listed by Howd et al. (2004), a RSC value greater than 20% was used in the calculation of California Public Health Goals for those chemicals in drinking water. Howd et al. (2004) also noted that "[a] default RSC of 0.2 is based on tradition, not data."

A recent Government Accountability Office report (GAO (2011) calculated the effect of using different RSC factors on the determination of drinking water health reference levels (HRLs) for a hypothetical chemical with an RfD of 0.5 µg/kg/day. While holding all other variables constant, RSC values of 20%, 50%, and 80% were inserted into the equation. The corresponding HRLs were 3.5 ppb (20%), 8.8 ppb (50%), and 14 ppb (80%).

A RSC may be calculated in two ways. The subtraction method allocates 100% of the RfD among the various sources of exposure. So, the daily exposure from all exposure routes other than drinking water and fish consumption are first subtracted from the RfD, then the remainder of the RfD is allocated to drinking water and fish consumption. The percentage method does not attempt to quantify exposures from other sources, but rather simply allocates a percentage of total exposure to drinking water plus fish consumption and to other sources.

EPA has chosen to use the percentage method as the default approach. EPA states that in most cases, they lack adequate data to use the subtraction method and that the percentage method is more appropriate for situations in which multiple media criteria exist (EPA 2000a). The GAO report (GAO 2011) notes that the percentage method is considered to be the more conservative option and generally yields a lower water quality criteria value. The GAO illustrated the difference in outcome by using the data for a hypothetical chemical to calculate drinking water health reference values (HRV) using both methods. Using the subtraction method, the HRV was 12.3 ppb. Using the percentage method, the HRV was 8.8 ppb, a 1.4-fold reduction.

6.2.2 *Body Weight*

The HHAWQC methodology document (EPA 2000a) recommends using a BW of 70 kg. This number was chosen in part because it is in the range of average values for adults reported in several studies and in part because it is the default body weight used in IRIS calculations. However, in 2011, EPA released an updated edition of the Exposure Factors Handbook (EPA 2011b). Based on data from the National Health and Nutrition Examination Survey (NHANES) 1999-2006, the new handbook recommends a mean BW value of 80 kg for adults.

The RfD is defined as "an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime" (EPA 2000b). The RfD expresses this daily exposure as a function of body weight (mg of chemical per kg of body weight), so the daily exposure that is likely to be without appreciable risk will be lower for an individual with a lower body weight than for an individual with a higher body weight. Thus, the lower the body weight used in the calculation of the HHAWQC, the lower the resulting criteria. For this reason, the choice to use 70 kg as the default body weight adds to the conservatism of the HHAWQC and yields criteria values approximately 12.5% lower than those calculated using the more accurate population mean of about 80 kg BW recommended by EPA in the latest Exposure Factors Handbook (EPA 2011b).

6.2.3 *Drinking Water Intake*

EPA (2000a) cites several reasons for including the drinking water exposure pathway in the derivation of HHAWQC:

(1) Drinking water is a designated use for surface waters under the CWA and, therefore, criteria are needed to assure that this designated use can be protected and maintained.

(2) Although rare, there are some public water supplies that provide drinking water from surface water sources without treatment.

(3) Even among the majority of water supplies that do treat surface waters, existing treatments may not necessarily be effective for reducing levels of particular contaminants.

(4) In consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users to bear the costs of upgraded or supplemental water treatment.

These reasons make it clear that 2 L/day was selected as the default water consumption rate in support of larger goals related to pollution prevention and maintenance of designated use and does not represent a consideration of actual direct risk of adverse effect to any individual consumer. As EPA itself noted, it would be rare for anyone to use untreated surface water as a source of drinking water. The only direct consumption of untreated surface waters that might be considered to be routine is incidental ingestion during swimming, for which the EPA (2011b) recommended upper percentile default rates are 120 mL/hr for children and 71 mL/hour for adults. Using the 95^{th} percentile estimate for time spent swimming each month (181 minutes) (EPA 2011b), annual daily average water consumption rates of 0.012 L/day (children) and 0.007 L/day (adults) can be calculated.

The default water consumption rate of 2L/day represents reported consumption of water from "community water," which is defined as tap water from a community or municipal water source. It does not represent a realistic level of consumption of untreated surface waters, which is likely to occur only as an incidental event of water-related recreational activities. However, by using 2 L/day in the calculation of the HHAWQC, EPA is deriving criteria values that are based on the assumption

that the general population is indeed consuming 2 L/day of untreated surface water. Thus, the use of 2 L/day in the HHAWQC can insert a significant level of conservatism into the calculations.

The impact of the use of 2 L/day varies according to the BAF/BCF of the chemical. For chemicals with high BAFs/BCFs, the impact of drinking water intake on the ultimate HHAWQC is minimal due to the much larger contribution of the "fish intake x BAF" factor in the equation. However, for substances with low BAFs/BCFs, the impact is much greater. Table 6.1 shows the effect of changing drinking water intake rates on the HHAWQC of some example compounds with different BCFs.

Table 6.1 Human Health Ambient Water Quality Criteria Calculated for Varying Drinking Water Intakes

		HHAWQC (µg/L)		
Compound	BCF	DI = 2L/day (current default)	DI = 1L/day (mean DI for adults[1])	DI = 0.007L/day (ingestion while swimming)
Methyl bromide	3.75	47.4	91.96	1,349.40
Arsenic	44	0.017	0.031	0.137
BEHP[2]	130	1.17	1.53	2.19
Chlordane	14100	0.000804	0.000807	0.000811
PCBs	31200	0.0000639	0.0000640	0.0000641

[1]EPA 2011
[2]Bis(2-ethylhexyl)-phthalate

6.2.4 *Fish Consumption*

Note: Appendix A of this document contains a thorough treatment of topics related to the collection and interpretation of data used for deriving fish intake rates (FIs) (or fish consumption rates, FCRs) and applied in the derivation of HHAWQC. The appendix was prepared by Ellen Ebert, a recognized expert on interpretation of fish collection and consumption survey data.

Surveys of Fish Consumption - FIs tend to be overestimated in most surveys for a number of reasons. Individuals who respond to surveys with long recall periods tend to overestimate their participation in activities that are pleasurable to them. Creel surveys tend to be biased toward higher representation of more avid anglers who have high success rates and, thus, may consume at higher rates than the typical angler population. Short-term diet recall surveys tend to incorrectly classify people who eat a particular type of food infrequently as "non-consumers" and overestimate consumption by "consumers." Often people classified as "non-consumers" are excluded from the summary statistics of short-term diet recall survey resulting in an overestimate for ingestion rates for the entire survey population. Finally, when specific information is lacking from survey data, decisions are generally made during analysis of the survey data to ensure that consumption will not be underestimated (e.g., relatively large meal sizes will be substituted for unknown meal sizes, frequency of meals reported will be assumed to be consistent throughout the year regardless of fishing season, etc.) More detailed discussion of surveys used to determine FIs may be found in Appendix A.

Consumption of Marine and Imported Fish - As noted in Section 5.4 above, EPA's HHAWQC methodology document recommends that fish consumption rates be based on consumption of

freshwater and estuarine species only and that any consumption of marine species of fish should be accounted for in the calculation of the RSC (EPA 2000a). However, the surveys used as the basis for EPA's recommended default fish consumptions rates collected information on the total consumption of fish of any species and from all sources, e.g., purchased or sport-caught fresh, frozen, or canned fish from local, domestic, or international sources (EPA 2011b). Surveys that collect information on the specific species consumed reveal that the majority of finfish consumed by Americans are marine species (Table 6.2). Also, as reported by the NOAA Fisheries Service[6], most of the seafood consumed in the U.S. is not caught in U.S. waters. In fact, about 86 percent of the seafood consumed in the U.S. is imported. Thus, the fish consumption rate used in the calculation of HHWQC significantly overestimates consumption of fish from regulated freshwater/estuarine waters by the majority of the population.

Table 6.2 Per Capita Consumption of Seafood in the U.S. – Top 10 Species (MBA 2011)

Type of Seafood	Pounds Consumed per Person/Year	Additional Comments
Shrimp	4	85% imported, mostly farmed, some wild caught
Canned tuna	2.7	Marine species
Salmon	2	Marine species
Tilapia	1.5	Farmed fish, most are imported
Pollack	1.2	Marine species
Catfish	0.8	Farmed fish, from both domestic and imported sources
Crab	0.6	
Cod	0.5	Marine species
Pangasius	0.4	Primary source is fish farms in Asia
Clams	0.3	

Additional discussion of the basis for excluding marine fish from fish consumption rate determinations may be found in Appendix B, which addresses issues relevant to the accumulation of persistent, bioaccumulative, and toxic chemicals by salmon in the context of the development of fish consumption rates in the state of Washington.

Consumption of Fish from Regulated Waters - Default assumptions that the general population consumes fish taken from contaminated water bodies every day and year of their entire life represent additional conservative assumptions. When applied to establishing permit limits or the risk

[6] http://www.noaanews.noaa.gov/stories2011/20110907_usfisheriesreport.html

assessment of a specific site or waterbody, the HHAWQC inherently assumes that 100 percent of the fish consumed over a lifetime are taken from that waterbody. This may be a reasonable assumption when the chemical constituents of concern are ubiquitous so that it is possible that individuals might receive similar levels of exposure even if they fish multiple waterbodies, but is likely to overestimate potential risk when applied to a single waterbody or one that is unique in terms of its chemical concentration or sources of the chemical in question. While it is possible individuals could obtain 100 percent of their fish from a single waterbody, this is not typical unless the waterbody is very large or represents a highly desirable fishery. In addition, individuals are likely to move many times during their lifetimes and, as a result of those moves, may change their fishing locations and the sources of the fish they consume. Finally, it is likely that most anglers will not fish every year of their lives. Health issues and other demands, like work and family obligations, will likely result in no fishing activities or reduced fishing activities during certain periods of time that they live in a given area. Thus, these assumptions add conservatism to the derivation of HHAWQC.

Implied Harvest Rate - EPA's default rate of 17.5 g/day indicates the amount of fish that is actually consumed. In order to achieve that rate, one must harvest 58 g/day of whole fish [assuming EPA's recommended edible portion of 30 percent (EPA 1989)] to yield 17.5 g/day of edible fish. When annualized, this results in 21,300 grams of fish per person or 47 pounds of fish per consumer per year. When considered over the 70-year exposure period (as assumed in the HHAWQC calculation), this results in the total removal of 3,300 pounds of fish/person during that period. In addition, if that individual is providing fish to a family of four, it would be necessary to remove roughly 13,000 pounds of fish from a single waterbody during that 70-year span. This represents a significant level of fishing effort and harvest and likely represents a substantial overestimate of any actual fish that is likely to be harvested from a single waterbody by a single individual.

Source of HHAWQC Default FIs - The food intake survey upon which the default fish consumption rates were based were short-term surveys. Numerous researchers have reported that the long-term average daily intake of a food cannot be determined using these short-term cross-sectional surveys (Tran et al. 2004). The use of short-term surveys has been shown to overestimate long-term food intakes in the upper percentile ranges (Tran et al. 2004) that are typically used by EPA in exposure assessments, especially for infrequently consumed foods (Lambe and Kearney 1999) like fish. Additional discussion of the limitations of the use of short-term survey data on fish consumption may be found in Appendix A, Section 3.2.2.

Summary - The fish consumption rates used in calculating HHAWQC can have a significant impact on the resulting HHAWQC. This is because the HHAWQC are proportional to the fish consumption rates (as the rate increases, the HHAWQC decreases) and there is substantial variability in the rates of fish consumption among the consuming population. In addition, the potential exposure through the fish consumption pathway is dependent upon a number of different variables including the types of fish consumed, the sources of those fish, and the rates at which they are consumed. The quantification of fish consumption rates is complicated by the methods used to collect consumption information, the availability of fish from regulated sources, and the habits of the targeted population of fish consumers.

The selection of fish consumption rates when calculating HHAWQC is discussed in more detail in Appendix A.

6.2.5 *Cooking Loss*

The derivation of HHAWQC is based on the assumption that there will be no loss of chemicals from fish tissues during the cooking process. However, numerous studies have shown that cooking reduces the levels of some chemicals. For example, Zabik et al. (1995) reported that cooking significantly reduced levels of the DDT complex, dieldrin, hexachlorobenzene, the chlordane complex, toxaphene,

heptachlor epoxide, and total PCBs. Similarly, Sherer and Price (1993), in a review of published studies, reported that cooking processes such as baking, broiling, microwaving, poaching, and roasting removed 20-30% of the PCBs while frying removed more than 50%.

In its development of Fish Contaminant Goals (FCGs) and Advisory Tissue Levels, the State of California uses a cooking reduction factor to account for cooking loses for some chemicals:

> FCGs take into account organochlorine contaminant loss during the cooking process. The concentration of PCBs and other organic contaminants in fish are generally reduced by at least 30 percent, depending on cooking method… As such, a cooking reduction factor of 0.7 was included in the FCG equation for organic compounds (allowing for 70 percent of the contaminant to remain after cooking) (CA 2008).

By not incorporating a chemical-specific factor to adjust for cooking loss, the exposure level from fish consumption will be overestimated for organic compounds, thus lending an additional layer of conservatism to the resulting HHAWQC.

6.2.6 *Exposure Duration*

As noted in Section 5, exposure duration is an implicit element in the derivation of HHAWQC and a value of 70 years, or an approximate lifetime, is assumed. While average lifetimes may be approximated by 70 years, it is generally considered conservative to assume that an individual would be continuously exposed to substances managed through the development of HHAQWC because waters contaminated with such substances do not exist everywhere and it is unlikely that many persons would reside only in contaminated areas, and drink and fish only in these waters for an entire lifetime. Choosing to assume a 70-year exposure duration may be justified in cases where a pollutant is ubiquitous in the environment and thus it could reasonably be assumed that ingestion of drinking water and locally caught fish from essentially all freshwater locations would lead to similar levels of exposure. There is little evidence, however, supporting the ubiquity of most substances for which HHAWQC have been established (though an exception might be justified for mercury or other pollutants for which atmospheric deposition is the dominant mechanism contributing substances to surface waters).

Perhaps more significantly, however, it is uncommon for people to reside in a single location for their entire life. EPA's Exposure Factors Handbook (EPA 2011) contains activity factors, including data for residence time, from several US studies. Table 6.3 summarizes some of these results.

Table 6.3 Values for Population Mobility

	Mean	90th Percentile	95th Percentile
Residential Occupancy Period (Johnson and Capel 1992)	12 years	26 years	33 years
Current Residence Time (US Census Bureau 2008)	8 years (median) 13 years (mean)	32 years	46 years

As with other survey results, there is some uncertainty and potentially some bias associated with the residency periods reported in these studies. Additional studies are discussed (EPA 2011) concerning the distance people move, when they do move. However, the data clearly suggest that the central tendency (mean or median) and upper percentile values are substantially less than the 70 year

exposure period assumed by EPA. The assumption of a 70 exposure duration overestimates median exposure duration by 8-fold, mean exposure duration by approximately 6-fold and the 90th percentile by 2- to 3-fold. Thus, the choice to use 70 years is conservative for most non-ubiquitous chemicals. Table 6.4 shows the effect on some example HHAWQC when assuming exposure durations of 70 and 30 years.

Table 6.4 HHAWQC Calculated Based on 70 and 30 Year Exposure Durations

	HHAWQC (µg/L)	
Compound	70 year exposure duration	30 year exposure duration
Arsenic	0.017	0.040
BEHP	1.17	2.73
Chlordane	0.000804	0.00187
PCBs	0.0000639	0.000149

6.2.7 *Exposure Concentration*

As noted in Section 5, implicit with the derivation of HHAQWC is the assumption that both the water column and fish tissue concentrations exist at their maximum allowed values for the entire 70 year exposure duration. In reality, water column concentrations vary over time and space. The assumption that concentrations are always the maximum allowed is unnecessarily conservative as a practical matter because, as described in the following paragraphs, regulations governing water quality in the US would not allow a substance to persist in a water body at the HHAQWC concentration for such a period.

EPA's Impaired Waters and Total Maximum Daily Load Program provides guidance to states concerning when waters are considered to be impaired. The EPA guidance is not specific as to recommendations for identifying stream impairments due to exceedances of HHAWQC and many state impaired stream listing methodologies lack specific provisions unique to the basis for establishing HHAWQC (i.e., exposure over a 70 year lifetime). However, it is common that states will consider listing a stream that exceeds WQC for chronic aquatic life (i.e., the CCC) and human health more than 10% of the time (i.e., the "10% rule"). Indeed, EPA guidance for listing impaired surface waters (EPA 2003b) states:

> "Use of the '10% rule' in interpreting water quality data in comparison with chronic WQC will generally be more appropriate than its use when making attainment determinations where the relevant WQC is expressed "concentration never to exceed ___, at any time." Chronic WQC are always expressed as average concentrations over at least several days. (EPA's chronic WQC for toxics in freshwater environments are expressed as 4-day averages. On the other extreme, EPA's human health WQC for carcinogens are calculated based on a 70-year lifetime exposure period.) Using the '10% rule' to interpret data for comparison with chronic WQC will often be consistent with such WQC because it is unlikely to lead to the conclusion that water conditions are better than WQC when in fact, they are not."

The guidance above suggests that listing of waters using the 10% rule is likely to be over protective for chronic aquatic life criteria. That is, it is considered unlikely that a water exceeding the chronic WQC 10% or less of the time would exist, on average, at the criterion value for the 4-day averaging period on which chronic WQC are based. By this same logic, it is an essentially impossible scenario

that a water exceeding a HHAWQC 10% or less of the time would average at the criterion value for the 70 year averaging period on which HHAWQC are based.

It may be more realistic, instead, to predict a mean or median water column concentration using the HHAWQC as an upper percentile value occurring in the stream. Considering the 10% rule, one might predict the average water column concentration by assuming that the HHAWQC is the 90th percentile value in a distribution of water column concentrations existing over 70 years. By way of example, Table 6.5 illustrates the effect of variable stream concentrations on the ratio of the 90th percentile concentration to the mean concentration. An approximately normal distribution is assumed for these examples.

Table 6.5 Ratio of 90th Percentile Upper Bound Concentration to the Mean (normal distribution)

	Assumed Distribution	HHAWQC	Standard Deviation and Coefficient of Variation[1]	Estimated Mean[2]	Ratio HHAWQC/Mean
Substance X	Normal	1	0.25	0.68	1.5x
Substance Y	Normal	1	0.50	0.36	2.8x
Substance Z	Normal	1	0.60	0.23	4.3x

[1]The coefficient of variation (or relative standard deviation) is the ratio of the standard deviation to the mean and represents the degree of relative variability of the data around the mean.
[2]The 90th upper percentile of a normal distribution lies about 1.28 standard deviations from the mean.

The same general characteristic would be expected for stream concentrations that are log-normally distributed, which is a more common situation. Assuming that the values used in the normal distribution case in the previous table apply to the logarithms of the original data, a ratio of the antilogs of the HHAWQC (90th percentile value) and mean values in the normal distribution case can be calculated. Results are shown below in Table 6.6.

Table 6.6 Ratio of 90th Percentile Upper Bound Concentration to the Mean (lognormal distribution)

	Assumed Distribution	Antilog of HHAWQC	Standard Deviation of log concentrations	Estimated Geometric Mean[1]	Ratio HHAWQC/Geometric Mean
Subst. X	Lognormal	10	0.25	4.8	2.1x
Subst. Y	Lognormal	10	0.50	2.3	4.4x
Subst. Z	Lognormal	10	0.60	1.7	5.9x

[1]The geometric mean is equal to the antilog of the Estimated Mean in the normal distribution table.

As can be seen in Tables 6.5 and 6.6, the actual mean can be a small fraction of the upper 90th percentile value. In these examples the degree of conservatism embodied in the HHAWQC value ranges between 1.5x and 5.9x.

6.3 Compounded Conservatism

Compounded conservatism is the term used to describe the "impact of using conservative, upper-bound estimates of the values of multiple input variables in order to obtain a conservative estimate of risk…" (Bogen 1994). Bogen (1994) pointed out that "safety or conservatism initially assumed for each risk component may typically magnify, potentially quite dramatically, the resultant safety level of a corresponding final risk prediction based on upper-bound inputs." In the HHAWQC derivation process, compounded conservatism plays a role both in the determination of individual factors of the Equations 3.1, 3.2, and 3.3 (i.e., in the toxicity factors and explicit and implicit exposure elements) and in the equations' use of multiple factors, each based on upper bound limits and/or conservative assumptions.

In addition to the conservatism embodied in the selection of individual components of the calculations (both explicit and implicit), the fundamental underlying assumption, which is that the most sensitive subpopulations will be exposed to maximum allowable concentrations over a full lifetime, is a highly unlikely and highly protective scenario. For example, the derivation of HHAWQC is based on the assumptions that an individual will live in the same place for their entire life (70 years) and that 100% of the drinking water and fish consumed during those 70 years will come from the local water body being regulated.

The suggestion that the use of multiple default factors based on upper bound limits and/or conservative assumptions lead to a situation of compounded conservatism has been the subject of considerable discussion (see Section 6.0). However, in a staff paper, EPA suggests that "when exposure data or probabilistic simulations are not available, an exposure estimate that lies between the 90th percentile and the maximum exposure in the exposed population [should] be constructed by using maximum or near-maximum values for one or more of the most sensitive variables, leaving others at their mean values" (EPA 2004). This appears to be an acknowledgement that adequately protective assessments do not require that each, or even most, component parameter(s) be represented by a 90th or 95th percentile value.

Similarly, in the 2005 Cancer Risk Assessment Guidelines, EPA (2005) stated:

> Overly conservative assumptions, when combined, can lead to unrealistic estimates of risk. This means that when constructing estimates from a series of factors (e.g., emissions, exposure, and unit risk estimates) not all factors should be set to values that maximize exposure, dose, or effect, since this will almost always lead to an estimate that is above the 99th-percentile confidence level and may be of limited use to decision makers.

Viscusi et al. (1997) provided a simple example to illustrate compounded conservatism. In Superfund exposure assessments, EPA states that they consider "reasonable worst case" exposures to be in the 90-95th percentile range (Viscusi et al. 1997). However, the use of just three conservative default variables (i.e. 95th percentile values) yields a reasonable worst case exposure in the 99.78th percentile. Adding a fourth default variable increases the estimate to the 99.95th percentile value. In a survey of 141 Superfund sites, the authors reported that the use of conservative risk assessment parameters in site assessments yields estimated risks that are 27 times greater than those estimated using mean values for contaminant concentrations, exposure durations, and ingestion rates.

In a recent report on the economics of health risk assessment, Lichtenberg (2010) noted that the use of conservative default parameters is intended to deliberately introduce an upward bias into estimates of risk. Lichtenberg (2010) also stated that "the numbers generated by such procedures can't really be

thought of as estimates of risk, since they bear only a tenuous relationship to the probability that individuals will experience adverse health consequences or to the expected prevalence of adverse health consequences in the population." Indeed, he pointed out that the number of actual cancer deaths that can be attributed to all environmental and occupational causes is much lower than the number that is predicted by risk assessments (Doll and Peto 1981, as cited by Lichtenberg 2010). Lichtenberg (2010) describes concerns about compounded conservatism by saying:

> …regulators continue to patch together risk estimates using a mix of "conservative" estimates and default values of key parameters in the risk generation process. Such approaches give rise to the phenomenon of compounded conservatism: The resulting estimates correspond to the upper bound of a confidence interval whose probability is far, far greater than the probabilities of each of the components used to construct it and which depends on arbitrary factors like the number of parameters included in the risk assessment.

6.4 Summary

Most of the components of the equations used to calculate HHAWQC contain some level of conservatism. The toxicity factors in and of themselves contain multiple conservative parameters, leading to a compounding of conservatism in their derivation. The default RSC is the most conservative allowable level derived using the more conservative of two possible approaches. The default body weight of 70 kg is 10 kg less than the EPA currently recommended value of 80 kg. The derivation process for the HHAWQC does not take into account expected cooking losses of organic chemicals. The compounded conservatism that results from the use of multiple conservative factors yields a HHAWQC that provides a margin of safety that is considerably larger than EPA suggests is required to be protective of the population, even when sensitive or highly exposed individuals are considered. Tables 6.7 and 6.8 illustrate the impact of replacing just two default parameters, body weight and drinking water intake, with average values and allowing for cooking loss on the HHAWQC for methyl bromide and bis(2-ethylhexyl)-phthalate (BEHP).

Table 6.7 Impact of Multiple Conservative Defaults/Assumption on Methyl Bromide HHAWQC

Parameters Used	HHAWQC (µg/L)
Default	47
Factor of 0.7 included for cooking loss	48
Factor of 0.7 included for cooking loss + DI default (2 L/day) replaced by mean value of 1 L/day	94
Factor of 0.7 included for cooking loss + DI default (2 L/day) replaced by mean value of 1 L/day + Default BW of 70 kg replaced by current EPA recommended BW of 80 kg	107

Table 6.8 Impact of Multiple Conservative Defaults/Assumption on BEHP HHAWQC

Parameters Used	HHAWQC (µg/L)
Default	1.17
Factor of 0.7 included for cooking loss	1.39
Factor of 0.7 included for cooking loss + DI default (2 L/day) replaced by mean value of 1 L/day	1.93
Factor of 0.7 included for cooking loss + DI default (2 L/day) replaced by mean value of 1 L/day + Default BW of 70 kg replaced by current EPA recommended BW of 80 kg	2.20

Not only do the individual components of the equations represent a variety of conservative assumptions, the underlying premise upon which calculations of HHAWQC are based is itself highly conservative. It assumes that 100 percent of the fish and drinking water consumed by an individual over a 70 year period is obtained from a single waterbody (or that a chemical is ubiquitous in all water), that the chemical is present at the HHAWQC at all times, an individual consumes fish every year at the selected upper bound consumption rate, and that no loss of the chemical of interest occurs during cooking.

In addition, the toxicological criteria used to develop the HHAWQC have been selected to be protective of the most sensitive individuals within the exposed population and have been combined with conservative target risks. It is unlikely that this combination of assumptions is representative of the exposures and risks experienced by many, if any, individuals within the exposed population.

Tables 6.9 and 6.10 summarize the primary sources of conservatism found in both the explicit and implicit toxicity and exposure parameters of HHAWQC derivation and, for some parameters, quantify the extent of that conservatism.

Table 6.9 Conservatism in Explicit Toxicity and Exposure Parameters

Explicit Exposure Parameter	Default Value	Represents:	Default is conservative because:	Impact of conservatism on HHAWQC (if known)
RfD	N/A	Estimate of daily exposure likely to be without appreciable risk of adverse effects over a lifetime	Bioavailability not typically considered, effects of compounded conservatism in use of multiple UFs	Larger RfD yields higher HHAWQC, magnitude uncertain and varies between compounds
RSD	N/A	Dose associated with incremental risk level of 10^{-6}	based on upper bound risk estimate	Magnitude uncertain, varies between compounds
Relative Source Contribution (RSC)	20%	Fraction of total exposure attributable to freshwater/ estuarine fish	For most chemicals, available data support a larger RSC	Larger RSC yields 1.5x to 4x higher HHAWQC
Body Weight (BW)	70 kg	Adult weight, average for the general population	Mean body weight for adults is now 80 kg	Use of 80 kg yields 1.125x higher HHAWQC
Drinking Water Intake (DI)	2 L/day	86^{th} percentile of general population	Assumes all water consumed is at HHAWQC and that all drinking water is untreated surface water	Magnitude is compound specific[7]
Fish Intake (FI)	17.5 grams/ day for general population and sportfishers 142.4 grams/ day for subsistence fishers	90th percentile per capita consumption rate for the U.S. adult population	Represents an upper percentile, most people eat less fish	Magnitude is compound specific[8]
Bioconcentration Factor (BCF)	Substance specific	Tissue:water ratio at 3% tissue lipid	NA	NA

[7] HHAQWC are inversely proportional to DI value for substances with low BCFs. The DI value has very little influence on HHAWQC for substances with high BCFs.

[8] HHAQWC are inversely proportional to FI value for substances with high BCFs. The FI value has very little influence on HHAWQC for substances with low BCFs.

Table 6.10 Conservatism in Implicit Exposure Parameters

Implicit Exposure Parameter	Default Value	Represents:	Default is conservative because:	Impact of conservatism on HHAWQC (if known)
Cooking Loss	zero	loss of organic chemical during cooking	Does not account for the known 20-50% reduction in concentration of organic chemical in fish tissues following cooking	Inclusion of a factor to account for cooking loss yields 1.25x to 2x higher HHAWQC
Exposure Duration	70 years	Length of time a person is exposed	Assumes 100% of drinking water and fish consumed over the course of 70 years will come from a regulated water body	For non-ubiquitous compounds, recognizing that residency periods are much shorter than 70 years yields HHAQWC that are 2x to 8x higher.
Exposure Concentration	HHAWQC	Concentration in water body of interest equal to HHAWQC	Assumes concentration is always equal to HHAWQC without regard for changes in input or in flow characteristics	Magnitude uncertain but could easily be 1.5x to more than 4x
Relative Bioavailability	1	Bioavailability from fish and water compared to bioavailability in the experiment from which the toxicity benchmark was derived.	Some chemicals are less bioavailable in water or fish tissue than in the experiments from which toxicity benchmarks were derived.	Magnitude is chemical specific

7.0 IMPLICATIONS OF HHAWQC FOR FISH TISSUE CONCENTRATIONS AND CHEMICAL EXPOSURES VIA FISH CONSUMPTION

7.1 Fish Tissue Concentrations

The purpose for including factors for fish intake and bioaccumulation/bioconcentration in the derivation of HHAWQC is to account for consumption of chemicals that are contained within fish tissues. An underlying assumption of this approach is that the HHAWQC correspond to a chemical concentration in edible fish tissue that yields an acceptable daily intake when fish from surface waters

are consumed at the default intake rates (e.g., 17.5 g/day general population or 142 g/day subsistence anglers). Once a HHAWQC is calculated, the allowable fish tissue concentration (FTC) associated with that HHAWQC can be easily derived using the same equation. One way of assessing the overall conservatism of the process through which HHAWQC are derived is to compare the associated allowable fish tissue concentrations to existing fish tissue concentration data and concentrations found in other foods, as well as other guidelines or risk-based levels used to regulate chemical concentrations in edible fish tissues (e.g., fish consumption advisory "trigger levels," US Food and Drug Administration (FDA) tolerances).

Appendix C, "Fish Tissue Concentrations Allowed by USEPA Ambient Water Quality Criteria (AWQC): A Comparison with Other Regulatory Mechanisms Controlling Chemicals in Fish," illustrates this type of analysis using six example compounds: arsenic, methyl bromide, mercury (total, inorganic, organic), PCBS (total), chlordane, and bis-(2-ethylhexyl)phthalate (BEHP). The analysis revealed that:

- Concentrations of PCBs and mercury in fish from virtually all surface waters in the U.S. exceed FTCs associated with HHAWQC derived using the FI rate for subsistence anglers (142 g/day).
- FTCs associated with HHAWQC derived using the FI rate for the general public (17.5 g/day) are 20 times to 4,000 times lower (more stringent) than fish consumption advisory "trigger levels" commonly used by state programs.
- Although about 50% of fish samples collected during a national survey had PCB levels greater than the allowable PCB FTC associated with the HHAWQC, only about 15% of the nation's reservoirs and lakes (on a surface area basis) are subject to a fish consumption advisory. When the FI for subsistence anglers is used to calculate a HHAWQC for PCBs, the percentage of samples exceeding the associated FTC increases to 95%.
- The FDA food tolerances for PCBs, chlordane, and mercury in fish are, respectively, 500, 27, and 2.5 times greater than the FTCs associated with the HHAWQC for those chemicals. If the subsistence angler FI rate (142 g/day) is used to calculate the HHAWQC, the FDA food tolerances for those chemicals are, respectively, 4,000, 214, and 20 times greater.

These results indicate that, with respect to FTCs, the HHAWQC as they are currently calculated, with a default FI rate of 17.5 g/day, provides a wide margin of safety below the FTCs considered acceptable by states (as indicated by FCA trigger levels) and by the FDA (as indicated by food tolerances).

7.2 Chemical Exposures via Fish Consumption

Once the FTC associated with a HHAWQC is calculated, that value can also be used to estimate the allowable daily dose of that chemical. Comparing the allowable daily dose associated with HHAWQC with actual exposures to the general population via other sources provides an indication of the potential health benefits that might be gained by increasing the default fish consumption rate and thus lowering the HHAWQC. Appendix C shows the results of such a comparison for six example compounds (arsenic, methyl bromide, mercury (total, inorganic, organic), PCBS (total), chlordane, and BEHP and indicates that for all of these chemicals, exposure via consumption of fish from surface waters to which HHAWQC apply represents only a small percentage of the total exposure from all sources. Therefore, reducing exposures to chemicals via fish consumption by lowering HHAWQC may not provide any measurable health benefits.

8.0 CONCLUSIONS

HHAWQC are derived by EPA, or by authorized states or tribes, under the authority of Section 304(a) (1) of the Clean Water Act (CWA). The methodology by which HHAWQC are derived is based on equations that express a risk analysis. The values used in the HHAWQC equation are based on scientific observations (generally a range of observations) and, thus, have a scientific basis. However, the selection of a single value to represent the full range of observations represents a policy choice and is a subjective decision. Therefore, HHAWQC, though based on science, represent a policy (i.e., non-scientific) choice (EPA 2011a). EPA has stated that their goal in setting HHAWQC is to "protect individuals who represent high-end exposures (typically around the 90th percentile and above) or those who have some underlying biological sensitivity" (EPA 2004). To that end, its selections for individual default parameter values are typically upper percentiles of a distribution (e.g., a 90th percentiles value for fish consumption rate) or conservative assumptions (e.g., 100% of water used for drinking and cooking during a 70 year lifespan is untreated surface water).

The parameters used in the derivation of HHAWQC may be divided into two categories, toxicity parameters and exposure parameters. Toxicity parameters fall into three categories: 1.) non-carcinogenic effects, for which the parameter is the RfD, 2.) non-linear carcinogenic effects, for which the parameters are the POD and UF, and 3.) linear carcinogenic effects, for which the parameter is the RSD, which is derived from the slope factor and the target incremental cancer risk. Derivation of an RfD, selection of a POD and UFs, modeling the dose-response for carcinogenic effects, and calculating the slope factor (m) are based on science, but also involve a variety of policy decisions. These policy decisions all embody some degree of conservatism, such as the use of multiple 95th percentiles and upper bound confidence limits. Thus, the factors representing toxicity in the HHAWQC derivation equation certainly represent conservative (i.e., selected to more likely overestimate than underestimate risks) estimates of toxicity and act to drive HHAWQC toward lower concentrations.

Explicit exposure parameters include the RSC, BW, DI, FI, and BAF. There are also implicit parameters that, while not components of the equations used to calculate HHAWQC, are assumptions that underlie HHAWQC derivation. As with the toxicity parameters, most of the exposure parameters are based on scientific observations, generally a range of observations and thus have a scientific basis. However, selection of a single value to represent the full range of observations is a policy choice. Default values for these parameters and the degree of conservatism associated with them are summarized in Tables 6.9 and 6.10, which shows that these parameter values represent upper percentile values and highly conservative assumptions that act to drive HHAWQC toward lower concentrations.

EPA acknowledges in more recent guidance that the existence of the phenomenon of compounded conservatism, which occurs when the combination of multiple highly conservative assumptions leads to unrealistic estimates of risk. It suggests that in order to avoid this problem when constructing estimates from a series of factors (e.g., exposure and toxicity estimates), not all factors should be set to values that maximize exposure, dose, or effect (e.g., EPA 2005). However, in spite of that, most of the parameters used for the derivation of HHAWQC are set at the 90th (or higher) percentile level.

The overall level of conservatism embodied within the HHAWQC derivation process is illustrated by comparing the allowable fish tissue concentration implied by the designation of HHAWQC to existing guidelines or risk-based levels used to regulate chemical concentrations in edible fish tissues, such as fish consumption advisory "trigger levels" and US Food and Drug Administration (FDA) tolerances. Fish tissue concentrations associated with HHAWQC derived using the fish intake rate for the general public (17.5 g/day) are 20 times to 4,000 times lower (more stringent) than fish consumption advisory "trigger levels" commonly used by state programs. Similarly, FDA food tolerances for PCBs, chlordane, and mercury in fish are, respectively, 500, 27, and 2.5 times greater

than the HHAWQC-associated fish tissue concentrations and if the subsistence angler fish intake rate (142 g/day) is used to calculate the HHAWQC, the FDA food tolerances for those chemicals are, respectively, 4,000, 214, and 20 times greater.

Following a consideration of the overall level of conservatism contained within the HHAWQC, the level of protectiveness that EPA has indicated that states should achieve, and concerns that have been expressed by certain segments of the public and some state regulators and elected officials, three issues in particular seem to stand out. The first is the idea that HHAWQC represent an estimate of likely actual exposures to the public, such that, for example, if a HHAWQC is set at 42 ppb, the general public will be exposed to 42 ppb and therefore, any subgroups that may, e.g., consume more fish than average, will not be adequately protected by a 42 ppb HHAWQC. However, a consideration of the sources of the various parameters used to calculate the HHAWQC, as provided in preceding sections of this report, clearly shows that this is not the case.

The second is the idea that, because the HHAWQC for carcinogens are based on a 10^{-6} risk level for the general population, highly exposed subgroups whose risk level might be 10^{-5} or 10^{-4} are not being adequately protected. A consideration of the concept of population risk, as described in Section 6.1.3 demonstrates that this is not the case. Even if a small subgroup of the general population has higher exposures (e.g., higher rates of fish consumption), the expected number of excess cancers corresponding to individual risks at the 10^{-4} risk level is essentially zero. Indeed, in actual practice, in Federal regulatory decisions related to small population risks, the *de minimis* lifetime risk is typically considered to be 10^{-4}.

Finally, there is the belief that increasing the fish consumption rates used to derive HHAWQC which will, in turn, lower HHAWQC, will benefit public health, particularly for populations of high level consumers of fish from regulated surface waters. However, an analysis of six chemicals, selected to represent a range of chemical classes, clearly shows that exposures via consumption of fish from regulated water bodies is only a small percentage of the total dietary exposure from all sources. Thus, the establishment of more stringent HHAWQC may not provide any measurable public health benefit.

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APPENDIX A

FISH CONSUMPTION RATE (FCR)

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1.0 INTRODUCTION

A key component of the equation used to derive ambient water quality criteria (AWQC) is the long-term fish consumption rate (FCR). Selection of an appropriate FCR can be challenging for a number of reasons. In certain cases, there may not be relevant, local or regional fish consumption data available from which to select rates. In other instances, numerous studies of fish consumption behaviors may have been conducted, but the studies report a wide range of FCRs for similar consumer populations. Often, in light of the variability in FCRs, there is a tendency for regulators to select the most conservative (highest) of the available rates to ensure that HHAWQC will be protective of potentially exposed populations, thereby adding considerable conservative bias to the HHAWQC. While there is always variability in consumption rates due to differing behaviors among the consumers, in many cases, the variability among the reported rates for similar populations is a consequence of the survey design, methodology, and approach used to analyze the data, rather than actual variability in consumption rates. It is important to understand how the approaches used to collect and analyze fish consumption data may bias results so that the most appropriate and representative rates can be selected for the development of HHAWQC.

2.0 CURRENT EPA GUIDANCE

EPA's (2000) methodology for deriving AWQC recommends that, when available, consumption rates for populations of concern should be drawn from local or regional survey data. The consideration of local and regional survey data is important in deriving AWQC because these data may vary widely depending upon the waterbodies to which the AWQC will be applied, the population of individuals who may consume fish from those waterbodies, seasonal influences on fishing, availability of desirable species, and the particular consumption habits of those individuals. In many situations, the population of consumers may be the general population who consume fish from commercial sources; in other situations, the only consumers may be the population of fishermen who catch and consume their own fish from a particular waterbody. Typically, recreational fishermen are the population that is likely to consume the most fish from a specific waterbody as they may repeatedly fish that waterbody over time. This is a common rationale for using the habits of this population as a basis for deriving an FCR to be used in developing AWQC.

When local or regional survey data are not available, EPA has historically recommended that a default FCR of 17.5 g/day be used (EPA 2000). This rate is an estimate of the 90th percentile rate of consumption of freshwater and estuarine finfish and shellfish by adults in the general population of the United States. It is an annualized, long-term rate that indicates that the targeted population may consume roughly one half-pound fish meal every two weeks (28 meals/year) from the waterbodies to which the AWQC will be applied. It is based on the USDA's Continuing Food Studies data (USDA 1998) and is recommended by EPA for deriving AWQC because it represents an estimate of high end fish consumption by the general population and average consumption among sport anglers. If subsistence populations are present, EPA (2000) states that a default consumption rate of 142.4 g/day may be used. This rate indicates that this population may consume roughly 229 half-pound meals of fish per year or more than four meals per week.

In addition, EPA (2011) has evaluated a substantial portion of the fish consumption literature and has presented the results of its analysis in its revised *Exposure Factors Handbook*. This guidance presents

the findings of the studies and the estimates that EPA has derived based on its analysis of the data. A variety of recommended FCRs are presented for the general population of the United States, individuals who consume sport-caught fish from marine waters, individuals who consume sport-caught fish from freshwaters, and various subpopulations of fishermen. While the previous version of the *Exposure Factors Handbook* made specific recommendations of FCRs to be used, the revised version does not provide specific recommendations. Instead, it presents a range of values from studies that it identified as being relevant and reliable and instructs readers to select the value that is most relevant to their needs.

One difficulty with the way that the FCRs are presented in EPA's tables of recommendations is that not all studies are conducted in the same way. While the text of that guidance discusses the methodologies, strengths and weaknesses of each of those studies, it presents the resulting rates as if they are equivalent. However, the choices made in study design, target population, and approach to data analysis result in a wide range of FCRs. This variability among the FCRs presented can be confusing, resulting in a tendency for risk managers to select rates at the high end of those ranges to ensure protection of public health. The variability, however, is primarily the result of differences in the types of populations and fisheries studied, and the study designs employed. It is important to consider all of these factors in selecting an FCR (Ebert et al. 1994). When setting AWQC, it is important to select values that are representative of the target population to ensure that public health is being protected without putting unmanageable or unnecessary burdens on those who must comply with the AWQC (Ebert et al. 1994).

3.0 ANALYSIS OF FCR SURVEY DATA

While there are many studies of fishing consumption behavior available, it is important to consider the quality of the studies for the purpose of estimating FCRs. Many fishing surveys include collection of some data related to consumption of fish but often that is not the purpose for which the surveys were designed. Instead they may have been designed to determine dietary preferences, assess compliance with advisories, estimate fishing effort and success, determine angler preferences, etc. As such, while they may contain some information about consumption by the surveyed individuals, the data collected may not be adequately detailed or comprehensive to permit the estimation of reliable, long-term FCRs for that population.

For example, Connelly et al. (1992) conducted a survey of New York recreational anglers that provided information about sport-caught fish consumption but the study was designed for the purpose of providing information about anglers' knowledge of fishing advisories in New York and the impacts of the advisories on their fishing and consumption behavior. While it collected information about the number of meals and species consumed, it did not collect information about the size of fish meals. In order to use these data, one must make an assumption about the size of each meal, which in turn affects the rates derived from the study. When EPA (2011) analyzed these data to derive consumption rates, they assumed that each meal was 150 g in size based on a study of the general population conducted by Pao et al. (1982). Had EPA made different assumptions about meal size, they might have derived substantially higher or lower consumption rate estimates. It cannot be determined from the available data whether the rates derived by EPA were actually representative of consumption rates for the surveyed population.

There are a number of other survey design and analysis issues that affect the estimation of FCRs that may be considered in deriving AWQC. To better understand the nuances of FCRs derived from surveys of target populations, it is important to understand the influence that survey design and analysis can have on consumption rate estimates. These issues are discussed below.

3.1 Survey Methods

Fish consumption surveys can be conducted in a number of different ways. These methods include creel (or intercept) surveys, recall mail and telephone surveys, fishing diaries, and dietary recall studies. Each of these methods can be designed to provide information based on short- or long-term periods of recall (periods of time over which individuals are asked to remember their fish consumption behaviors).

While each of the survey methods can be used to estimate rates of consumption, each method has particular strengths and weaknesses and the survey design can greatly affect the resulting FCR estimates. Thus, the survey method used, the recall period, and the target population all need to be considered carefully when comparing FCRs that are reported. Many times the magnitude of the estimated FCRs are an artifact of the study methodology rather than a reflection of actual differences in fish consumption behaviors.

3.1.1 Creel Surveys

Historically, creel surveys have been used by fisheries managers to collect information about catch and harvest rates and determine the adequacy and characteristics of fishery stock. In some cases, however, creel surveys are modified to collect specific information about fish consumption based on individual fishing trips to a particular waterbody. Generally, survey clerks make contact with individuals who are fishing on a particular survey day to ask them what they have caught and what they intend to eat. Typically individuals are only interviewed once during a survey period (no repeat interview) although sometimes repeat interviews are part of the survey design and the responses on multiple interview days are combined for the individual.

Creel surveys are very effective for collecting information about consumption from a specific waterbody by the individuals who use that waterbody. In addition, if there is a particular subpopulation that uses the fishery differently from the general angler population, those individuals will be identified and their consumption habits captured.

While creel surveys provide reliable information about the fish catch on the day of the interview, they are subject to a number of limitations when attempting to estimate long-term average FCRs, which are the rates that are generally used in developing AWQC.

- Consumption rates based on creel surveys are subject to avidity bias; that is, there is a greater chance of interviewing more avid anglers because they are present at the fishery more frequently. More avid anglers are likely to be more successful anglers and, if they harvest fish for consumption, their rates of consumption are likely to be higher than the typical anglers' consumption rates. In order to use creel survey data to estimate consumption habits of the total user population, it is necessary to make a correction for avidity bias so that the results are representative of the entire angler population that uses the fishery (EPA 2011).

  EPA (2011) discusses this phenomenon in its discussion of FCRs in its 2011 *Exposure Factors Handbook*, stating that "in a creel study, the target population is anyone who fishes at the locations being studied. Generally in a creel study, the probability of being sampled is not the same for all members of the target population. For instance, if the survey is conducted for one day at a site, then it will include all persons who fish there daily but only about 1/7 of the people who fish there weekly, $1/30^{th}$ of the people who fish there monthly, etc. In this example, the probability of being sampled … is seen to be proportional to the frequency of fishing...[B]ecause the sampling probabilities in a creel survey, even with repeated interviewing at a site, are highly dependent on fishing frequency, the fish intake distributions reported for these surveys are not reflective of the corresponding target populations. Instead, those individuals with high fishing frequencies are given too big a weight and the distribution

is skewed to the right, i.e., it overestimates the target population distribution." (EPA 2011, p. 10-3)

To correct for avidity bias, the survey sample is typically weighted based on the reported frequency of fishing by survey participants (EPA 2011; Price et al. 1994). For example, a single day of surveying may have encountered three individuals: 1) one individual who fished with a frequency of one day per year; 2) one individual who fished with a frequency of one day per month; and 3) one individual who fished daily. If those individuals ate one half pound (227 g) fish meal on each day of fishing, their annualized average daily FCRs would be 0.62, 7.5 and 227 g/day, respectively. Based on this 3-person sample, one would conclude that the average consumption rate for these three individuals was 78 g/day. However, if the survey were to be conducted at that location daily throughout the year, it is likely that it might have encountered 365 individuals who fished once per year, 12 individuals who fished once per month, and one individual who fished daily. Thus, the total user population would be 396 individuals, representing 396 points on the fish consumption distribution for the total user population. If their FCRs were identical to the rates for the individuals interviewed during the single day of the survey, the result would be 365 individuals consuming 0.62 g/day, 30 individuals consuming 7.5 g/day, and 1 individual consuming 227 g/day. Thus, for this total angler population, the average rate would be 1.7 g/day. This is substantially lower than the average of 78 g/day based on the actual sample of three individuals. This demonstrates the considerable conservative bias introduced to the FCR estimate if avidity bias is not corrected. Actual corrections depend on the frequency of sampling and the population sampled and so need to be made on a study-by-study basis.

While it is now recognized that avidity bias needs to be considered when analyzing survey data to derive estimates that are representative of the total consuming population, this was not generally done for historical surveys and is still often not done by current study authors. Instead, the consumption rates presented in many survey reports reflect the consumption rates derived from only those individuals who were sampled and thus are biased toward more frequent anglers and consumers. Sometimes it is possible to make these corrections retroactively if the raw data are still available, but often this is not the case. As a result, many consumption estimates that are presented based on creel survey data have not been adjusted to reduce this conservative bias and consequently overestimate consumption rates for the total target population.

- Short-term behavior captured during a single snapshot in time may not be representative of long-term behavior because of variability in fishing effort and success. There may be substantial seasonal variations in the habits of anglers due to fishing regulations, climate, and the availability of target species. Consequently, information collected during a single interview may not be representative of activity on previous or subsequent trips or at other times of the year. Because of limited time for conducting interviews, it is difficult to ask enough detailed questions to allow development of a reliable estimate of the long-term rates of consumption. In addition, the assumptions that must generally be made to extrapolate from short-term data to estimate long-term behaviors add greatly to the uncertainties associated with those estimates.

  Creel surveys are effective at characterizing the consumption habits of individuals who use a specific fishery and are helpful in identifying any subpopulations of fish consumers that are present. It is more challenging, however, to derive a long-term estimate of consumption or to expand the results to a larger geographic area unless very detailed information is collected and there is an appropriate correction for avidity bias.

3.1.2 *Mail Surveys*

Mail surveys are a good tool for collecting detailed information about fishing and consumption behaviors. Generally, mail surveys are designed to randomly sample the target population. Often, for

fish consumption, the target population is recreational anglers and mailing addresses are obtained from fishing licenses sold within the target area. Mail surveys can generally collect more detailed information over a longer period of recall, ranging from months to a year. There are, however, some limitations associated with the use of mail surveys.

- Response rates may be low, unless there is a concerted follow-up effort. If rates are very low, then the resulting FCRs may not be representative of the entire target population. In this case, rates are generally overestimated due to the fact that individuals who choose to respond to the survey tend to self-select; that is, the individuals who are most likely to return a mail survey are those for which fishing is an important activity. These individuals tend to be more avid anglers who fish more frequently than the typical angler population and have a higher rate of success in catching fish. Thus, consumption rates based on data collected in a survey with a low response rate may be biased higher than rates that would be estimated if the entire angler population was equally represented in the survey data.

- Because mail surveys often focus on a longer period of recall, the resulting FCRs are subject to recall bias. It is possible that difficulties in recalling specific information about fishing activity may result in the omission of some meals; however, data on the biases associated with long-term recall periods for recreational activities indicate that individuals tend to overestimate their participation, particularly if the issue being investigated is salient for them (Westat 1989). Thus, the tendency is for FCRs to be overestimated with longer recall periods.

- It can be difficult to target certain subpopulations of fish consumers (e.g., high end consumers, specific ethnic groups, individuals who fish a particular waterbody, etc.) with a mail survey. Individuals who are homeless or migrant will not be captured, and those individuals who have limited language skills and/or low levels of literacy may not understand the survey questions and, thus, may choose not to complete and return it. Thus, these groups may be under-represented in the survey sample.

Mail surveys are often conducted to collect information on a statewide or regional basis. If well designed, they can provide detailed information about the fish consumption behaviors of study participants as they can be completed at the respondent's leisure rather than requiring instantaneous recall of past events. However, FCRs derived from mail surveys may be overestimated if recall periods are long. They may also be overestimated if response rates are low because often non-respondents are less interested in the subject of the survey and, therefore, choose not to participate. In this case, however, data collected through follow-up contact with non-respondents can be used to adjust survey results.

3.1.3 *Telephone Surveys*

Telephone surveys generally consist of the one-time collection of data from a survey participant by telephone. Lists of telephone numbers of individuals within the target population are developed either through the random selection of telephone numbers from all telephone listings in a given area (e.g., statewide, population within certain counties, or population within certain zip codes near a specific waterbody or fishery) or, in the case of surveys of recreational anglers, may be based on information obtained from fishing licenses purchased. Survey respondents are asked to recall information about past fishing trips and fish consumption behavior.

Telephone surveys are rarely used in isolation, however, and are often a follow-up to surveys that have been previously sent to the targeted individuals, thereby providing an opportunity for those individuals to review the survey questions before being asked to respond to them (EPA 1992). They may also be conducted to provide information about non-response bias (for those individuals who did

not respond to a mail survey effort) or to confirm or add to data that were collected in the field during a creel survey (EPA 1992).

Telephone surveys are effective in evaluating regional information and can reach large numbers of individuals (EPA 1992) but also have limitations, including the following:

- Individuals who are being interviewed by telephone are rarely willing to spend more than 10 or 15 minutes participating in a telephone interview, particularly when they have had no warning that they will be called. This limits the amount of information that can be captured from them and is likely to result in recall bias due to the fact that individuals may not recall information completely or accurately when they are unprepared to do so. In addition, because of limited time, they can only be asked general information about their long-term fish consumption habits or specific information about their most recent activities.

- Because telephone surveys generally only include a single interview with an individual, they are subject to bias due to the fact that the responses of the participants may only reflect their most recent activities. Thus, if the telephone interview occurs at a time that the respondent is actively fishing or consuming fish, the resulting data may over-estimate his long term level of activity. At the same time, if the telephone interview occurs during a period of inactivity, his long term consumption activity may be under-estimated.

- Individuals who do not have telephones cannot be included in the sample population. Because those individuals are likely to be low income individuals who cannot afford the cost of a telephone, this segment of the population is likely to be under-represented in the survey sample. Similarly, individuals with unlisted numbers will not be included in the survey.

- Recent telephone surveys may be biased toward an older, higher income population if they have not included the sampling of cell phones in addition to land lines, as younger people are more likely than older individuals to rely completely on cell phones. In addition, even if cell phones are sampled, it is not always possible to accurately sample the geographic location targeted because cell phones are not tied to specific addresses (individuals may move to a different home or area but retain the same cell phone number).

- Telephone surveys can be useful if the general population of a given area is being targeted or if anglers are being targeted and the telephone numbers have been obtained from recent fishing licenses. However, if the target population is a particular socioeconomic subpopulation (e.g., ethnicity or income level), it is very difficult to identify those individuals in advance when selecting a list of telephone numbers. Thus, the smaller the target population, the larger the survey effort necessary to gain enough data about the subpopulation or group of interest.

All of these issues can affect the FCR estimates that are derived based on a telephone survey. The most important considerations are the way that the short-term recall information has been used to estimate long term consumption rates and the attention to avoiding the bias introduced in survey results if certain segments of the population are not well represented in the sampling.

3.1.4 *Fishing Diaries*

Diary studies are an excellent means of collecting detailed information about specific fishing trips and fish meals. In these studies, individuals from the targeted population are recruited to participate in the study and are asked to keep a diary of the fishing trips taken. These studies can be short- or long-term studies. For long-term studies, individuals are generally asked to complete monthly diaries and can record very detailed information about every trip taken and every harvested fish that was consumed. If the individuals complete the diaries in a timely fashion, these studies minimize the potential for

recall bias and also increase the level of detail that the person is able to recall (e.g., the size of a fish meal, the species consumed, the number of people who shared in the meal, etc.). If this information is collected over a long time period (e.g., for example, monthly diaries completed over a one year period), it can result in very accurate estimates of long-term fish consumption.

One difficulty with long-term diary studies is that there can be a high level of attrition because people tire of recording their information and so stop completing the diaries. However, while the information gathered may only be partial (e.g., several months of the targeted one-year period for the study), the level of detail provided in the diary and the partial data can still yield valid estimates of long-term fish consumption behaviors by the study participants (Balogh et al. 1971).

3.1.5 *Diet Recall Studies*

Diet recall studies are a form of diary study but are generally shorter term. In these studies, individuals are commonly asked to record all foods eaten during a one- or two-day period. The days may be consecutive days or two different days during the study period. These recall studies work well for foods that are consumed on a regular basis (i.e., foods that are consumed daily or at least once every two days) and when evaluating population-level trends, but are not as effective for developing reliable estimates of long-term consumption behavior of foods that are consumed less regularly (as discussed in more detail in Section 3.2.2)). Thus, for those individuals who consume fish daily or several times per week, the estimated rates of consumption based on these data may be representative of their behavior.

However, for many individuals, fish is not consumed on a daily or regular basis. This is particularly true of sport-caught fish, which may only be consumed occasionally (e.g., once per week or less or only during a specific time of the year) (Ebert et al. 1994). As discussed in more detail in Section 3.2.2, short-term recall periods may substantially bias the results by incorrectly assuming that individuals who did not consume during the recall period are non-consumers, and leaving them out of the consumption rate distribution, thereby skewing that distribution toward more frequent consumers. This results in overestimated consumption rates for the total population. In addition, the timing of the diet recall study can substantially affect the resulting consumption estimates if there is a seasonal component to the consumption habits of sport-fishermen. For example, in most states, fishing regulations limit the harvest for individual fish species to certain times of the year. Some individuals have a strong preference for a certain species and only consume fish when those species are available. Thus, while they may consume those fish regularly during that season, they may not consume fish at all during the remainder of the year. If the diet recall survey is conducted during the season when they are regularly consuming those fish, and the survey is not carefully designed to address seasonal variations, their annualized, average FCRs will be overestimated. Conversely, if the diet recall study is conducted during the time when these fish are not being consumed, their FCR will be underestimated as it will, by necessity (due to lack of consumption information) be assumed that they are non-consumers. Because of this, their consumption will not be included in the consumption rate distribution from the survey, thereby biasing that distribution to more frequent consumers and higher consumption rates.

3.2 Analysis of Survey Data to Derive FCRs

Data from surveys can be analyzed a number of different ways and the approach to analysis will depend, in part, on survey design. The key consumption metric for deriving AWQC is to derive an annualized average daily FCR. When estimating these FCRs, it is necessary to understand the size of each meal consumed and the frequency with which those meals are consumed.

There are two common approaches for estimating consumption rates. These include an approach based on reported meal frequency and size, and an approach based on the amount of fish harvested and consumed on a yearly basis.

The meal frequency approach requires that information on the number and size of meals consumed by the surveyed individual over a period of time be collected and then extrapolated to the extent necessary to derive an annualized daily average FCR. Thus, for example, if the survey respondent indicates that he or she eats 26 half-pound [227 gram (g)] fish meals per year, the ingestion rate would be calculated as follows:

FCR = 26 meals/yr * 227 g/meal * 1 yr/365 days = 16.2 g/day

Similarly, if the respondent indicates that she eats 1 meal every two weeks, her FCR is calculated as follows:

FCR = 0.5 meal/week * 227 g/meal * 52 weeks/year * 1 yr/365 days = 16.2 g/day

Alternatively, the harvest rate approach uses information about the mass of fish actually harvested by the survey participant over time, adjusts that mass by the edible portion of the fish (total mass minus the mass of the parts not consumed by the angler, such as viscera, head, bones, etc.) and the number of people to share in the fish meal. Thus, if a survey respondent indicates that he or she harvested 40 kg (88 pounds) of fish during a year, the default edible fraction of 30 percent (EPA 1989) is used, and it is reported that a total of 2 adults consumed the fish, the FCR would be calculated as follows:

FCR = 40,000 g whole fish/yr * 0.30 g edible/g whole * 1/2 persons * 1yr/365 days = 16.4 g/day

Depending upon the survey approach used and the questions asked, one method may be more appropriate than the other. There are some limitations of each of these approaches, however, that need to be considered.

- There are uncertainties about the meal method due to the fact that the size of fish meals may vary considerably. Meals of store-purchased fish are likely to be fairly consistent due to the fact that a consistent amount of fish may be purchased for consumption. The same is not true for sport-caught fish. Meal sizes will vary depending upon the mass of fish harvested on a given day and the number of individuals consuming it. Thus, because individuals are generally asked to estimate the size of fish meals consumed, they may or may not accurately represent the variety of meal sizes that are actually consumed over time if the fish are sport-caught fish. While individuals involved in the surveys are often provided with photographs of meals of different sizes, these estimated meal weights may not be representative of the fish actually consumed due to differences in mass resulting from cooking, the way the fish were prepared, and the density of the fish tissue. In addition, although they may provide their estimated average weekly rate of consumption, this weekly rate may vary considerably by season due to changes in weather, fishing time, or availability of target species. Unless data are collected to specifically capture these variations, there is substantial uncertainty introduced by this approach.

- There are also uncertainties introduced when using the harvest method because individuals may not recall exactly how much fish they have harvested over time, and the portion sizes of the individuals who share in the consumption of the fish may vary. Thus, if two people share in the catch it will normally be assumed that the total mass should be divided by two; however, the portions consumed by those individuals may not be equivalent. In addition, there may be some variability around the edible portion of the fish depending on the parts consumed by the survey participants, the fact that edible portions vary somewhat by species, and the number of individuals who share in individual fish meals.

3.2.1 *Identifying "Consumers" and "Non-Consumers"*

When determining the population to be targeted in selecting an FCR for use in developing AWQC, it is important to determine who is likely to be exposed to that chemical via the consumption of fish. Clearly, individuals who never consume fish will have no potential for exposure via this pathway so that the emphasis needs to be on the individuals who actually consume fish as this will be the potentially exposed population. However, depending upon the waterbodies to which the AWQC will be applied, the fish consuming population will vary. If the AWQC will be applied to waterbodies that are commercially fished, then there is potential for exposure to the general population, because they will have access to that fish through commercial sources such as fish markets, grocery stores and restaurants. However, if the waterbodies that are the focus of the AWQC are not commercially fished, then the fish from those waterbodies will not be available to the general population. The only sources of those fish are the recreational anglers who fish those waterbodies.

Once the target population has been identified, it is necessary to identify the FCRs for the individuals within that population who consume fish. Depending upon the survey approach used, this determination can be challenging. For example, if the AWQC are to be applied to commercially fished waterbodies, then the general population who have access to those fish is the target population. However, most surveys of the general population collect information about total fish consumption including consumption of fresh, frozen, canned and prepared fish and shellfish obtained from stores and restaurants, which are most often imported from locations outside of the area of influence of the AWQC, as well as sport-caught fish and shellfish from local sources.

Even if the survey has distinguished among different sources of fish, the identification of consumers may be affected by the survey method. As discussed in more detail in Section 3.2.2 below, short-term diet recall studies, which are often used to evaluate food consumption within the general population, often misclassify individuals as non-consumers. Thus, while the rates are reportedly based on consumers of those fish, they are likely to be excluding a large proportion of actual consumers who have lower frequency of consumption.

3.2.2 *Limitations on the Use of Short Recall Period Survey Data*

Attempting to extrapolate long-term FCRs based on short recall period survey data presents a number of problems. These include the potential misclassification of non-consumers, the overestimation of FCRs based on data collected as a snapshot in time, and the lack of consideration of variation over time.

In general, the length of recall period affects the resulting estimated rates of consumption with shorter term studies resulting in higher estimated rates of consumption than studies with longer recall periods. The higher rates of consumption from the short-term studies may not be a reflection of actual differences in the behaviors within the surveyed populations but may instead be an artifact of the short recall period (EPA 2011; Ebert et al. 1994).

Short-term dietary recall studies can result in misclassification of participants as non-consumers and consequently overestimate consumption rates for true consumers within the surveyed population. Essentially, when a diet recall survey is conducted, if an individual does not indicate that fish was consumed during the recall period, that individual is identified as a non-consumer and is assumed to have zero consumption. When this occurs, rates are reported as either "per capita" rates (which include the non-consumers and their estimated rates of 0 g/day) or as "consumers only" rates, which means that all of the individuals who did not consume fish during that period of time are excluded from the reported results and only those individuals who did consume fish during that period are counted in the consumption rates.

The USDA dietary data that form the basis for EPA's (2000) default FCR of 17.5 g/day were collected using a dietary recall study of survey participants during two non-consecutive 24-hour periods (EPA, 2000). Because of the way in which sampling was conducted, the actual fish consumption behaviors reported are strongly biased toward those respondents who consume fish with a high frequency. All of the individuals included as fish consumers in the USDA estimate consumed fish at least once during the 2-day sampling period. To use these data to estimate long-term consumption rates, EPA assumes that the consumption behavior that occurred during the 2-day period is the same as the consumption behavior that occurs throughout every other 2-day period during the year. Thus, if an individual reported eating one fish meal during the sampling period, the extrapolation used to estimate long-term consumption was the assumption that the individual continues to eat fish with a frequency of one meal every two days, or as many as 183 meals per year. If it is assumed that an individual eats one-half pound (227 g) of fish per meal, this results in a consumption rate of 114 g/day. However, the individual who consumed fish during that sampling period may not actually be a regular fish consumer. In fact, that fish meal could have been the only fish meal that the individual consumed in an entire year. Thus, that person's FCR would be substantially overestimated using this extrapolation method.

Conversely, individuals who did not consume fish during the 2-day sampling period were assumed to be non-consumers of fish, despite the fact that those individuals may simply have been fish consumers who coincidentally did not consume fish during the 2-day sampling period. Because there are no data upon which to base consumption estimates for these individuals, they were assumed to consume 0 g/day. However, they may in fact consume fish with a frequency ranging from as little as zero meals per year to as much as one meal per day (or even more than one meal per day) on all days except the two that USDA conducted the survey. As with the high consumers identified in the USDA database, there is no way to determine whether 0 g/day consumers are actually non-consumers or just individuals who did not consume fish during the 2-day survey period.

There can be enormous variability in the frequency of consumption of specific foods (Balogh et al. 1971; Garn et al. 1976), and the variability in the number of fish meals may be further enhanced by seasonal effects. For example, recreational fishermen in many states are only permitted to fish during certain months due to fishing regulations. Thus, it is possible that their sport-caught fish ingestion rates are substantially higher during the fishing season, when fresh fish are readily available, than they are during the remainder of the year. In addition, many anglers target specific species and only fish when those species are available. For example, many anglers in the Pacific Northwest target salmon, which are only available during their time-limited spawning runs. Thus, they may not fish at all or consume sport-caught fish during other times of the year when the salmon are not available.

Because of this phenomenon, there is a tendency, if only "consumers" are considered, for short-term recall surveys to report substantially higher FCRs than do surveys with longer periods of recall. This is well demonstrated in EPA's (2011) tables of relevant fish consumption studies. For example, when reviewing EPA's relevant studies of statewide[9] freshwater recreational fish intake (EPA 2011, Table 10-5), FCRs appear to be highly variable, with means for "consuming" anglers ranging from 5.8 to 53 g/day and 95th percentile (95th %ile) values ranging from 26 to 61 g/day.[10] However, one of those studies collected data from individuals on a single day (ADEM 1994), one involved a single interview but also included a 10-day dietary diary component (Balcom et al. 1999), one involved a 90-day recall period (Williams et al. 1999), one included a 7-day recall period but also collected some

[9] There are additional studies provided on EPA's table of relevant studies but those studies are waterbody specific and thus are not directly comparable with the statewide studies.

[10] 95th percentiles are not available for all studies listed in EPA's Table 10-5. For example, EPA reports the highest mean rates for studies conducted in Alabama and Connecticut but provides no 95th percentile values from those studies. Thus, those studies cannot be included in the comparison of 95th %ile rates.

information on seasonal variation for the remainder of the year (West et al. 1989), and the remainder of the studies collected data for a 1-year recall period. When the statewide studies are segregated by recall period, the bias toward higher consumption rates based on shorter recall periods is apparent, as shown below.

Rates for Sport-caught Freshwater Fish Consumption (Adult consumers) from Statewide Studies by Recall Period (Table 10-5, EPA 2011)

Recall Period	1-day		1-day interview and 10-day diary		90 day				1 year	
Metric	Mean	95th %ile	Mean	95th %ile	Mean	95th %ile	Mean	95th %ile	Mean	95th %ile
FCR (g/day)	53	NA	53	NA	20	61	14	39	5.8-14	26-43
Study	ADEM 1994		Balcom et al. 1999		Williams et al. 1999		West et al. 1989		Ebert et al. 1993; Benson et al. 2001, Connelly et al. 1996, Fiore et al. 1989	

NA: Not available. This value was not presented by EPA (2011)

[a]The West et al. 1989 study requested information about a 7 day recall period but also collected some information on variation in behavior during different seasons of the year which were used to estimate long-term FCRs.

[b]A subsequent West et al. (1993) study collected information for a 7-day recall period but collected no longer term information that could be used to annualize the rates. While the means from the 1989 and 1993 surveys were nearly identical, the 95th percentile for the 1993 study (78 g/day; EPA 1997) was substantially higher than the 95th percentile of 39 g/day that was derived from the 1989 survey data.

Consumption of sport-caught fish is likely to have a seasonal component, particularly in states where fishing may occur for only a portion of the year. Like other seasonal foods, it is likely that these foods are eaten more frequently during their seasons than they are at other times of the year. For example, fresh, local strawberries are only available in the northeastern United States for a few weeks during the summer. When they are available locally, it is likely that strawberries are consumed in greater quantities than they are when they are out of season and can only be imported from other locations and purchased from supermarkets. That is not to say that they are never eaten when they are out of season but rather that if individuals were to be asked about their strawberry consumption during the time that fresh strawberries are in-season, it is likely that they would overestimate their consumption for other times of the year when local strawberries are not available. At the same time, if they were asked in the winter to report their strawberry consumption, it is likely that they would underestimate their strawberry consumption during the summer when fresh, local strawberries are readily available. These seasonal variations are important in terms of their affect on estimating long term consumption rates. While the USDA survey (upon which EPA's rate of 17.5 g/day is based) collected data on two different days, the survey days were no more than 10 days apart. Thus, the rates of consumption for all foods that are seasonally affected would have been dependent upon the timing of those survey days and would not necessarily reflect the participants' long-term average consumption rates.

EPA (2011) has acknowledged that short-term dietary records are problematic when attempting to estimate long-term rates of consumption, particularly for upper bound FCR estimates. In its review of NHANES 2003-2006 study data, EPA (2011, p. 10-16) stated, "the distribution of average daily intake rates generated using short-term data (e.g., 2-day) does not necessarily reflect the long-term distribution of average daily intake rates." In addition, in its discussion of the limitation of the West et al. (1993) study of Michigan anglers EPA (2011, p. 10-38) stated: "However, because this survey

only measured fish consumption over a short (1 week) interval, the resulting distribution will not be indicative of the long-term fish consumption distribution, and the upper percentiles reported from the U.S. EPA analysis will likely considerably overestimate the corresponding long-term percentiles. The overall 95th percentile calculated by U.S. EPA (1995) was 77.9; this is about double the 95th percentile estimated using yearlong consumption data from the 1989 Michigan survey." In addition, when discussing the USDA methodology, EPA (1998, p. 10-107) stated that "[t]he non-consumption of finfish or shellfish by a majority of individuals, combined with consumption data from high-end consumers, resulted in a wide range of observed fish consumption. This range of fish consumption data would tend to produce distributions of fish consumption with larger variances than would be associated with a longer survey period, such as 30 days." As a result, upper-bound fish consumption estimates based on these data will be biased high and overestimate actual upper-bound consumption rates for the total population of consumers.

Short-term recall periods generally result in an overestimate of consumption behavior, particularly for foods that are not eaten on a daily basis. While this does not appear to greatly affect central tendency values for the populations studied (EPA 2011; Garn et al. 1976), the inverse relationship between upper-bound FCRs and the length of survey recall period has been clearly demonstrated (Ebert et al. 1994).

3.2.3 *Estimating Means and Upper Percentiles*

Once FCRs have been calculated for the individual survey respondents, they are typically evaluated statistically to define a central tendency or upper-bound estimate of consumption to be used in deriving AWQC. The central tendency may be an arithmetic mean, geometric mean, or a median (50th percentile value) of the range of consumption rates derived. Because the estimated FCR distribution (the range of rates) is generally very highly skewed, as are consumption rates for most foods (Garn et al. 1976), with a very large number of individuals consuming fish at very low FCRs and a few individuals consuming at high rates, the arithmetic mean is typically not a good estimate of actual central tendency. For example, in the statewide survey of Maine's recreational anglers, which included rates ranging from 0.02 to 183 g/day, the median rate of consumption by individuals who ate at least one fish meal from Maine's freshwater bodies during the year was 2 g/day but the arithmetic mean FCR for this same population was 6.4 g/day and represented the 77th percentile of the distribution of FCRs from that survey (Ebert et al. 1993).

Upper-bound FCRs may be calculated in a number of ways. For some surveys, they may be calculated as the 95th upper confidence limit of the arithmetic mean consumption rate. Alternatively, for some surveys, FCR results are ranked in order of magnitude and then the upper-bound value is selected as the 95th percentile of that distribution. Thus, for example, in the same Maine survey for which there were 1,053 FCRs calculated, the 95th percentile value of 26 g/day represented the FCR reported for angler 1,000 after order ranking of the results (Ebert et al., 1993).

3.2.4 *Consumption of Resident and Anadromous Fish Species*

It is important that the FCR used in deriving AWQC reflects consumption of the fish species that will be affected by the AWQC. This will ensure that FCRs are not overestimated.

Estimated FCRs are generally based on the total consumption of fish, and may include fish of a variety of types, including resident finfish, anadromous finfish, and shellfish. For example, the FCR recently adopted by Oregon Department of Environmental Quality was supported by state-specific data on consumption for which a substantial portion of the consumption was the ingestion of anadromous species such as salmon and steelhead. Anadromous species are not substantially affected by local water quality in estuaries and rivers because they are only present in those waterbodies when they are juveniles and when they return as adults to spawn. They spend the majority of their lives in

marine waters and are typically harvested during their return spawning runs. As a result, any chemical constituents that are present in their bodies are predominantly the result of exposures they have received during their time in marine waters. Thus, changes in AWQC for local waterbodies will not affect the concentrations of those chemicals in their edible tissues. Instead the fish that are sensitive to changes in local water quality are the resident species that spend their entire life stages in local waters.

This is an important consideration for states, such as Oregon and Washington, where a substantial portion of the fish harvested for consumption are anadromous fish. For example, the Columbia River tribes consume, on average, nearly three times more anadromous fish (including salmon, trout, lamprey and smelt) as they do resident species (CRITFC 1994). Similarly, Toy et al. (1996) reported that at the 95th %ile consumption rate for the combined Tulalip and Squaxin tribes, who fish Puget Sound, 95% of the total finfish consumed were anadromous species.

Because the AWQC approach incorporates a chemical-specific bioaccumulation factor, it essentially assumes that fish are in equilibrium with constituent concentrations in the water bodies of interest. This is not likely to be the case for anadromous species because of the short time period during which they are in fresh and estuarine waters. For example, after hatching, juvenile Chinook salmon spend several months in the Columbia River before they begin their out-migration to marine feeding areas. They generally return to the river to spawn between the ages of two and six years (ODFW, 1989) and do not generally feed during their spawning run. These fish, which provide a substantial portion of the freshwater fish harvested both commercially and recreationally from the river, are clearly not at equilibrium with their surroundings.

Because migrating fish do not spend adequate time in a particular river reach to achieve equilibrium with concentrations in the water column and sediments there, the bioaccumulation factor used in developing the AWQC overestimates the tissue concentrations in such fish that can be attributed to that reach. It is only the resident species that will be impacted by local water quality. Consequently, the use of an FCR that includes anadromous fish substantially overestimates exposure to local chemicals. For example, if an individual has a total FCR of 20 g/day and 90 percent of the fish consumed during the year are anadromous fish, only 10 percent of the fish consumed, or 2 g/day, are resident fish that are likely to be affected by changes in local water quality. Thus, to use a total FCR of 20 g/day overestimates the individuals' actual potential for exposure due to local contaminants by a factor of 10. Instead, it is the consumption rates for resident species that should be used to derive AWQC because it is these species that will be affected by changes in water quality.

Not all states have the type of access to anadromous species that occurs in the Pacific Northwest. Thus, these fish will not constitute a substantial fraction of consumers' diets in many areas of the country. This makes it extremely important to ensure that the FCRs that are used in developing AWQC for a specific region are based on fish consumption information for that region and not simply based on a one-size-fits-all approach for selecting consumption rates.

3.2.5 *Consumption of Freshwater and Estuarine Species*

In developing AWQC in coastal states, the FCRs that are used typically do not differentiate between the ingestion of freshwater and estuarine finfish and shellfish. This is because AWQC need to be applied to a number of different types of water bodies. However, this assumption is very conservative when one considers permitting of individual discharges that occur in specific areas of individual water bodies and may only affect freshwater areas. If there is a permitted discharge to a freshwater body, the consumption of estuarine fish and shellfish is likely to be irrelevant. Similarly, if there is a discharge to an estuarine area, the freshwater fish upstream will likely not be affected by that discharge. Thus, inclusion of rates of consumption of freshwater and estuarine finfish and shellfish is

a very conservative assumption for these specific applications, providing an additional level of health protection when AWQC are applied to specific waterbodies.

4.0 POPULATION RISK

AWQC are typically derived using a target individual risk level of 1 in 1,000,000 million (1E-06) risk for carcinogens and a hazard index of 1 for non-carcinogens. For carcinogens, this target risk represents the increased probability that an individual will develop cancer as a result of exposure through the consumption of fish tissue. The background rate for contracting cancer is roughly 30 percent; thus, when a 1E-06 risk level is selected as the target risk, this means that the probability of an individual contracting cancer increases from 30 percent to 30.0001 percent.

There is, however, another risk metric that should be considered in selecting an FCR. This risk metric is known as the population risk. It is calculated by multiplying the target risk level by the size of the affected population to predict the number of excess cancer cases that might result from that exposure. Thus, if the target risk is 1 in one million, and the size of the population is one million people, the population risk will be calculated as 1 excess cancer over the combined lifetimes of 1 million individuals who are actually exposed as a result of the modeled exposures.

Population risk is an important consideration in selecting an FCR for use in developing AWQC because as the size of the exposed population decreases, the population risks also decrease when the same target risk level is used. The higher the FCR selected for a particular population, the smaller the population to which that FCR applies. For example, if the FCR selected is a 95^{th} percentile rate, it is assumed that it is protective of all but 5 percent of the exposed population or 50,000 of the 1 million people provided in the example above. Thus, if the same target risk level of 1E-06 is used with this reduced population, the resulting population risk is 0.05 excess cancers within a population of 1 million people. In other words, in order to reach the target risk of 1 excess cancer, it would be necessary for a population of 20 million people to have lifetime exposures equivalent to the estimated exposure conditions.

EPA (2000) states that both a 1E-06 and 1 in 100,000 (1E-05) target risk level may be acceptable for the general population as long as highly exposed populations do not exceed a target risk level of 1E-04 or 1 in 10,000. In other words, if an AWQC is based on a 1E-06 risk level and an FCR if 17.5 g/day is used, this means that if there is a subpopulation of individuals who consume fish at a rate of 175 g/day, they will be protected at a risk level of 1E-05, and in order for a subpopulation to exceed the recommended upper bound risk level of 1E-04 outlined in EPA's (2000) methodology, they would have to consume more than 1,750 g of fish daily throughout their lifetimes.

EPA (2000) states that "[a]doption of a 10-6 or 10-5 risk level, both of which States and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes. EPA believes that such State or Tribal decisions are consistent with Section 303(c) if the State or authorized Tribe has identified the most highly exposed subpopulation, has demonstrated that the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation" (EPA 2000).

Selection of an FCR to be used in developing AWQC is as much a policy decision as a technical decision. There are wide ranges of FCRs available depending upon the population targeted for study and it is important that the target population be identified so that the selection of an FCR rate can be based on that target population and the target risk level can consider both individual and population risks for that population.

5.0 DISCUSSION

When selecting an FCR for establishing HHAWQC, it is critical that a number of important issues be considered. These include: 1) identifying the target population of fish consumers and the waterbodies that will be affected by changes in HHAWQC; 2) evaluating and selecting FCRs based on fish consumption studies that provide reliable, long-term information on the fish consumption habits of the target populations and waterbodies; and 3) consideration of both individual and population risks in selecting an FCR.

Generally speaking, the population of interest for the development of HHAWQC consists of those individuals who consume freshwater or estuarine finfish and/or shellfish from the area of interest. If the waters to which HHAWQC are to be applied are commercially fished, then this population will include members of the general population who may consume fish from a wide variety of commercial and recreational sources. In this case, FCRs should be based on general population studies of good quality. If, however, the waterbodies of interest are not commercially fished, then the target population includes those anglers who catch and consume their own fish from those waterbodies and the FCR should be selected from regionally-appropriate studies of consumption by recreational anglers.

HHAWQC are used as environmental benchmarks and as objectives in the development of environmental permits. While they are applicable to all ambient waters in a state, they are most often considered for individual water bodies when state regulatory agencies are developing permitting and effluent limits. Thus, assumptions that are already judged and selected to be conservative when one is attempting to develop statewide criteria, become extremely conservative when considering individual water bodies.

In light of the way in which HHAWQC are applied in permitting, the approach used to develop HHAWQC includes a number of highly conservative assumptions, particularly for constituents that are limited and localized. The conservative assumptions used in the development of HHAWQC and subsequently applied to permitting typically include:

- FCRs that include the combined consumption of freshwater and estuarine fish and shellfish and, in some areas, include anadromous species that are not impacted by local water quality conditions;
- 100 percent of the fish consumed in a lifetime are obtained from a single, impacted waterbody;
- There is no reduction in chemical concentration that occurs as a result of cooking or preparation methods;
- Concentrations of compounds in fish are in equilibrium with compound concentrations in the water body; and,
- The allowable risk level upon which they are typically based is one in one million. This means that the probability of developing cancer over a lifetime increases from 30% to 30.0001%.

There are a very small number of individuals, if any, to whom all of these conservative assumptions would apply.

EPA's recommended FCR of 17.5 g/day can reasonable be judged as conservative and protective when used in establishing AWQC for a number of reasons.

- It is based on survey data collected by the USDA, which are surveys of the general population, and includes information about many species and meals of fish that would not be found in the waterbodies that are subject to the HHAWQC. The reported fish meals were obtained from numerous sources and included fresh, frozen, prepared and canned fish products that may have been produced in other regions of the United States or other countries and, consequently, not derived from local waterbodies. Thus, the USDA data overestimate the consumption of locally caught fish, particularly if there are no commercial fisheries, and certainly overstate consumption from individual waterbodies that are regulated under the HHAWQC.
- As discussed previously, this rate is based on 24-hour dietary recall data. Use of such data to estimate long term consumption rates for any population results in biased and highly uncertain estimates.
- HHAWQC based on that consumption rate, combined with other very conservative assumptions that are included in the HHAWQC calculation, ensure that risks of consuming fish from a single regulated waterbody are likely to be substantially overestimated and, therefore, will also be protective of individuals who are at the high end of the consumption distribution.

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APPENDIX B

A BRIEF REVIEW OF ISSUES RELEVANT TO THE ACCUMULATION OF PERSISTENT, BIOACCUMULATIVE, AND TOXIC (PBT) CHEMICALS BY SALMON

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1.0 INTRODUCTION

In September 2011 Washington State Department of Ecology (WDOE) issued Publication No. 11-09-050, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*. This technical support document (TSD) was generated to support decision making regarding how to obtain an appropriate fish consumption rate (FCR) for use in calculating water quality standards for protecting human health (HHWQS). One of the issues WDOE raised in this TSD was whether consumption of salmon should be included in whatever FCR is ultimately used in these calculations, and if it is concluded that salmon should be included in an FCR, how to do so.

The driver behind this is human exposure to toxic chemicals, specifically via consumption of fish (or aquatic tissue in general). The greatest risk to human health from consumption of fish is generally understood to result from the presence of persistent, bioaccumulative, and toxic (PBT) chemicals. Thus the primary factor in determining the appropriateness of including consumption of salmon in an FCR is where salmon actually pick up these contaminants. A brief review of what is known about this subject is presented herein.

2.0 WHERE SALMON ACCUMULATE PBT CHEMICALS

As discussed by NOAA (2005), different runs of salmon exhibit different life histories. More specifically, NOAA described stream-type and ocean-type life histories. Behavioral attributes of these two general types of salmon are summarized in Table B1.

From Table B1, different species of salmon and different runs of the same species can exhibit distinctly different life histories, including how much time is spent in freshwater and where in freshwater systems this time is spent. These differences are potentially significant in that they may lead to differences in the mass (burden) of chemical contaminants (e.g., PBT chemicals) ultimately accumulated by the salmon, and in the fraction of this ultimate burden accumulated in freshwater vs. saltwater. Although the latter may not be relevant when assessing the risk to human health resulting from eating contaminated fish in general, it is relevant when considering what fraction of this overall risk results from accumulation of contaminants in freshwater systems vs. saltwater systems.

This last point is directly relevant to the question of whether there is any utility in including consumption of salmon in an FCR that will be used to drive remedial action(s) on the geographically limited scale of a single state. If a significant fraction of the contaminant burden found in salmon is accumulated in true freshwater systems it makes sense that the consumption of salmon be included in an FCR. However, if accumulation in the open ocean dominates, inclusion of salmon in an FCR makes no sense because there is no action the state can take that will have a significant effect on the contaminant burden found in returning adult salmon.

Table B1 A Summary of the Juvenile Characteristics of Stream and Ocean Life History Types

Stream-Type Fish	Ocean-Type Fish
Species	
Coho salmon	Coho salmon
Some Chinook populations	Some Chinook populations
Steelhead	Chum
Sockeye	Pink
Attributes	
Long period of freshwater rearing (>1 yr)	Short period of freshwater rearing
Shorter ocean residence	Longer ocean residence
Short period of estuarine residence	Longer period of estuarine residence
Larger size at time of estuarine entry	Smaller size at time of estuarine entry
Mostly use deeper, main channel estuarine habitats	Mostly use shallow water estuarine habitats, especially vegetated ones

[SOURCE: NOAA 2005]

Exclusion of salmon from an FCR does not imply that human exposure to contaminants due to consumption of salmon should not be accounted for when assessing overall risks to human health. Instead, these issues should be weighed when deciding whether salmon are accounted for when assessing the risks resulting from consumption of freshwater fish (by including consumption of salmon in an FCR) or when assessing the risks resulting from consumption of saltwater or marine fish (salmon would be backed out of the risk assessment for deriving a freshwater HHWQS via the relative source contribution or RSC). Ultimately, the issue of where the risks from consumption of salmon are counted appears to be an academic question. The more important factor (from the perspective of characterizing risk) is to ensure that consumption of salmon is not double counted by including it in both an FCR and as a component of the RSC.

In any case, the issue of salmon (or anadromous fish in general) is unique in that it is quite likely that a generic salmon will accumulate contaminants in both freshwater and saltwater habitats, and that the relative fraction accumulated in one habitat vs. the other will vary with species, run, and even individual. Taken to the extreme, this implies that each run needs to be evaluated independently to determine where contaminants are accumulated. However, much of the scientific literature supports accumulation in the open ocean as the dominant pathway for uptake of PBT chemicals by salmon, with the work of O'Neill, West, and Hoeman (1998), West and O'Neill (2007), and O'Neill and West (2009) providing perhaps the most thorough examination of the issue.

Figure B1 is taken from O'Neill and West (2009) and shows that levels of polychlorinated biphenyls (PCBs) in adult Chinook salmon (fillets) collected from a wide range of geographic locations are relatively uniform except for fish taken from Puget Sound, which show three to five times higher

levels of PCBs than fish taken from other locations. As discussed by the authors, these data can be interpreted as indicating accumulation of PCBs in Puget Sound and/or along the migratory routes of these fish, which, depending on the specific runs, can pass through some highly contaminated Superfund sites (e.g., Duwamish Waterway). However, O'Neill and West (2009) concluded that, on average, >96% of the total body burden (mass) of PCBs in these Puget Sound Chinook was accumulated in the Sound and not in natal river(s).

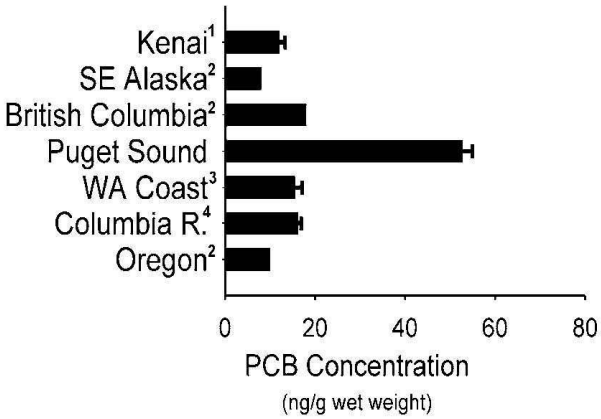

Figure B1 Average (±SE) PCB Concentration in Chinook Salmon Fillets
Data for Puget Sound were based on 204 samples collected by the Washington Department of Fish and Wildlife from 1992 to 1996; data for other locations were taken from the following (indicated by superscript numbers): [1]Rice and Moles (2006), [2]Hites et al. (2004; estimated from publication), [3]Missildine et al. (2005), and [4]United States Environmental Protection Agency (USEPA 2002)
[SOURCE: O'Neill and West 2009]

The basis for this conclusion is presented in Table B2, which compares PCB concentrations and body burdens in out migrating Chinook smolts collected from the Duwamish River and adults returning to the Duwamish.

Table B2 Concentration of PCBs (ng/g) and Body Burden of PCBs (total ng/fish) in Out-migrating Chinook Salmon Smolts and Returning Adults from the Contaminated Duwamish River, Washington

Variable	Smolts	Adults
Number of samples	80	34
Mean fish weight (g)	10	6,000
Whole body PCB concentration (ng/g)[a]		
Mean	170	57
95th percentile	860	88
PCB body burden (ng/fish)[a]		
Mean	2,100	350,000
95th percentile	9,200	800,000
Mean % of PCB body burden from the most contaminated smolts[b]	—	3.8

[a] Values for smolts are from J. P. Meador (National Oceanic and Atmospheric Administration Fisheries, Northwest Fisheries Science Center, personal communication); values for adults were estimated from measured muscle tissue concentration using the fillet–whole-body regression (see Methods) for PCBs.

[b] Contaminant data were only available for out-migrating subyearling smolts, so only samples with adults that went to sea as subyearlings were included in the analysis.

[SOURCE: O'Neill and West 2009]

These data show that even the most contaminated out migrating smolts contained no more than 4% of the body burden (mass) of PCBs found in returning adults. Thus, >96% of the PCB mass (burden) found in the returning adults was accumulated in Puget Sound. Even allowing for an order of magnitude underestimate in the body burden of out migrating smolts, O'Neill and West (2009) concluded that accumulation in freshwater would account for <10% of the average PCB burden ultimately found in adults returning to the Duwamish. By extension, this analysis supports the conclusion that Chinook salmon passing through uncontaminated estuaries during out migration accumulate a dominant fraction of their ultimate PCB body burdens in the open ocean. Other researchers have also reached this conclusion using their own data (e.g., Johnson et al. 2007; Cullon et al. 2009).

However, this analysis does not explain why Chinook salmon collected in Puget Sound exhibit higher concentrations of PCBs than Chinook salmon collected from other locations (Figure B1). Ultimately, O'Neill and West (2009) attributed this to a combination of factors, specifically PCB contamination of the Puget Sound food web (e.g., West, O'Neill, and Ylitalo 2008) combined with a high percentage of Chinook displaying resident behavior. That is, a large fraction of out migrating Chinook smolts take up permanent residence in the Sound, where they feed from a more contaminated food web than found in the open ocean. These factors would not affect Chinook runs or runs of any other species associated with natal rivers that discharge to saltwater outside Puget Sound.

Overall, these data support the position that, as a general rule, the predominant fraction of the ultimate PCB burden found in harvested adult fish is accumulated while in the ocean-phase of their life cycle (e.g., Cullon et al. 2009; Johnson et al. 2007; O'Neill and West 2009). Although this conclusion is specific to PCBs, there is no reason to suppose that it would not also hold for other legacy PBTs (e.g., DDT, dioxins) or globally ubiquitous PBTs (e.g., PBDEs, methylmercury) in general (e.g., Cullon et al. 2009). Because concerns about human consumption of fish are driven by risks from exposure to PBTs, driving the FCR higher by including salmon would thus appear to be of limited utility from the

perspective of protecting human health simply because these contaminants are accumulated in the ocean.

With that said, there are sufficient data to conclude that the food web in Puget Sound is contaminated with PCBs to a greater degree than the food web in the open ocean. To the extent that this is a result of true local sources (e.g., sediment hotspots), there may in fact be some "local" action that can be taken to reduce PCBs, or potentially other PBTs, in Puget Sound salmon. However, this is totally dependent on identification of localized sources amenable to remediation, and not simply a conclusion that the food web is contaminated (e.g., West and O'Neill 2007).

Again, simply increasing the FCR by including salmon will have essentially no positive effect on human health given that the dominant fraction of PBT body burdens in salmon appears to be accumulated in the open ocean, and not in waters immediately subject to in-state loadings.

3.0 PBT ACCUMULATION BY DIFFERENT SALMON SPECIES

As discussed, there is ample evidence that the body burdens of PBTs found in returning adult Chinook salmon depend to a significant extent on the life history of the specific run. Beyond this, there are interspecies differences in migratory and feeding behavior that suggest Coho, sockeye, pink, and chum salmon will not accumulate PBTs to the same extent as Chinook salmon under similar exposure scenarios (Groot and Margolis 1991; Higgs et al. 1995). Perhaps the most significant factor differentiating Chinook from the other salmon species is that Chinook tend to eat more fish (Higgs et al. 1995). Thus they effectively feed at a higher trophic level than the other species of salmon, and would be expected to accumulate greater burdens of PBT chemicals even when sharing the same habitat. This is in fact observable. For example, when looking at adult Chinook and Coho returning to the same rivers, O'Neill, West, and Hoeman (1998) found that Chinook muscle contained, on average, almost twice the total PCB concentrations found in Coho muscle. This was also true for adults collected in Puget Sound proper (O'Neill, West, and Hoeman 1998).

Differences between species can also manifest in sub-adults. For example, Johnson et al. (2007) reported ΣPCB concentrations in juvenile wild Coho collected from five different estuaries ranging from 5.9 to 27 ng/g (wet weight; whole body minus stomach contents). The corresponding range for wild Chinook juveniles collected from the same estuaries was 11 to 46 ng/g (wet weight; whole body minus stomach contents). Overall, PCB concentrations in juvenile Coho were, on average, equivalent to nominally 50% of those found in the paired Chinook juveniles. This is essentially the same ratio observed by O'Neill, West, and Hoeman (1998) in adult fish.

All this indicates that PBT residues in salmon will vary within species depending on the specific run, and between species regardless (i.e., even when different species share the same general habitat). Thus, grouping all salmon together does not provide an accurate assessment of PBT doses delivered to human consumers due to consumption of salmon. This suggests that human health risk assessments should, as a general rule, incorporate salmon on a species-specific basis, if not a run-specific basis.

Certainly, none of this is supportive of adopting a single default value for the dose of any contaminant received by humans via consumption of salmon. Thus adoption of a single default FCR for salmon is also not supported.

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APPENDIX C

FISH TISSUE CONCENTRATIONS ALLOWED BY USEPA AMBIENT WATER QUALITY CRITERIA (AWQC): A COMPARISON WITH OTHER REGULATORY MECHANISMS CONTROLLING CHEMICALS IN FISH

Kevin Connor And Paul Anderson, ARCADIS-US

1.0 INTRODUCTION

For chemicals that are capable of concentrating in fish, Ambient Water Quality Criteria for the Protection of Human Health (HH-WQC) are derived based on the uptake of the chemical by edible fish and an assumed level of fish consumption by anglers (USEPA 2000). It follows that for these chemicals, there is an allowable fish tissue concentration corresponding with each HH-WQC. The associated allowable concentrations are risk-based benchmarks analogous to other risk-based thresholds applied to edible fish in other circumstances and, therefore, the comparison with the more formal screening levels or guidelines is of interest. This appendix first describes how these allowable fish tissue concentrations, which are an integral component of the HH-WQCs, are derived. Next, several comparisons are presented between these allowable fish tissue concentrations and existing fish concentration data, concentrations found in other foods, as well as other guidelines or risk-based levels used for regulating chemical concentrations in edible fish, such as fish consumption advisory (FCA) "trigger levels" issued by state and federal agencies, and U.S. Food and Drug Administration (USFDA) tolerances, illustrating the differences in these values.

These comparisons will focus on a short list of chemicals for which an HH-WQC has been established and for which fish tissue concentration data are likely to be available. This list is comprised of the following chemicals:

- arsenic
- methyl bromide
- mercury (total, inorganic and organic)
- PCBs (total)
- chlordane; and
- bis-(2-ethylhexyl)phthalate (DEHP)

These six chemicals were selected based on several considerations: 1) propensity for accumulating in fish; 2) inclusion in fish tissue monitoring programs; 3) inclusion in recent studies measuring chemicals in other foods; 4) inclusion in specific analyses estimating human (dietary) intake; and 5) subject of FCAs in at least one state. Not all of these criteria were satisfied for each of the six example chemicals; nor did the available data allow comparisons to be made for all six chemicals; however, in general, at least four of the six chemicals could be included in each of the comparisons that were undertaken as part of this analysis.

2.0 ALLOWABLE FISH TISSUE CONCENTRATIONS DERIVED FROM THE HH-WQCS

The HH-WQCs are established based on two exposure pathways: use of surface water as a source of drinking water; and the consumption of fish that may be caught and eaten from the surface water. The

same algorithms that are used to calculate the HH-WQC can be rearranged to "back-calculate" an allowable fish tissue concentration.[11] Such values could be termed a water quality-based fish tissue concentration (FTC_{WQ}). These values are therefore a function of the same exposure assumptions, toxicity values and target risk level of 1×10^{-6} (for carcinogenic effects) used in calculating the HH-WQC.

The fish consumption rate (FCR) is an important factor in determining the HH-WQCs for chemicals having a moderate or high bioaccumulation potential. This analysis employs three different FCRs. As intended for the general population of fish consumers, we used the U.S. Environmental Protection Agency's (USEPA's) previously recommended default FCR of 6.5 grams/day or the current USEPA-recommended FCR of 17.5 grams/day. The choice between these two FCRs for each of the six chemicals was based on the derivation of the current HH-WQC, as published by USEPA. Specifically, the FCR used by USEPA to derive the current WQC for each chemical was selected for this analysis. For all but one chemical, this FCR was 17.5 grams/day. The exception was arsenic, where the HH-WQC is still based on an FCR of 6.5 grams/day. (The FTCs based on a FCR of 17.5 grams/day are referred to as the $FTC_{WQ\text{-}17.5}$ in the remainder of this appendix. Note that the recreational consumption rate FTC for arsenic is also referred to as $FTC_{WQ\text{-}17.5}$ despite being based on a FCR of 6.5 grams/day.)

Applying a FCR of 142.4 grams/day produced another set of FTC_{WQ} (referred to as the $FTC_{WQ\text{-}142}$ in this appendix); this FCR represents a higher-end fish intake, which USEPA specifically recommends for subsistence anglers and is similar to the FCR recently adopted by the state of Oregon for state-wide ambient water quality criteria (Oregon DEQ 2011). The resulting FTC_{WQ} for the six chemicals represent concentrations a regulatory agency might use to restrict consumption of fish in areas where there was reason to believe that subsistence fishing was known to occur. FTC_{WQ} calculated for the six chemicals are summarized in Tables C1a (based on a FCR of 6.5 or 17.5 gram/day) and C1b (based on a FCR of 142 gram/day).

FTC_{WQ} were derived from both the "water + organism" and the "organism only" HH-WQC. The former assumes that a surface water body is used as a source of drinking water and a source of fish consumption. The latter assumes that a surface water body is used only for consumption of fish. The influence of the drinking water consumption pathway is minor, or negligible for chemicals with a high bioconcentration factor (BCF), such as polychlorinated biphenyls (PCBs) and chlordane; however, it is important for chemicals with lower BCFs, such as methyl bromide, arsenic, and BEHP. For these chemicals, the use of the water and organism HH-WQC means that the allowable fish tissue concentration (i.e., FTC_{WQ}) will be substantially lower, because the target risk levels must be split between these pathways. However, the resulting FTC_{WQ} would be assumed to be applicable in most areas because most states require that surface water bodies be protected for use as a source of drinking water.

[11] Mathematically, this is the equivalent of multiplying the HH-WQC by the BCF, as long as a pathway-specific HH-WQC is used, i.e., based on the "organism only" or "water+organism" HH-WQC values.

Table C1a Allowable Fish Tissue Concentrations Derived from HH-WQC ($FTC_{WQ-17.5}$) for Six Chemicals: FCR = 17.5 g/day[1]

		HH-WQC Category[2]			
		Water+Organism		Organism Only	
Chemical	BCF (L/kg)	HH-WQC (µg/L, ppb)	$FTC_{WQ-17.5}$ (µg/kg, ppb)	HH-WQC (µg/L, ppb)	$FTC_{WQ-17.5}$ (µg/kg, ppb)
PCBs	31,200	6.4E-05	2.0	6.4E-05	2.0
Methyl bromide	3.75	47	178	1,493	5,600
Arsenic	44	0.018	0.77(1)	0.14	6.2
Mercury	7,343	0.054	394(3)	0.054	400
Chlordane	14,100	8.0E-04	11.3	8.1E-04	11.4
BEHP	130	1.2	15	2.2	286

Notes:
[1] Tissue concentration for arsenic was calculated based on former FCR of 6.5 g/day, because current HH-WQC still uses this value.
[2] Assumed use of the surface water body
[3] USEPA has established a Fish Tissue WQC for methylmercury of 300 ppb, which would be expected to supersede this value.

Despite the limited applicability of "organism only" FTC_{WQ} concentrations, they are still presented in some of the comparisons below because some regulatory agencies have derived FCA trigger levels based on fish consumption only or such triggers may be applied to waters not designated as a drinking water source (e.g., estuaries).

Table C1b Allowable Fish Tissue Concentrations Derived from HH-WQC (FTC_{WQ-142}) for Six Chemicals: FCR = 142 g/day

		HH-WQC Category[1]			
		Water+Organism		Organism Only	
Chemical	BCF (L/kg)	HH-WQC (µg/L, ppb)	FTC_{WQ-142} (µg/kg, ppb)	HH-WQC (µg/L, ppb)	FTC_{WQ-142} (µg/kg, ppb)
PCBs	31,200	7.9E-6	0.25	7.9E-6	0.25
Methyl bromide	3.75	38.7	145	184	690
Arsenic	44	4.9E-3	0.21	6.4E-3	0.28
Mercury	7,343	6.7E-3	49.2(2)	6.7E-3	49.3(2)
Chlordane	14,100	1.0E-04	1.4	1.0E-04	1.4
BEHP	130	0.24	31.8	0.27	35.2

Notes:
[1] Assumed use of the surface water body
[2] USEPA has established a Fish Tissue WQC for methylmercury of 300 ppb; this value does not apply to subsistence levels of fish consumption, but the unique approach applied to mercury by USEPA could have an effect on these values.

3.0 MEASURED FISH TISSUE CONCENTRATIONS IN U.S. LAKES AND RESERVOIRS: COMPARISON WITH FTC_{WQ}

Several federal and state programs have provided data on the fish tissue concentrations of environmental chemicals in U.S. lakes and rivers. In addition to nationwide programs sponsored by USEPA, such as the National Study of Chemical Residues in Fish (USEPA 1992), some states have ongoing fish monitoring programs or have sponsored targeted studies. Many of these programs are focused on a particular set of compounds or a particular area.

The National Study of Chemical Residues in Lake Fish Tissue (or "National Lake Fish Tissue Study", or NLFTS) was a statistically-based study conducted by USEPA Office of Water, with an objective of assessing mean levels of selected bioaccumulative chemicals in fish on a national scale. The results represent concentrations throughout the U.S. based on samples collected from 500 lakes and reservoirs in 48 states (USEPA 2009; Stahl et al. 2009). The sampling phase was carried out from late 1999 through 2003. The focus on lakes and reservoirs, rather than rivers and streams, was based on the greater tendency of lakes for receiving and accumulating environmental chemicals. A *National Rivers and Streams Assessment*[12] is currently in progress, and it would be of interest to examine the fish tissue concentration data from this survey when the data become available. It is likely that any fresh water survey of a national scope, whether it included bound or flowing water bodies would find a broad range of fish tissue concentrations, with the concentrations being more highly influenced by the location and history of the water body.

The NLFTS included PCBs, dioxins, polycyclic aromatic hydrocarbons (PAHs), 46 pesticides, arsenic and mercury. Adult fish were collected from two categories: predator and bottom-dwelling, with the predatory fish comprised of largemouth bass (50%), walleye (10%) and northern pike (7%), and bottom-dwelling species comprised of common carp (26%), white sucker (20%) and channel catfish (16%). A summary of the results from this study is shown in Table C2a.

Table C2a Concentrations in Fish as Reported by the National Lake Fish Tissue Study (USEPA 2009)

	Predator (Fillets) (µg/kg, ppb)			FTC_{WQ} Water+Organism (µg/kg, ppb)	
Chemical	Mean	50th %ile	90th %ile	$FTC_{WQ\text{-}17.5}$	$FTC_{WQ\text{-}142}$
PCBs	13.2	2.2	18.2	2.0	0.25
Arsenic	ND(2)	ND(2)	ND(2)	0.77	0.21
Mercury	352	285	562	394	49
Chlordane	ND(2)	ND(2)	3.6	11.3	1.4

Notes:

[1] National Lake Fish Tissue Study (NLFTS) (USEPA 2009); data from 486 predator fillet samples

[2] Infrequent detection in fish. Arsenic was detected at <1% of sampling locations, for predatory fish with a detection limit of 30 ppb. Chlordane was detected at 1-5% of sampling locations (for predatory fish) with a detection limits of 0.02 (alpha) and 0.49 (gamma) ppb. BEHP was detected at 1-5% of sampling locations (for predatory fish) and results are not provided by USEPA (2009).

[12] http://water.epa.gov/type/rsl/monitoring/riverssurvey/index.cfm

The NLFTS was not focused on areas specifically affected by industrial activities or historic releases. The water bodies included in this survey were selected at random with an objective of capturing typical levels of the chemicals analyzed. In fact, many lakes were included that could be regarded as pristine, likely to have been affected by only minimal human activity. Therefore, the resulting data could be representative of 'background' concentrations, which are from unavoidable depositional inputs of the chemicals of interest. However, because many of the water bodies included the NLFTS may have been affected by specific discharges or historic releases, we refer to the resulting data being only representative of typical levels for U.S. lakes. For simplicity, only the data representing predatory fish were included in this analysis, because these are the species likely to be targeted by anglers. The bottom-dwelling fish, which were included in the NLFTS to represent ecological (wildlife) exposures, contained substantially higher concentrations of PCBs (6 times greater at the median) and chlordane (1.7 ppb vs. ND), but lower concentrations of mercury (4 times lower at the median).

As shown in Table C2a, this study provided data for PCBs and mercury, as well as for arsenic and chlordane. Arsenic and chlordane were reported at very low frequencies of detection making quantitative comparisons between fish concentrations and FTCs challenging. Nevertheless, because the detection limits for chlordane (0.02 ppb for alpha and 0.5 ppb for gama) are less than the $FTC_{WQ-17.5}$ (11.3 ppb), and the 90th percentile of the distribution of chlordane concentrations is roughly 3 times lower than the $FTC_{WQ-17.5}$, NLFTS data do demonstrate that chlordane concentrations in predatory fish from the large majority of U.S. surface waters are below the $FTC_{WQ-17.5}$. This also suggests that current concentrations of chlordane in most U.S. surface waters are unlikely to be above the HH-WQC derived based on the consumption rate of recreational anglers.

A similar evaluation could not be conducted for arsenic. The reported arsenic detection limits was above the $FTC_{WQ-17.5}$ derived from the HH-WQC, precluding a comparison with the $FTC_{WQ-17.5}$ absent making assumptions about the concentration of arsenic in fish samples with non-detectable concentrations. As a specific example, the NLFTS reported a method detection limit (MDL) for inorganic arsenic of 30 ppb, even using a state-of-the-art analysis, Method 1632A for the speciation of arsenic. Given that the $FTC_{WQ-17.5}$ for arsenic is 0.77 ppb, it is not possible to determine whether concentrations in predator fillets are above or below that $FTC_{WQ.}$ Assuming detection limits for arsenic cannot be easily refined, this comparison does suggest that it is not possible to demonstrate compliance with the arsenic $FTC_{WQ-17.5.}$

For PCBs, the NLFTS data indicate that a substantial portion of predatory fish from U.S. lakes exceed the $FTC_{WQ-17.5}$ for PCBs (2 ppb). The extent of this exceedance depends on whether the data are represented by the mean concentration (13.2 ppb), which exceeds the $FTC_{WQ-17.5}$ by a factor of about 6x, or the median (i.e., 50th percentile) concentration (2.3 ppb), which is nearly equivalent to the $FTC_{WQ-17.5}$. While this comparison indicates the average concentration of PCBs in fish throughout the U.S. is substantially higher than the $FTC_{WQ-17.5}$, it does not follow that fish in most surface waters of the U.S. have PCB concentrations greater than both of the FTC_{WQ}s. The difference between the mean and median concentration comparisons for this data set likely arises because the data are skewed, with the majority of samples having relatively low concentrations. As noted above, the 50th percentile of the distribution of PCB concentrations in predatory fish from U.S. lakes is approximately equal to the $FTC_{WQ-17.5}$. Assuming the BCF accurately reflects the relationship between the PCB concentration in fish and water, the comparison of the $FTC_{WQ-17.5}$ to the 50th percentile indicates that roughly half of sampled U.S. waters had PCB concentrations that met or were below the HH-WQC derived based on the consumption of recreational anglers. .

The mean mercury concentration of the NLFTS data (352 ppb) is slightly lower than the $FTC_{WQ-17.5}$ for mercury (394 ppb). The percentile data provided by USEPA (2009) indicate the distribution of

mercury concentrations in predatory fish is also skewed, though a smaller proportion of the samples (approximately 25%) exceed the mercury $FTC_{WQ-17.5}$ than exceeded the PCB $FTC_{WQ-17.5.}$

The results of parallel comparisons with FTCs derived based on subsistence anglers (i.e., FTC_{WQ-142}) lead to a different conclusion for three for the four compounds (chlordane, PCBs and mercury). The arsenic FTC_{WQ-142} is about four times lower than the $FTC_{WQ-17.5}$ and is also below the typical detection limits for inorganic arsenic, precluding any meaningful quantitative comparisons with the FTC_{WQ-142}.

The detection limit for alpha chlordane is slightly above the FTC_{WQ-142} and the detection limit for gamma is slightly below (see footnotes to Table C2a). Additionally, the 90th percentile of the distribution of chlordane concentrations is only about 2.5 times higher than the $FTC_{WQ-142.}$ These comparisons suggest that typical concentrations of chlordane may be similar to or less than the FTC_{WQ-142} in many U.S. surface waters, though the upper percentiles of the distribution do exceed the FTC_{WQ-142}, in some cases, substantially (Table C2a).

The FTC_{WQ-142} is about 10 times lower than the $FTC_{WQ-17.5}$ for PCBs and mercury (Table C2a). With the increase in FCR, the average fish tissue concentration exceeds the FTC_{WQ-142} by approximately 50x and 7x for PCBs and mercury, respectively (Table C2a). Additionally, the majority of the distribution of PCB and mercury concentrations is above the $FTC_{WQ-142.}$ For both chemicals, the concentration at the 5th percentile of the distribution exceeds the $FTC_{WQ-142.}$ These comparisons indicate that if HH-WQC were to be revised using an FCR of 142 grams/day, assumed to be representative of subsistence anglers, the concentrations of PCBs and mercury in fish from virtually all surface waters in the U.S. would exceed the allowable fish concentration associated with such an HH-WQC.

Several state programs have surveyed fish tissue concentrations, often including PCBs, metals and/or pesticides. The state data assembled for our analyses included surveys conducted by Washington State Department of Ecology (WA-DOE) and by the Florida St. Johns River Water Management District (SJRWMD). Overall, the state programs include more recent data (through 2011) than those presented in the NLFTS (through 2003). These are much more limited data sets compared to the data from the NLFTS. Additionally, the number of observations from each state varies by chemical and in some instances all the data points are from a single state (e.g., all PCB data are from Washington).

Table C2b Measured Concentrations in Fish Samples from Washington and Florida

	Data from State Programs (µg/kg, ppb)			FTC_{WQ}[1] (µg/kg, ppb)	
Chemical	Mean[2]	50th %ile	90th %ile	$FTC_{WQ-17.5}$	FTC_{WQ-142}
PCBs	27.4	22.1	49.8	2.0	0.25
Mercury	191	120	408	394	49
Chlordane	1.4	0.62	2.8	11.3	1.4

Notes:
Based on data provided by J. Beebe (NCASI) and comprised of data from Washington State WA-DOE (2011), WA-EIMS, http://www.ecy.wa.gov/eim), and St. Johns River Water Management District (SJRWMD), Florida (http://sjr.state.fl.us).
[1] FTC_{WQ} derived from water and organism HH-WQC.
[2] Data included: for PCBs, 45 samples from WA-EIMS; for mercury, 1598 samples from WA-EIMS and SJRWMD; and for chlordane, 382 samples from SJRWMD.

The mean concentration of PCBs in predatory fish (27.4 ppb), is about 14 times and 100 times higher than the $FTC_{WQ-17.5}$ and FTC_{WQ-142}, respectively. In fact, both FTC_{WQ}s are well below the minimum reported concentration (9.7 ppb) from this data set. Assuming these data were collected from waters potentially affected by PCB releases suggests that meeting the HH-WQC, based on either the recreational of subsistence FCR, in such waters is likely to be a challenge. To the extent these data are only from Washington, this finding may only apply to waters of that state.

The mean concentrations of mercury and chlordane from state programs are below their respective $FTC_{WQ-17.5}$ by approximately 2x- and 8x-, respectively (Table 4-2b) suggesting that a substantial portion of the surface waters in these states would meet an HH-WQC derived based on an FCR assumed to be representative of a recreational angler. The mean concentration of chlordane is equal to the FTC_{WQ-142}. If the chlordane distribution from these two states has a similar "shape" to the distribution in the national survey, this comparison suggests that a substantial portion of surface waters in these two states would meet an HH-WQC based on an FCR representative of a subsistence angler. Fewer waters are likely to meet such an HH-WQC for mercury, given that the mean concentration exceeds the FTC_{WQ-142} by approximately 4x.

Arsenic was included in several of the state databases, however, inorganic arsenic was not detected at measurable concentrations. As discussed above for the NLFTS data, meaningful comparison of inorganic arsenic concentrations to FTCs is precluded because MDLs are greater than the FTCs.

4.0 COMPARISON OF FTC_{WQ} TO FCA TRIGGER LEVELS ESTABLISHED BY STATE OR OTHER PUBLIC HEALTH AGENCIES

Most states and various federal agencies have programs for the protection of anglers who may eat fish containing trace amounts of chemicals. These programs are responsible for issuing FCAs for lakes and reservoirs where particular chemicals have been detected at levels in fish that exceed some risk-based "trigger level." While the approach to setting FCAs may differ, most programs use a risk-based approach to develop guidelines that are intended to be protective of the health of the angler communities with a wide margin of safety. USEPA (2000) issued guidance that could be used to establish some uniformity in the methods used to derive FCAs, but most states are maintaining programs and guidelines that have served them for many years. A common feature of both federal and state guidelines is the movement away from a single trigger level and towards a progression of trigger levels, each associated with an increasing level of restricted intake for the fish (and chemical) in question. Despite this increased complexity, USEPA (2000) also provided screening values (SV) based on moderate (recreational) and high (subsistence) levels of fish consumption, termed SVrec and SVsub, respectively, and shown in Table 4-3 for PCBs, arsenic, chlordane, and mercury.

Also shown in Table 4-3 are examples of FCA trigger levels from state programs that publish numerical benchmarks for this purpose. For states that have adopted a series of trigger levels, this analysis presents the levels based on either a "no more than 2 meal per month" restriction (noted as "L2" in Table 4-3), or a 'do not eat' advisory (complete restriction, notes as "R" in Table 4-3). Two 8-ounce (227 g) meals per month is assumed to be comparable to the 17.5 gram/day FCR applied by USEPA to the derivation of HH-WQC.[13]

[13] The guidelines from WI-DNR and MI-DCH, however, only included a one meal per month advisory level, and the concentrations accompanying this advisory level are shown for these two agencies (noted as "L1" in Table 4-3).

Table C3 USEPA Screening Values for Fish and FCA Trigger Levels Used by Select State Agencies[1]

	Federal USEPA (2000)[2] (µg/kg, ppb)		Select State Programs (µg/kg, ppb)			FTC_{WQ} Organism Only Values (µg/kg, ppb)	
Chemical	SV(rec)[3]	SV(sub)[3]	WI-DNR	MI-DCH	WV-DHHS	$FTC_{WQ\text{-}17.5}$	$FTC_{WQ\text{-}142}$
PCBs	20	2.5	220 (L1) 2,000 (R)	200 (L1) 2,000 (R)	150 (L2) 1,340 (R)	2.0	0.25
Arsenic	26	3.3	--	NA	140 (L2) 1,250 (R)	6.2	0.28
Mercury	400	50	500-1000 (NS)	500 (L) 1,500 (R)	220 (L2) 1,880 (R)	400	49
Chlordane	114	14	660 (L1) 5,620 (R)	300 (NS)	880 (L2) 7,660 (R)	2.2	1.4

Notes:
R: Restricted, referring to 'do not eat' advisory.
L: Limited, or a limited amount of consumption is advised.
L1: Limited to 1 meal per month.
L2: Limited to 2 meals per month.
NS: Not stated whether the value represents a restriction or a limit.
[1] Wisconsin Department of Natural Resources (WI-DNR), 2007, 2011; Michigan Department of Community Health (MI-DCH), 2008; West Virginia Department of Health and Human Services (WV-DHHS).
[2] USEPA, 2000. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume 1.
[3] Screening values (SV) for the recreational and subsistence angler.

When compared to these FCA trigger levels, the $FTC_{WQ\text{-}17.5}$ for PCBs, arsenic and chlordane are 20-4,000 times lower (more stringent) (Table C3). For mercury, the $FTC_{WQ\text{-}17.5}$ is comparable to the trigger levels prompting some restriction on fish consumption, but is as much as 4x lower than the level where a 'do not eat' advisory is prompted. $FTC_{WQ\text{-}142}$ are between 200-8,000 times lower than the FCA trigger levels for PCBs, arsenic, and chlordane, and 4 to 40 times lower than the trigger levels for mercury (Table C3).

As shown in Table C3, the USEPA SVs are either similar or 10x higher than the FTC_{WQ} derived from the HH-WQC. Because these USEPA values are intended to be generic screening-level benchmarks, they are very conservative compared to the trigger levels used by the most state programs (discussed further below).

Comparing the USEPA SVs to FTC_{WQ} for chemicals for which noncancer endpoints are the driver, such as mercury, SVs are the same as the FTC_{WQ}s. For the other three constituents, for which the cancer endpoint is most sensitive, the SVs are approximately 10 times higher, because SVs are derived based on a $1x10^{-5}$ target risk level, rather than a $1x10^{-6}$ target risk level.

In contrast, fish advisory trigger levels used by public health agencies in Wisconsin, Michigan, and West Virginia (Table C3) are less stringent, and in general, would require substantially higher concentrations of arsenic, chlordane and PCBs than allowed by the HH-WQC before issuing even a moderate restriction on fish consumption. Based on our survey of state "trigger levels" and recent

reviews comparing the FCAs between states (IWG-ACA, 2008; Scherer et al. 2008), we believe that the FCAs from Wisconsin, Michigan, and West Virginia are likely to be representative of the FCAs from many state programs. Scherer et al. (2008) found the FCAs among states to be quite similar, despite some variation in the methods used to develop the FCAs. Many state programs rely on less-stringent food tolerance levels as the basis for their trigger levels; this choice is consistent with the desire by States to consider the value of their recreational fisheries and the benefits of fish consumption, while protecting the public from potential chemical risks. The difference in the State vs. EPA trigger levels is due to several factors. As noted previously, state guidelines are typically based on a series of FCA trigger levels, giving the States the ability to partially restrict fish consumption at many concentration levels. Further, the ability to issue consumption limits for specific target fish species also permits states to allow higher fish tissue concentrations. Lastly, state agencies are more likely to apply lower assumed fish consumption rates based on local or regional surveys conducted within the state.

A key illustration of the conservative nature of the FTCs is provided by a comparison of the proportion of samples in the NLFTS data set that exceed an FTC_{WQ} to the proportion of waters in the U.S. that have a fish consumption advisory. As described above approximately 50% of fish samples have PCB concentrations that exceed the $FTC_{WQ\text{-}17.5}$ and over 95% exceed the $FTC_{WQ\text{-}142}$. Yet, only about 15% of the nation's lakes are subject to a fish consumption advisory (USEPA 2009). Given that a goal of both an HH-WQC and an FCA is protection of the health of anglers, the much larger proportion of waters estimated to potentially pose an unacceptable risk when an HH-WQC is used than measured by the posting of an FCA, suggests that the derivation of HH-WQC by USEPA is substantially more conservative than the derivation of FCAs by state agencies.

5.0 COMPARISON OF FTC_{WQ}S TO HEALTH-BASED LIMITS FOR FISH OR OTHER FOODS

Other federal and global agencies charged with protection of food safety have established guidelines for ensuring the safety of foods in commerce. The most notable examples in the U.S. are the food tolerances established by USFDA. These tolerances have been used as a guideline for assessing the safety of food, largely animal products, such as beef, chicken, fish, milk and eggs. These tolerances are typically less stringent than analogous values derived using USEPA methods for risk assessment. Unlike the USEPA, the USFDA must balance potential economic concerns with the potential benefits to public health; in other words, the USFDA must consider the consequences of its actions on the U.S food supply. USEPA exposure limits and screening levels may also be considered for their economic consequences, but this review is conducted outside of the Agency and only after the value has been derived. Regardless, USFDA tolerances are risk-based concentrations and many risk assessors and scientists support the idea that the tolerances are protective of the public health (Cordle et al. 1982; Maxim and Harrington 1984; Boyer et al. 1991). Due to recent incidents in Europe in which PCBs were accidentally introduced into animal feeds, the European Commission (EC) has set maximum levels for PCBs in foods and feedstuffs, including fish (EC, 2011). The limits were based on a report of the European Food Safety Authority (EFSA) deriving allowable exposure levels, and on monitoring data compiled throughout the European Union (EU). The EU considered both the public health protection and the feasibility of attaining these limits, based on current levels measured in foods.

FTC_{WQ} derived from the HH-WQC are in all cases well below both the USFDA and EU food tolerance levels (Table C4). The USFDA tolerance for PCBs in fish of 2,000 ppb is 1,000 times higher than the $FTC_{WQ\text{-}17.5}$ and 8,000 times higher than the $FTC_{WQ\text{-}142}$.

Table C4 Comparison of FTC_{WQ} to Food Safety Guidelines for Chemical Concentrations in Fish

	Food Safety Standards		HH-WQC-Based Threshold for Fish	
Chemical	USFDA Tolerance for Fish[1] (µg/kg, ppb)	EU Limit for Fresh Fish[2] (µg/kg, ppb)	FTC_{WQ} FCR = 17.5 (µg/kg, ppb)	FTC_{WQ} FCR=142 (µg/kg, ppb)
PCBs	1,000 (action level) 2,000 (limit)	250(3)	2.0	0.25
Mercury	1,000 (action limit)	--	394	49.2
Chlordane	300	--	11.3	1.4

Notes:
[1] USFDA (1998, 2011); Values are based on wet weight.
[2] European Commission (EC) 2011. Commission Regulation No. 1259/2011.
[3] EC Limit for PCBs is 125 ng/g wet wt. for the sum of 6 'marker' congeners, which comprise about 50% of the PCBs in fish. Therefore, to be applicable to a measure of total PCBs, this value was multiplied by a factor of 2 (EC, 2011).

6.0 TYPICAL INTAKES OF THE CHEMICALS IN THE U.S. POPULATION: COMPARISON TO THE ALLOWABLE DAILY INTAKES DERIVED FROM THE HH-WQC

The goal of an HH-WQC is to limit exposure of the population to chemicals in water such that an allowable dose (or risk) is not exceeded. If the dominant exposure pathway for a chemical is direct contact or use of surface water, then compliance with the AWQC may, indeed, limit overall exposure to allowable levels. However, if other pathways also contribute to overall exposure and, in particular, if the other pathways represent larger exposures than surface water, then establishment and enforcement of a stringent surface water criterion may not provide a measurable public health benefit. This section compares exposures allowed by the HH-WQC to the potential exposures from a limited set of other exposure sources or pathways for five chemicals.

One of the key assumptions used to derive FTC_{WQ} is an allowable daily intake of each constituent in question. This allowable daily intake is a toxicologically-derived value and is represented by a reference dose (RfD) (for noncancer endpoints) or a risk-specific dose (RSD) (when cancer is the endpoint). The RSD is equal to the target risk level (typically 1×10^{-6}) divided by the cancer slope factor (CSF) for a particular constituent.

As shown in Table C5, the RfDs and RSDs for the six chemicals evaluated in this appendix range from 0.35 µg/day for PCBs to 98 µg/day for methyl bromide.[14] These are the toxicity values chosen by USEPA for the derivation of HH-WQC.

Another way to estimate the allowable daily dose associated with the HH-WQC, and the FTC_{WQ} in particular, is to multiply the allowable fish tissue concentrations (i.e., the FTC_{WQ}) by the assumed FCR of 17.5 grams/day. The results, as shown in Table C5 as "Fish Dose", represent the dose of each chemical that someone would receive who ate fish containing chemicals at concentrations equal to the FTC_{WQ}.

[14] Traditional units of dose in mg/kg-day are converted to units of intake (µg/day) by multiplying by an adult body weight of 70 kg and a conversion factor of 1000 µg/mg.

For PCBs, mercury and arsenic, very low, but measurable daily intakes by the U.S. population are based on releases of these substances into the environment and their presence in trace quantities in the food supply. Arsenic occurs naturally in soils and groundwater and, therefore, there is a normal daily intake that varies by region. For BEHP, the presence of trace amounts in food stems from its use in plastic food packaging materials (Fromme et al. 2007). A summary of the data used to provide an estimate of the typical daily intake of each chemical is presented below.

PCBs: The intake of PCBs through foods, mainly animal products, has declined dramatically in the last 30 years. However, Schecter et al. (2010) recently carried out a market-basket survey of several types of foods and found measurable levels in enough foods to propose a daily intake of about 0.1 µg/day for a typical resident of the U.S. Other studies in Europe have proposed slightly higher intake levels (as high as 0.8 µg/day), but overall, corroborate the findings of Schecter et al. (2010). This range of typical dietary intakes of PCBs is 3 times to as much as 20 times greater than the risk-specific dose (RSD) used to derive the HH-WQC (0.035 µg/day) (Table C5). Thus, the HH-WQC is based on an exposure limit for PCBs that is routinely exceeded by the typical PCB intake that occurs through dietary exposures.

BEHP: Considerable effort has been made to estimate the human exposure to phthalate esters, which arises from food packaging materials, e.g., plastic food wraps. A German study by Fromme et al. (2007) provides the most reliable estimates of intake, based on a study using both samples of dietary items and biomonitoring data. Because phthalate ester exposures are derived from plastic packaging/wrapping that is sold across the globe, intakes estimated by this study for a German population are likely to be comparable to those in U.S. The authors report a median BEHP intake of 2.4 µg/kg-day (162 µg/day) which is approximately 30 times greater than the RSD used by the HH-WQC (Table C5). Thus, the HH-WQC is based on an exposure limit for BEHP that is routinely exceeded by the typical intake that occurs through dietary exposures.

Table C5 Allowable vs. Actual Daily Intakes for Select Chemicals

	Allowable Daily Intakes Used as the Basis for the HH-WQCs		Measured or Estimated Average Daily Intakes Derived from Food		
	Value [RfD or RSD] (µg/day)	Fish Dose[1] (µg/day)	Intake (µg/day)	Group	Note
PCBs	0.035 [RSD]	0.035	0.1-0.8	all	(a)
Methyl bromide	98 [RfD]	3.1	6.5 (mean); 310 (95th %ile)	male	(b)
			10 (mean); 350 (95th %ile)	female	
Arsenic	0.04 [RSD]	0.014	3.6 / 2.7 (avg.); 9.4 (90th %ile)	male	(c)
			2.8 / 2.4 (avg.); 11.4 (90th %ile)	female	
Mercury	7 [RfD]	7	8.6 (mean); 166 (90th %ile)	male	(d)
			8.2 (avg.); 204 (90th %ile)	female	
BEHP	5 [RSD]	0.26	162 (median); 309 (95th %ile)	all	(e)

Notes:
RfD, Reference Dose; RSD, Risk-Specific Dose
[1] Computed as FTC_{WQ} [from Table C1a] x FCR [17.5 g/day]
(a) Range is based on the results of several studies (Darnerud et al. 2006; Arnich et al. 2009; Roosens et al. 2010; Schecter et al. 2010).
(b) Cal-EPA 2002; assumed body weight of 70 kg for adults.
(c) Meacher et al. 2002; assumed body weight of 70 kg for adults.
(d) MacIntosh et al. 1996.
(e) Fromme et al. 2007.

Arsenic: A study by Meacher et al. (2002) represents a comprehensive evaluation of total inorganic arsenic exposure in the U.S. population. The authors discuss other studies with a similar aim and conclude that the average daily intake, primarily from food and drinking water, is in the range of 1 to 10 µg/day. Estimates of average daily intakes are 60 to 90 times greater than the RSD. Thus, the HH-WQC is based on an exposure limit for arsenic that is exceeded by a wide margin, by typical dietary intakes of arsenic.

Methyl bromide: The concentrations detected in foods are mainly in animal products, such as milk, which makes estimates of a one-time exposure as high as 4-5 µg/kg-day, but with average daily exposures likely to be less than 1 µg/kg-day, according to a study by Cal-EPA (2002). While 95th percentile values (310-350 µg/day) are more than 40 times higher that the mean intake estimates, it can be concluded that typical methyl bromide intakes based on diet are likely to be below the RfD of 98 µg/day. Thus, for methyl bromide, dietary intakes would not appear to hinder the objective of limiting the exposures based on fish consumption.

Mercury: The predominant human intake is from concentrations in predatory and deep-sea fish such as tuna. Average daily intakes are estimated to be about 8 µg/day (MacIntosh et al. 1996) and are comparable to the RfD of 7 µg/day (Table C5). Thus, for mercury, it is not uncommon for the consumption of store-bought tuna to provide an intake equivalent to the RfD; achieving this level of exposure would at least appear to be an achievable public health objective.

In summary, estimated daily intakes for five of the six chemicals could be obtained from the literature (Table C5). For PCBs, arsenic and BEHP, the chemicals for which potential cancer risk is the most sensitive endpoint, the estimated daily intake for the U.S. population is between 3 times to 90 times greater than the RSD. In surface waters with fish that have concentrations that are no more than a 2-times lower than the FTC, based on the comparisons shown in Table C5, decreasing exposures to the levels associated with HH-WQC would be likely to have no discernible effect on the intake of these chemicals in the community.

7.0 SUMMARY AND CONCLUSIONS

This paper described the derivation of allowable fish tissue concentrations (referred to as FTC_{WQ}) associated with HH-WQC for a select group of chemicals. FTC_{WQ} are based on the same exposure and toxicity factors used to derive the HH-WQC. Separate FTC_{WQ} were derived for USEPA's recommended fish consumption rate for recreational anglers (17.5 grams/day, $FTC_{WQ\text{-}17.5}$) and subsistence anglers (142 grams/day, $FTC_{WQ\text{-}142}$). Given the nearly 10x higher consumption rate assumed for subsistence anglers compared to recreational anglers, $FTC_{WQ\text{-}142}$ were lower than the $FTC_{WQ\text{-}17.5}$ for every chemical by about 10x. FTC_{WQ} were compared to: (1) concentrations measured in fish from U.S. water bodies; (2) trigger levels used by State agencies to set fish consumption advisories; and (3) allowable concentrations set by other US and international health agencies. Additionally, ADIs used to derive FTC_{WQ} were compared to estimated daily dietary intakes from all sources.

PCB concentrations in about half of the fish from the NLFTS exceeded the $FTC_{WQ\text{-}17.5}$ and PCB concentrations in essentially all fish from the NLFTS exceeded the $FTC_{WQ\text{-}142}$. (Additionally, all of the fish from two state-specific surveys had PCB concentrations above the $FTC_{WQ\text{-}17.5}$ and the $FTC_{WQ\text{-}142}$.) The mercury concentrations for the majority of fish in the NLFTS were below the $FTC_{WQ\text{-}17.5}$ but most fish had mercury concentrations above the $FTC_{WQ\text{-}142}$. Chlordane was not detected in the majority of NLFTS samples with detection limits below the $FTC_{WQ\text{-}17.5}$ and the $FTC_{WQ\text{-}142}$ suggesting the majority of fish have chlordane concentrations below either FTC_{WQ}. Arsenic was not detected in majority of NLFTS; however, unlike chlordane, the method detection limit for arsenic exceeds both the $FTC_{WQ\text{-}17.5}$ and the $FTC_{WQ\text{-}142}$ by more than 30x, precluding the possibility of determining whether arsenic concentrations meet the HH-WQC. Thus, whether nationwide fish tissue concentrations meet the FTC_{WQ} depends upon the chemical of interest and whether recreational or subsistence angler consumption rates are used to derive the FTC_{WQ}. It does appear that if HH-WQC were to be revised using an FCR of 142 grams/day, the concentrations of PCBs and mercury in fish from virtually all surface waters in the U.S. would exceed the allowable fish concentration associated with such HH-WQC.

$FTC_{WQ\text{-}17.5}$ for PCBs, arsenic, and chlordane were 20 to 4,000 times lower (more stringent) than FCA trigger levels commonly used by state programs. For mercury, the $FTC_{WQ\text{-}17.5}$ was comparable to typical state trigger levels prompting some restriction on fish consumption, but it was as much as 4 times lower than the level where a 'do not eat' advisory is prompted. Again, the comparisons were much more remarkable using the $FTC_{WQ\text{-}142}$. $FTC_{WQ\text{-}142}$ were between 200 times and 8,000 times lower than the FCA trigger levels for PCBs, arsenic, and chlordane, and 4 times to 40 times lower than the state trigger levels for mercury. These comparisons were based on the guidelines from a select number of states, including Wisconsin, Michigan, and West Virginia; however, the FCA trigger

levels were comparable among this small group of states, and based on our review of guidelines in many other states not included in this analysis, we believe that these states can be considered representative of many other state programs.

A comparison of FCAs to the NLFTS data provides another comparison that highlights the conservatism of the FTC_{WQ} (and the HH-WQC from which they were derived). Approximately 50% of fish samples from the NLFTS had PCB concentrations that exceeded the $FTC_{WQ-17.5}$ and over 95% exceeded the FTC_{WQ-142}. However, only about 15% of the nation's lakes and reservoirs (on a surface area basis) are subject to a FCA based on PCBs (USEPA 2009). Thus, use of HH-WQC indicated that a much larger proportion of US surface waters pose an unacceptable risk than indicated by FCA postings. This comparison further illustrates that the assumptions used by USEPA to derive HH-WQC are more conservative than the assumptions used by state agencies to derive FCAs.

Various agencies, both Federal and international, have established concentration limits for fish as a food in commerce. The FDA food tolerances are the most notable example. FTC_{WQ} were compared to FDA tolerance limits and a recently established EU limit for PCBs in fish. The $FTC_{WQ-17.5}$ for PCBs of 2 ppb is 500 times lower than the FDA action limit of 1,000 ppb and 125 times lower than an EU limit of 250 ppb. The FTC_{WQ-142} is 1,000x and 4,000x lower than the EU and FDA action limits, respectively. The FDA tolerance of 300 ppb for chlordane is similarly much less stringent than either the $FTC_{WQ-17.5}$ (11.3 ppb) or the FTC_{WQ-142} (1.4 ppb) for chlordane. The FDA action level for mercury of 1,000 ppb is similar to but still higher than either the $FTC_{WQ-17.5}$ (394 ppb) or the FTC_{WQ-142} (49 ppb) for mercury. These comparisons indicate that HH-WQCs are limiting fish tissue concentrations to levels substantially below those considered to be without significant risk by public health agencies whose goal is to ensure the safety of edible fish.

Lastly, allowable daily intakes (RfDs for noncancer endpoints, RSDs for the cancer endpoint) assumed by the FTC_{WQ} were compared to estimates of the daily intake of arsenic, BEHP, mercury and PCBs obtained from the open literature. Specifically, daily intakes were taken from studies that measured concentrations in various foodstuffs. Typical daily dietary intakes of arsenic, BEHP and PCBs exceeded the allowable daily intakes used to derive HH-WQC by a substantial margin. The typical daily dietary intake of mercury, mostly from tuna, is comparable to the RfD used to derive the HH-WQC. Thus, for those compounds whose daily dietary intake is greater than the intake associated with surface water and already exceeds the allowable daily intakes used to establish HH-WQC, the establishment and enforcement of a more stringent HH-WQC may not provide a measurable public health benefit.

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Treatment Technology Review and Assessment

Association of Washington Business

Association of Washington Cities Washington

State Association of Counties

May 24, 2022

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Acronyms

Acronym	Definition
AACE	Association for the Advancement of Cost Engineering
AOP	advanced oxidation processes
AWB	Association of Washington Businesses
BAC	biological activated carbon
BAP	benzo(a)pyrene
BRS	Brine Recovery System
BOD	biochemical oxygen demand
BTU	British thermal unit
CEPT	Chemically-enhanced primary treatment
cf	cubic feet
CIP	clean in place
CNT	carbon nanotubes (CNTs)
CRITFC	Columbia River Inter-Tribal Fish Commission
Ecology	Washington Department of Ecology
EPA	U.S. Environmental Protection Agency
FCR	fish consumption rate
g/day	grams per day
GAC	granular activated carbon
gal	gallon
gfd	gallons per square foot per day
GHG	greenhouse gas
gpd	gallons per day
gpm	gallons per minute
GWh	giga watt hours
HDR	HDR Engineering, Inc.
HHWQC	human health water quality criteria
HRT	hydraulic residence time
IPCC	Intergovernmental Panel on Climate Change
kg	kilogram
kWh/MG	kilowatt-hours per million gallons
lb	pound
MBR	membrane bioreactor
MCL	maximum contaminant level
MF	microfiltration
mgd	million gallons per day
mg/L	milligrams per liter
MMBTU	million British thermal units
MWh/d	megawatt-hours per day
NF	nanofiltration
ng/L	nanograms per liter
NPDES	National Pollutant Discharge Elimination System
NPV	net present value
O&M	operations and maintenance
ODEQ	Oregon Department of Environmental Quality
PAC	powdered activated carbon
PAH	polycyclic aromatic hydrocarbons
PCB	polychlorinated biphenyls
PE	population equivalents
PIX	potable ion exchange
ppm	parts per million

Acronym	Definition
RO	reverse osmosis
SDWA	Safe Drinking Water Act
sf	square feet
SGSP	salinity gradient solar pond
SRT	solids retention time
Study Partners	Northwest Pulp and Paper Association/Association of Washington Business/Association of Washington Cities and Washington State Association of Counties consortium
TDS	total dissolved solids
TMDL	total maximum daily load
TSS	total suspended solids
UF	ultrafiltration
µg/L	micrograms per liter
USDA	U.S. Department of Agriculture
UV	ultraviolet
WAC	Washington Administrative Code
WAS	waste activated sludge
WLA	waste load allocation
WWTP	wastewater treatment plant
ZLD	zero liquid discharge

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Executive Summary

This study evaluated treatment technologies potentially capable of meeting the U.S Environmental Protection Agency (EPA) proposed human health water quality criteria (HHWQC) for the state of Washington (87 FR 19046, April 1, 2022). Through several Clean Water Act regulatory programs, promulgated water quality criteria influence the establishment of effluent limits in NPDES permits. HDR Engineering, Inc. (HDR) completed a literature review of potential technologies and an engineering review of the capabilities of those technologies to evaluate and screen candidate treatment methods for four pollutants: arsenic, benzo(a)pyrene (BAP), mercury, and polychlorinated biphenyls (PCBs). Four advanced treatment process trains were selected as alternatives to compare against an assumed existing baseline secondary treatment system commonly employed by industrial and municipal dischargers. These four alternatives included enhanced secondary treatment with ultrafiltration/reverse osmosis (UF/RO) and enhanced secondary treatment with ultrafiltration/granulated activated carbon (UF/GAC). Two additional alternatives included an advanced oxidation process (AOP) in a UF/AOP/GAC system and a UF/AOP/GAC/RO system to achieve additional pollutant removal. HDR developed capital costs, operating costs, and a net present value (NPV) for each alternative, including the incremental cost to implement improvements for an existing secondary treatment facility.

Currently, there are no known commercial, industrial, or municipal facilities that treat to the low concentration levels of the proposed HHWQC and anticipated effluent limits that are under consideration. Based on the literature review, research, effluent monitoring reports, and reports from bench scale studies, the following conclusions can be made from this study:

- Revised HHWQC based on EPA's proposed Human Health Criteria for Washington (Federal Register 2022) will result in very low water quality criteria for toxic constituents.
- There are limited "proven" technologies available for NPDES permittees to meet required effluent quality limits that would be derived from revised HHWQC.
    - Current secondary wastewater treatment facilities provide high degrees of removal for toxic constituents; however, they are not capable of compliance with water quality-based National Pollutant Discharge Elimination System (NPDES) permit effluent limits derived from the proposed HHWQC.
    - Advanced treatment technologies have been investigated and candidate process trains have been conceptualized for toxics removal.
        - Advanced wastewater treatment technologies may enhance toxics removal rates; however, they will not be capable of achieving an effluent limit at the level of EPA's proposed HHWQC for total PCB of 7E-06 ug/l (water and organisms). The lowest levels achieved based on the literature review were between

<0.00001 and 0.0002 µg/L, two orders-of-magnitude greater than the proposed HHWQC of 0.000007 µg/L.

- Achieving an effluent concentration at the current HHWQC for inorganic arsenic of 0.018 µg/L (water and organism) is questionable, even for the most elaborate treatment process trains, because little performance data is available from facilities operating at these low concentrations. Most treatment technology performance information available in the literature is based on drinking water treatment applications targeting a much higher Safe Drinking Water Act (SDWA) Maximum Contaminant Level (MCL) of 10 µg/L. Data from a confidential demonstration project using UF/RO/AOP shows performance to the same order-of-magnitude at <0.036 µg/L versus the-HHWQC 0.018 µg/L. It is possible this demonstration project is producing effluent near the proposed HHWQC for inorganic arsenic, however data to evaluate full technical and economic feasibility for this demonstration project was not available.
- The existing HHWQC for mercury is a fish tissue-based limit of 0.3 mg/kg (organism only). Science-based and site-specific factors must be employed to convert this tissue-based limit to a water column concentration. The range of potential water column concentrations for methylmercury associated with EPA's 0.03 mg/kg fish tissue concentration are lower than the approved analytical methods in 40 CFR part 136 for Method 1631E with a quantitation level of 0.0005 µg/L. Consequently, treatment facilities would need to target non-detectable levels of effluent mercury less than 0.0005 µg/L. Achieving this concentration for mercury in effluent appears unlikely.
- Achieving an effluent concentration at the EPA proposed HHWQC for Benzo(a) Pyrene of 1.6E-05 µg/l (water and organism) appears unlikely. Little information is available to assess the potential for advanced technologies to treat to this concentration. A municipal wastewater treatment plant study, showing the apparent technical limits of treatment capability, reported both influent and effluent BAP concentrations of <0.0057 µg/L, two orders-of-magnitude greater than the proposed HHWQC of 0.000016 µg/L (Ecology, 2010).

- Some technologies may be effective at treating identified pollutants of concern to achieve the full suite of EPA's proposed HHWQC, while others may not. It is therefore even more challenging to identify a technology that can meet all constituent limits simultaneously. Multiple technologies paired together may be necessary, further exacerbating the issue of economic feasibility.
- Implementation of additional treatment will result in additional collateral impacts including:

  - High energy consumption.
  - Increased air pollution emissions, including for greenhouse gas emissions, which may trigger environmental permitting obligations under the Clean Air Act.
  - Increased solids production from chemical addition. Additionally, the membrane and GAC facilities will capture more solids that require processing and utilization or disposal.
  - Increased physical space requirements at treatment plant sites for advanced treatment facilities and residuals management, including reverse osmosis reject brine processing.
  - Any facility expansion may trigger consideration of environmental justice impacts on Overburdened Communities and challenge land use permitting decision-making.

- The recognition that advanced treatment technology alone would not be capable of achieving water quality-based effluent limits resulting from the proposed HHWQC will force reliance on other regulatory tools in NPDES permitting to provide a compliance pathway. These tools might include long-term variances or compliance schedules, will be controversial, and undertaken with high transactions costs and uncertainty.
- Advanced treatment processes incur very significant capital construction and operating costs. Table ES-1 presents a summary range of these costs for the baseline secondary treatment, plus the and increment of additional costs for the advanced treatment technologies. The table is delineated by alternative, whereby each advanced treatment technology includes separate line items for the baseline cost, as well as the additional incremental cost to add advanced treatment technologies to the baseline and the total cost (sum of baseline and advanced treatment technologies). The table indicates that the unit NPV cost for baseline conventional secondary treatment ranges from $16 to $39 per gallon per day of treatment capacity. The unit cost for the advanced treatment alternatives increases the range from the low $30s to $120 on a per gallon per-day of treatment capacity. The resulting unit cost for improving from secondary treatment to advanced treatment ranges between $15 and $81 per gallon per day of treatment capacity. Unit costs were also evaluated for both a 0.5 and 25 mgd facility. The range of unit costs for improving a 0.5 mgd from secondary to advanced treatment is $31 to $168 per gallon per day of treatment capacity. The range of unit costs for improving a 25 mgd from secondary to advanced treatment is $18 to $74 per gallon per day of treatment capacity.

Table ES-1. Treatment Technology Costs for Baseline Secondary Treatment and Advanced Treatment Alternatives in 2022 Dollars for a 5-mgd Facility

Alternative	Total Construction Cost ($ Million)	O&M Net Present Value, ($ Million)**	Total Net Present Value, ($ Million)	NPV Unit Cost, ($/gpd)
Baseline (Conventional Secondary Treatment)	72 - 178	8 - 19	80 - 197	16 - 39
Advanced Treatment - UF/RO*				
Baseline (from the top of the table)	72 - 178	8 - 19	80 - 197	16 - 39
Additional Cost (beyond Baseline) for UF/RO*from Baseline	75 - 185	21 - 51	96 - 237	19 - 47
Total Cost (includes Baseline): Advanced Treatment - UF/RO*	148 - 364	29 - 70	176 - 434	35 - 87
Advanced Treatment - UF/GAC				
Baseline (from the top of the table)	72 - 178	8 - 19	80 - 197	16 - 39
Additional Cost (beyond Baseline) for UF/GAC	52 - 128	22 - 54	74 - 182	15 - 36
Total Cost (includes Baseline): Advanced Treatment - UF/GAC	125 - 307	29 - 72	154 - 379	31 - 76
Advanced Treatment - UF/AOP/GAC				
Baseline (from the top of the table)	72 - 178	8 - 19	80 - 197	16 - 39
Additional Cost (beyond Baseline) for UF/AOP/GAC	66 - 162	31 - 76	97 - 239	19 - 48

Alternative	Total Construction Cost ($ Million)	O&M Net Present Value, ($ Million)**	Total Net Present Value, ($ Million)	NPV Unit Cost, ($/gpd)
Total Cost (includes Baseline): Advanced Treatment - UF/AOP/GAC	138 - 340	39 - 95	177 - 435	35 - 87
Advanced Treatment - UF/AOP/GAC/RO*				
Baseline (from the top of the table)	72 - 178	8 - 19	80 - 197	16 - 39
Additional Cost (beyond Baseline) for UF/AOP/GAC/RO*	117 - 289	47 - 116	164 - 405	33 - 81
Total Cost (includes Baseline): Advanced Treatment - UF/AOP/GAC/RO*	190 - 467	55 - 135	244 - 602	49 - 120

*Assumes BRS for RO brine management, followed by evaporation ponds. Other options are available as listed in Section 4.3.2

**Includes the cost for labor.

mgd=million gallons per day
MG=million gallons
MF/RO=membrane filtration/reverse osmosis
MF/GAC=membrane filtration/granulated activated carbon
O&M=operations and maintenance
Net Present Value = total financed cost assuming a 5 percent nominal discount rate over an assumed 20-year equipment life.

Costs presented above are based on a treatment capacity of 5.0 mgd, however, existing treatment facilities range dramatically across Washington in size and flow treated. The key differences in cost between the baseline and the advanced treatment alternatives are as follows:

- Larger aeration basins than the baseline to account for the longer solids retention time (SRT) in activated sludge systems (>8 days for advanced treatment versus <4 days baseline secondary treatment).
- Additional pumping stations to pass water through the membrane facilities and granulated activated carbon facilities. These are based on maximum month flows because an equalization basin was incorporated.
- Membrane facilities (equipment, tanks chemical feed facilities, pumping, etc.) and replacement membrane equipment.
- Granulated activated carbon facilities (equipment, contact tanks, pumping, granulated activated carbon media, etc.)

- Additional energy and chemical demand to operate the membrane and granulated activated carbon facilities
- Additional energy to feed and backwash the granulated activated carbon facilities.
- Brine Recovery System facilities to further concentrate the brine reject. Brine Recovery System facilities are energy/chemically intensive and they require membrane replacement every few years due to the brine reject water quality.
- Membrane and granulated activated carbon media replacement represent a significant operation and maintenance cost.
- Additional hauling and fees for new and disposal of spent granulated activated carbon off-site.
- Advanced oxidation process costs to break down BAP and PCBs for increased removal efficiency.

The mass of pollutant removal by implementing advanced treatment was calculated based on reducing current secondary effluent discharges to revised effluent limits for the four pollutants of concern. These results are provided in Table ES-2 as well as a median estimated unit cost basis for the mass of pollutants removed.

Table ES-2. Unit Cost by Contaminant for a 5-mgd Facility Implementing Advanced Treatment using Ultrafiltration/Reverse Osmosis

Component	Arsenic	BAPs	Mercury	PCBs
Required HHWQC based Effluent Quality (µg/L)	0.018	0.000016	0.0005	0.000007
Current Secondary Effluent Concentration (µg/L)	5	0.006	0.025	0.002
Total Mass Removed (lb) over 20-year Period	1517	1.82	7.5	0.61
Median Estimated Unit Cost (NPV per total mass removed in pounds over 20 years)	$201,000	$170,000,000	$41,000,000	$500,000,000

µg/L=micrograms per liter
lb=pounds
NPV=net present value

Collateral adverse environmental impacts associated with implementing advanced treatment were evaluated. The key impacts from this evaluation include increased energy use, greenhouse gas production, land requirements and treatment residuals disposal. Operation of advanced treatment technologies could increase electrical energy by a factor of approximately 2 to 3 times over the baseline secondary treatment system. Direct and indirect greenhouse gas emission increases are related to the operation of advanced treatment technologies and electrical power sourcing, with increases of at least 50 to 100 percent above the baseline secondary treatment system. It is worthwhile

noting that residual materials from treatment, such as RO reject brine and spent carbon sorption media, may potentially be hazardous wastes and their disposal may be challenging to permit and implement.

1 Introduction

The purpose of this assessment is to update the 2013 Treatment Technology Review and Assessment (HDR 2013) that was prepared to analyze the technical feasibility and capital and operating costs of wastewater treatment technologies to address proposed Human Health-Based Water Quality Criteria (HHWQC). These proposed revisions of Washington's surface water quality standards regulation, WAC 173-201A, resulted from a multi-year public engagement activity led by the Department of Ecology. The state of Washington adopted this rule package in August 2015. The proposed criteria were considered to be the most stringent set of toxic pollutant standards in the United States and there were concerns about the ability of NPDES permittees to comply with Clean Water Act regulatory programs based on those criteria. A coalition of industrial and municipal NPDES permittees sponsored the HDR technology and cost assessment.

A tortuous administrative process was then set into motion. The Environmental Protection Agency responded by partially approving and partially disapproving Washington's adopted rule in a November 2016 Federal Register notice. In that notice the EPA alleged that disapproved criteria were not scientifically defensible and thus not protective of Washington's designated water uses. In the late 2016 notice, the EPA proposed and subsequently adopted a more stringent set of HHWQC based on re-consideration of tribal fish consumption, the incremental cancer risk level, and other input factors germane to the derivation of numeric criteria. A 2017 industry petition to the EPA requested a reconsideration of the partial disapproval determination and repeal of the November 2016 HHWQC. EPA granted this petition in May 2019, which then had the effect of returning Washington's HHWQC to the set adopted by the state in August 2015. The state of Washington, certain Indian tribes, and various environmental groups followed with a legal challenge of this EPA decision. These parties requested and the jurisdictional federal district court agreed to hold any legal proceedings in abeyance while EPA reconsidered its 2019 decision. In an April 1, 2022 Federal Register notice, the EPA has now proposed for adoption the HHWQC promulgated in November 2016. It is this set of more stringent numeric criteria that the Study Partners of this 2022 HDR technology and cost assessment is based on.

Water quality criteria serve as the foundation for the implementation of many Clean Water Act regulatory programs. For example, waterbodies not consistently achieving criteria are designated as such in the Clean Water Act Section 303(d) list of impaired waters. This listing triggers an obligation for the development of a total maximum daily load (TMDL) or water cleanup plan, designed to reduce loadings of the listed pollutant into the waterbody to ultimately lead to achievement of the standard. NPDES permittees contributing the listed pollutant are given a waste load allocation or "water quality-based effluent limits" set at concentrations equal to or below the water quality numeric criterion. The permittee may lose access to any "mixing zone." The Sections 303(d) listing may be based on either water column concentrations or fish tissue concentrations for pollutants which bioaccumulate. In waterbodies attaining the respective water quality criterion, a "reasonable potential analysis" is completed as an element of an NPDES permitting exercise to determine if a pollutant discharge could "cause or contribute" to the

exceedance of a water quality numeric criterion or anti-degradation requirement. Either of these permitting requirements can serve as a basis for establishing permittee effluent limits. The presumption is that more stringent HHWQC will, in time, drive lower effluent limits. A companion presumption holds that as EPA-approved analytical methods become more sensitive and/or as jurisdictional agencies more intensely evaluate ambient waterbodies or choose to monitor pollutants concentrations in fish tissues, the prevalence of "non-achievement" of HHWQC will increase.

The Study Partners led by the Northwest Pulp and Paper Association in a collaboration with the Association of Washington Business, Association of Washington Cities, and Washington State Association of Counties, hold NPDES permits authorizing wastewater discharges. The prospect of more stringent HHWQC, and the resulting needs for advanced treatment technologies to achieve lower effluent discharge limits, has led this consortium to sponsor a study to assess technology availability and capability, capital and operations and maintenance (O&M) costs, pollutant removal effectiveness, and collateral environmental impacts of candidate technologies.

The "base case" for the study began with the identification of four nearly ubiquitous toxic pollutants present in many industrial and municipal wastewater discharges, and the specification of pollutant concentrations in well-treated secondary effluent. The pollutants are arsenic, benzo(a)pyrene (BAP), mercury, and polychlorinated biphenyls (PCBs), which were selected for review based on available monitoring data and abundant presence in the environment. The purpose of this study is to review the potential water quality standards and associated treatment technologies able to meet those standards for four pollutants.

Established and industry accepted wastewater treatment processes and wastewater characteristics were used as the common baseline for comparison with all of the potential future treatment technologies considered. An existing secondary treatment process with disinfection at a flow of 5 million gallons per day (mgd) was used to represent existing conditions. Typical effluent biochemical oxygen demand (BOD) and total suspended solids (TSS) were assumed between 10 and 30 milligrams per liter (mg/L) for such a facility and no designed nutrient or toxics removal was assumed for the baseline existing treatment process.

Following a literature review of technologies, four advanced treatment processes for toxics removal were selected for further evaluation based on the characterization of removal effectiveness from the technical literature review and Study Partners' preferences. The combinations of advanced treatment processes led to four scenarios, all added to the baseline treatment:

- Ultrafiltration (UF)/Reverse Osmosis (RO)
- Ultrafiltration (UF)/Granular Activated Carbon (GAC)
- Ultrafiltration (UF)/ Advanced Oxidation Process (AOP)/ Granular Activated Carbon (GAC)
- Ultrafiltration (UF)/ Advanced Oxidation Process (AOP)/ Granular Activated Carbon (GAC)/Reverse Osmosis (RO)

The advanced treatment technologies are evaluated for their efficacy and cost to achieve the effluent limitations implied by the more stringent HHWQC. Various sensitivities are examined for a size range of treatment systems. Collateral environmental impacts associated with the operation of advanced technologies are also qualitatively described.

2 Derivation of the Baseline Study Conditions and Rationale for Selection of Effluent Limitations

Four pollutants were selected for study based on available monitoring data and abundance in the environment. The four toxic constituents are arsenic, benzo(a)pyrene (BAP), mercury, and polychlorinated biphenyls (PCBs).

2.1 Background

The Study Partners have selected four pollutants for which more stringent HHWQC are expected to be promulgated. Available monitoring information indicates these pollutants are ubiquitous in the environment and are expected to be present in many NPDES discharges. The four pollutants include the following:

- Arsenic
    - Elemental metalloid that occurs naturally and enters the environment through erosion processes. Also widely used in batteries, pesticides, wood preservatives, and semiconductors. Other current uses and legacy sources in fungicides/herbicides, copper smelting, paints/dyes, and personal care products.
- Benzo(a)pyrene (BAP)
    - Benzo(a)pyrene is a polycyclic aromatic hydrocarbon formed by a benzene ring fused to pyrene as the result of incomplete combustion. Its metabolites are highly carcinogenic. Sources include wood burning, coal tar, automobile exhaust, cigarette smoke, and char-broiled food.
- Mercury
    - Naturally occurring element with wide legacy uses in thermometers, electrical switches, fluorescent lamps, and dental amalgam. Also enters the environment through erosion processes, combustion (especially coal), and legacy industrial/commercial uses. Methylmercury is an organometallic that is a bioaccumulative toxin. In aquatic systems, an anaerobic methylation process converts inorganic mercury to methylmercury.
- Polychlorinated Biphenyls (PCBs)
    - Persistent organic compounds historically used as a dielectric and coolant in electrical equipment and banned from production in the U.S. in 1979. Available information indicates continued pollutant loadings to the environment as a byproduct from the use of some pigments, paints, caulking, motor oil, and coal combustion.

2.2 Assumptions Supporting Selected Ambient Water Quality Criteria and Effluent Limitations

The study design necessarily required certain assumptions to create a "baseline effluent scenario" against which the evaluation of advanced treatment technologies could occur. The Study Partners and HDR Engineering, Inc (HDR) developed the scenario. Details of the baseline effluent scenario are presented in Table 2-1. The essential assumptions and rationale for selection are presented below:

- It is assumed that EPA's April 2022 HHWQC proposal will be promulgated (and effectively replace the HHWQC in the current adopted WAC 173-201A-240 *Toxic Substances*). Table 2-1 summarizes the proposed EPA human health criteria for Washington in comparison with the existing Washington state criteria for the key parameters selected for evaluation; arsenic, benzo(a)pyrene (BAP), mercury, and polychlorinated biphenyls (PCBs).
- The evaluation scenario generally assumes that EPA's proposed HHWQC for ambient waters will become effluent limitations for many Washington NPDES permittees. The reasoning for this important assumption includes:
    - The state of Washington's NPDES permitting program is bound by the *Friends of Pinto Creek vs. EPA* decision in the United States Court of Appeals for the Ninth Circuit (October 4, 2007). This decision held that no NPDES permits authorizing new or expanded discharges of a pollutant into a waterbody identified as impaired, i.e. listed on CWA section 303(d) for that pollutant, may be issued until such time as "existing dischargers" into the waterbody are "subject to compliance schedules designed to bring the (waterbody) into compliance with applicable water quality standards." In essence, any new/expanded discharge of a pollutant causing impairment must achieve the HHWQC at the point of discharge into the waterbody.
    - If a waterbody segment is identified as "impaired" (i.e., not achieving a HHWQC), then Ecology will eventually need to produce a TMDL or water cleanup plan. For an existing NPDES permittee with a discharge of the pollutant for which the receiving water is impaired, the logical assumption is that any waste load allocation granted to the discharger will be at or lower than the numeric HHWQC (to facilitate recovery of the waterbody to HHWQC attainment). As a practical matter, this equates to an effluent limit established at the HHWQC.
    - The assumption is that no mixing zone is granted such that HHWQC will effectively serve as NPDES permit effluent limits. Prior discussion on the impact of the Pinto Creek decision, 303(d) impairment and TMDL Waste Load Allocations processes, all lend support to this "no mixing zone" condition for the parameters evaluated in this study.
    - EPA's proposed methylmercury tissue concentration criteria of 0.03 mg/kg would translate to water column concentrations lower than the

approved analytical methods in 40 CFR part 136 for Method 1631E with a quantitation level of 0.0005 µg/L. Therefore, dischargers would need to target non-detectable levels of effluent mercury less than 0.0005 µg/L.

- The assumed effluent limit for arsenic is taken from EPA's *National Recommended Water Quality Criteria* (2012) (inorganic, water, and organisms, 10^{-6} excess cancer risk). EPA promulgated arsenic HHWQC for Washington in the National Toxics Rule of 1992. EPA's federal rule in 2016 moved the arsenic criteria from 40 CFR 131.36 to 40 CFR 131.45. In 2019, EPA reversed its disapproval of some HHWQC for Washington, but left its disapproval of criteria for arsenic in place.

- Consistent with Ecology practice in the evaluation of proposed regulations, the HHWQC are assumed to be in effect for a 20-year period. It is assumed that analytical measurement technology and capability will continue to improve over this time frame and this will result in the detection and lower quantification of additional HHWQC in ambient water and NPDES discharges. In parallel fashion, it is assumed that Department of Ecology (and other state and federal agencies) will expand the reach, frequency, and speciation of toxic pollutants (and fish tissue) in ambient waterbodies. This constantly expanding knowledge base seems likely to reveal waterbody impairment and the presence of HHWQC in NPDES permittee discharges at concentrations above the very stringent HHWQC.
- It is assumed that NPDES permits will be renewed on a 5-year schedule and that the Department of Ecology will complete its statutory Clean Water Act Section 303(d) impaired pollutant/waterbody assessment on a 2-year frequency. While history suggests this pace of work may not happen, there should still be 3 to 4 occasions in the 20-year cycle when regulatory determinations on ambient/receiving waters and the resulting NPDES permitting evaluations occur.
- Ecology has a statutory obligation to provide a Significant Legislative Rule evaluation, one element of which is a "determination whether the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented" (RCW 34.05.328(1)(d)). EPA's April 2022 HHWQC proposal explains that its analysis as follows:

  > "…did not identify any incremental costs to any major point source discharge of process wastewater from POTW's or industrial facilities attributable to the proposed criteria revisions." (87 FR page 19059, April 1, 2022)

  EPA recognizes there may be the following:

  > "…costs to point sources over time to implement controls or modify processes to meet future permit limits…But it would be highly speculative to attempts to estimate potential costs either based on the possibility of measuring pollutant levels at lower levels as a result of future requirements or future technology…" (87 FR 19059, April 1, 2002)

This HDR Treatment Technology Review and Assessment is intended to provide information to allow comment on the EPA proposal and eventually Washington's Significant Legislative Rule obligation.

Other elements of the Study Partners work scope, as presented to HDR, must be noted:

- The selection of four toxic pollutants and development of a baseline effluent scenario is not meant to imply that each NPDES permittee wastewater discharge will include those pollutants at the assumed concentrations. Rather, the scenario was intended to represent a composite of many NPDES permittees and to facilitate evaluation of advanced treatment technologies relying on mechanical, biological, physical and chemical processes.
- The scalability of advanced treatment technologies to wastewater treatment systems with different flow capacities, and the resulting unit costs for capital and O&M, is evaluated.

Table 2-1. Summary of Effluent Discharge Toxics Limits

Constituent	Human Health Criteria based Limits to be met with no Mixing Zone (µg/L)	Basis for Criteria	Typical Concentration in Municipal Secondary Effluent (µg/L)	Typical Concentration in Industrial Secondary Effluent (µg/L)	Existing Washington HHC WAC 173-201A (water + org.) (µg/L)
Arsenic	0.018	EPA Federal Register 2022 Inorganic Arsenic (water + organisms)	0.500 to 5.0[a]	10 to 40[a]	10[b]
Benzo(a)Pyrene	0.000016	EPA Federal Register 2022 (water + organisms)	0.00028 to 0.006[c,d]	0.006 to1.9	0.0014
Mercury	0.0005	EPA Federal Register 2022 Methylmercury (organisms only) EPA Method 1631E[e]	0.003 to 0.050[f]	0.010 to 0.050[f]	0.14[g]
PCBs	0.000007	EPA Federal Register 2022 Total PCBs (water + organisms)	0.0005 to 0.0025[c,h,i,j,k]	0.002 to 0.005[l]	0.00017

[a] Best professional judgment (HDR 2013)

[b] Washington Human Health Criteria for Total Arsenic is the maximum contaminant level (MCL) developed under the Safe Drinking Water Act. The MCL for total arsenic is applied to surface waters where consumption of organisms-only and where consumption of water + organisms reflect the designated uses.

[c] Control of Toxic Chemicals in Puget Sound, Summary Technical Report for Phase 3: Loadings from POTW Discharge of Treated Wastewater, Washington Department of Ecology, Publication Number 10-10-057, December 2010.

[d] Removal of Polycyclic Aromatic Hydrocarbons and Heterocyclic Nitrogenous Compounds by A POTW Receiving Industrial Discharges, Melcer, H., Steel, P. and Bedford, W.K., Water Environment Federation, 66th Annual Conference and Exposition, October 1993.

[e] This range of potential water column concentrations for methylmercury associated with EPA's proposed 0.03 mg/kg tissue concentration are lower than the approved analytical methods in 40 CFR part 136 for Method 1631E with a quantitation level of 0.0005 µg/L. Consequently, treatment facilities would need to target non-detectable levels of effluent methylmercury less than 0.0005 µg/L.

[f] Data provided by Lincoln Loehr's summary of WDOE Puget Sound Loading data in emails from July 19, 2013.

[g] Washington Human Health Criteria for Mercury cross-references the EPA National Toxics Rule, 40 CFR 131.36.

[h] Spokane River PCB Source Assessment 2003-2007, Washington Department of Ecology, Publication No. 11-03-013, April 2011.

[i] Lower Okanogan River Basin DDT and PCBs Total Maximum Daily Load, Submittal Report, Washington Department of Ecology, Publication Number 04-10-043, October 2004.

[j] Palouse River Watershed PCB and Dieldrin Monitoring, 2007-2008, Wastewater Treatment Plants and Abandoned Landfills, Washington Department of Ecology, Publication No. 09-03-004, January 2009

[k] A Total Maximum Daily Load Evaluation for Chlorinated Pesticides and PCBs in the Walla Walla River, Washington Department of Ecology, Publication No. 04-03-032, October 2004.

[l] NCASI memo from Larry Lefleur, NCASI, to Llewellyn Matthews, NWPPA, revised June 17, 2011, summarizing available PCB monitoring data results from various sources.

2.2.1 Mercury

The water quality criteria for mercury adopted in most states for the protection of aquatic life and human health is generally in the range of 1 to 50 ppt (EPA 2007). Washington's water quality criteria are based on the 1992 National Toxics Rule (40 CFR 131.26) as summarized in (Table) (Ecology 2016). EPA approved analytical methods include Method 245.7 Mercury in Water for determination of mercury (Hg) in filtered and unfiltered water by cold-vapor atomic fluorescence spectrometry (CVAFS) with a quantitation level of 5.0 ng/L and Method 1631E Ultra Low-Level Mercury in Water by Oxidation, Purge & Trap, and Cold Vapor Atomic Fluorescence Spectrometry1631E with a quantitation level of 0.5 ng/L.

Table 2-2. Washington's Water Quality Standards for Mercury

Washington State Water Quality Standards (WAC 173-201A) Aquatic Life Criteria				National Toxics Rule (NTR) Human Health Criteria (1992)	
Acute Freshwater (µg/L)	Chronic Freshwater (µg/L)	Acute Marine (µg/L)	Chronic Marine (µg/L)	Organism Only (µg/L)	Organism + Water (µg/L)
2.1[a,b,c,d]	0.012d[e,f,g,h]	1.8[a,b,d,i]	0.025[e,f,g,h]	0.15[j,k]	0.14[j,k]

[a] Dissolved.
[b] A 1-hour average concentration not to be exceeded more than once every three years on average.
[c] The conversion factor used to calculate the dissolved metal concentration was 0.85.
[d] These ambient criteria in the table are for the dissolved fraction. The cyanide criteria are based on the weak acid dissociable method. The metals criteria may not be used to calculate total recoverable effluent limits unless the seasonal partitioning of the dissolved to total metals in the ambient water are known. When this information is absent, these metals criteria shall be applied as total recoverable values, determined by back-calculation, using the conversion factors incorporated in the criterion equations. Metals criteria may be adjusted on a site-specific basis when data are made available to the department clearly demonstrating the effective use of the water effects ratio approach established by USEPA, as generally guided by the procedures in USEPA Water Quality Standards Handbook, December 1983, as supplemented or replaced by USEPA or ecology. The adjusted site-specific criteria are not in effect until they have been incorporated into this chapter and approved by EPA. Information which is used to develop effluent limits based on applying metals partitioning studies or the water effects ratio approach shall be identified in the permit fact sheet developed pursuant to WAC 173-220-060 or 173-226-110, as appropriate, and shall be made available for the public comment period required pursuant to WAC 173-220-050 or 173-226-130(3), as appropriate. Ecology has developed supplemental guidance for conducting water effect ratio studies.
[e] Edible fish tissue concentration shall not be allowed to exceed 1.0 mg/kg of methylmercury.
[f] A 4-day average concentration not to be exceeded more than once every three years on the average.
[g] These criteria are based on the total-recoverable fraction of the metal.
[h] If the four-day average chronic concentration is exceeded more than once in a three-year period, the edible portion of the consumed species should be analyzed. Said edible tissue concentrations shall not be allowed to exceed 1.0 mg/kg of methylmercury.
[i] Marine conversion factors (CF) which were used for calculating dissolved metals concentrations are given below. Conversion factors are applicable to both acute and chronic criteria for all metals except mercury. The CF for mercury was applied to the acute criterion only and is not applicable to the chronic criterion. Conversion factors are already incorporated into the criteria in the table. Dissolved criterion = criterion x CF. Mercury CF = 0.85.
[j] Total.
[k] The human health criteria for mercury are contained in 40 C.F.R. 131.36. EPA 2022

Methylmercury Criteria

Once in the water, mercury can convert to the form methylmercury, which accumulates in fish and aquatic organisms. Consumption of exposed fish and aquatic organisms can lead to human health issues. Federal water quality criteria for methylmercury have been promulgated for surface waters in Washington (CFR 2022b). The applicable human health criteria are shown in Table .

Table 2-3. Proposed Methylmercury Human Health Criteria for Washington

Chemical	CAS No.	Relative source contribution, RSC (-)	Reference dose RfD (mg/kg d)	Organisms Only (µg/L)	Water & Organisms (µg/L)
Methylmercury	22967926	2.7E-05	0.0001	0.03 (mg/kg)[a]	{blank}

[a] This criterion is expressed as the fish tissue concentration of methylmercury (mg methylmercury/kg fish). See Water Quality Criterion for the Protection of Human Health: Methylmercury (EPA-823-R-01-001, January 3, 2001) for how this value is calculated using the criterion equation in the EPA's 2000 Human Health Methodology rearranged to solve for a protective concentration in fish tissue rather than in water.

Translation of Mercury Criteria

“The 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” (Ecology 2016).

Translation of the 0.03 mg/kg tissue concentration (Table 2-3) to a water column concentration is likely to result in values that are very low and lower than the analytical methods available for mercury (Method 1631E quantitation level of 0.0005 µg/L). The Washington water column concentration level of 0.012 µg/L (Table 2-2) was based on an edible fish tissue concentration not exceeding 1.0 mg/kg of methylmercury. A fish tissue concentration of 0.03 mg/kg is nearly two orders of magnitude lower, which implies a water column concentration far lower than 0.012 µg/L.

EPA's methylmercury criteria implementation guidance document outlines various options for translating fish tissue criteria into water column criteria (EPA 2010). As noted in the guidance document, translation is challenging because of numerous site-specific factors that can affect bioaccumulation, as well as the relative proportions of methyl and total mercury in the water column. As an example translation of methylmercury criteria to a water column concentration, a number of assumptions were made to apply EPA's methylmercury criteria implementation guidance document (NACASI 2022). EPA published national bioaccumulation factors (BAF) which are 680,000 L/kg for trophic level 3 fish and 2,700,000 L/kg for trophic level 4 fish. Assuming human consumption of 25 percent trophic level 3 fish and 75 percent trophic level 4 fish, the weighted BAF is approximately 2,200,000 L/kg. For human consumption of 25 percent trophic level 3 fish and 75 percent trophic level 4 fish, a person might consume a combination of some farm raised salmon and trout (trophic 3) along with tuna and wild caught salmon (trophic 4).Dividing the 0.03 mg/kg tissue criteria by the weighted BAF results in an equivalent water column concentration of approximately 0.000014 µg/L. Alternatively, assuming

consumption of 100 percent trophic level 2 fish where a person might consume mostly sardines, tilapia, and catfish, results in a BAF of approximately 120,000 L/kg. That translates to an equivalent water column concentration of approximately to 0.00025 µg/L. This range of potential equivalent water column concentrations of 0.000014 µg/L to 0.00025 µg/L is less than the Method 1631E quantitation level of 0.0005 µg/L. Consequently, treatment facilities would need to target non-detectable levels of methylmercury (NACSI 2022).

Ecology notes that Washington waters have a wide range of dissolved organic carbon (DOC) and particulate organic carbon (POC) concentrations. This means the national BAFs that were calculated using national default POCs and DOCs likely are not reflective of BAFs in many of Washington's waters (Ecology 2016). "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" (Ecology 2016).

2.3 Analytical Methods

The test procedures identified in CFR Title 40 Part 136 (CFR 2022b) specify the detection limits and quantitation levels for the analytical methods. When the detection limit and quantitation levels is not obtained, a matrix-specific detection limit with appropriate laboratory documentation is required. The approved analytical laboratory procedures for arsenic and mercury are listed in Table 2 4.

Table 2-4. CFR Part 136 List of Approved Inorganic Test Procedures

Parameter	Methodology	EPA	Standard Methods	ASTM	USGS/AOAC/Other
Arsenic, Total (mg/L)	Digestion, followed by any of the following	206.5 (Issued 1978)	--	--	--
	AA gaseous hydride	--	3114 B-2011 or 3114 C-2011	D2972-15 (B)	I-3062-85
	AA furnace	--	3113B-2010	D2972-15 (C)	I-4063-98
	STGFAA	200.9 Rev 2.2 (1994)	--	--	--
	ICP/AEC	200.5 Rev 4.2 (2003), 200.7 Rev 4.4 (1994)	3120 B-2011	D1976-12	--
	ICP/MS	200.8 Rev 5.4 (1994)	3125 B-2011	D5673-16	993.14, I-4020-05
	Colorimetric (SDDC)	--	350-As B-2011	D2972-15 (A)	I-3060-85
Mercury, Total (mg/L)	Cold vapor, Manual	245.1 Rev 3.0 (1994)	3112 B-2011	D3223-17	977.22, I-3462-85

Parameter	Methodology	EPA	Standard Methods	ASTM	USGS/AOAC/Other
	Cold vapor, Automated	245.2 (Issued 1974)	--	--	--
	Cold vapor, atomic fluorescence spectrometry (CVAFS)	245.7 Rev 2.0 (2005)	--	--	I-4464-01
	Purge and Trap CVAFS	1631E	--	--	--

The approved analytical laboratory procedures for benzo(a)pyrene (BAP) and polychlorinated biphenyls (PCBs) are listed in Table 2 5.

Table 2-5. CFR Part 136 List of Approved Test Procedures for Non-Pesticide Organic Compounds

Parameter	Methodology	EPA	Standard Methods	ASTM	USGS/AOAC/Other
Benzo(a)pyrene	GC	610	--	--	--
	GC/MS	625.1, 1625B	6410 B-2000	--	Note
	HPLC	610	6440 B-2005	D4657-92 (98)	--
PCB	GC	608.3	6410 B-2000	--	Note
	GC/MS	625.1	--	--	--

Table 2-6 summarizes the analytical laboratory detection levels and quantitation levels for arsenic, BAP, mercury, and PCBs. Detection level or detection limit means the minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero as determined by the procedure given in 40 CFR part 136, Appendix B.

Quantitation level, also known as minimum level of quantitation, is the lowest level at which the entire analytical system must give a recognizable signal and acceptable calibration point for the analyte. It is equivalent to the concentration of the lowest calibration standard, if the laboratory has used all method-specified sample weights, volumes, and cleanup procedures.

The proposed water quality standards for arsenic, BAP, mercury, and PCBs are very low concentration values, which in some cases are lower than the analytical laboratory methods are capable of detecting or quantifying.

Table 2-6. Summary of Analytical Laboratory Techniques Standard Levels

Parameter	Method Protocol	Detection Limit	Quantitation Level
Arsenic, Total	200.8	0.1 µg/L	0.5 µg/L
Mercury, Total	1631E	0.00005 µg/L	0.0005 µg/L
Benzo(a)Pyrene	610/625	0.5 µg/L	1.0 µg/L
PCB	608	0.25 µg/L	0.5 µg/L

The only method currently approved at 40 CFR Part 136 for monitoring PCBs in wastewater is Method 608.3 which targets only seven common Aroclor mixtures. Since most PCB contamination in the environment is highly weathered and often does not resemble any of the Aroclor mixtures, and there are non-Aroclor sources of PCB in the environment, Aroclor results are likely to underestimate total PCB levels or result in non-detect reports in a sample when compared to the analysis of individual PCB congeners. Congener methods identified in Table 2-7 are not yet approved at 40 CFR Part 136 for monitoring PCBs. Method 1628 detects all 209 PCB congeners and quantifies them either directly or indirectly. A total of 29 carbon-13 labeled PCB congeners are used as isotope dilution quantification standards. An additional 19 congeners are quantified by an extracted internal standard procedure, using one of the isotope dilution standards. The remaining 144 congeners are quantified against a labeled standard in the same homolog. This approach strikes a balance between enabling the laboratory to detect and quantify all 209 congeners, while not making the method too arduous. Method 1628 is not yet approved at 40 CFR Part 136 for use in Clean Water Act compliance monitoring (EPA 2022b).

Method 1668 determines chlorinated biphenyl congeners in environmental samples by isotope dilution and internal standard high-resolution gas chromatography/high-resolution mass spectrometry (HRGC/HRMS). EPA developed this method for use in wastewater, surface water, soil, sediment, biosolids and tissue matrices (EPA 2010). In water, detection limits range from approximately 7 to 77 parts per quadrillion (picograms per liter, pg/L) and quantitation levels range from approximately 20 to 200 pg/L, depending on the congener. The chlorinated biphenyls that can be determined by this Method are the 12 polychlorinated biphenyls (PCBs) designated as toxic by the World Health Organization (WHO): congeners 77, 81, 105, 114, 118, 123, 126, 156, 157, 167, 169, and 189. The Method also determines the remaining 197 chlorinated biphenyls, approximately 125 of which are resolved adequately on an SPB-octyl gas chromatographic column to be determined as individual congeners. The remaining approximately 70 congeners are determined as mixtures of isomers (co-elutions).

Table 2-7. Currently Not Approved Analytical Methods Pending Future Decisions

Parameter	EPA Method
PCB	1628
	1668

Table 2-8 presents a comparison of the analytical detection limit and quantitation level for arsenic, BAP, mercury, and PCBs with the EPA version of the Washington human health water quality standards,

Table 2-8. Comparison of Analytical Laboratory Techniques Standard Levels and Water Quality Standards

Parameter	Method Protocol	Detection Limit	Quantitation Level	EPA Proposed Water Quality Standard (Federal Register 2022)
Arsenic, Total	200.8	0.1 µg/L	0.5 µg/L	Water & Organisms 0.018 µg/L Organisms Only 0.14 µg/L This criterion refers to the inorganic form of arsenic only.
Mercury, Total	1631E	0.00005 µg/L	0.0005 µg/L	Methylmercury Organisms Only 0.03 mg/kg This criterion is expressed as the fish tissue concentration of methylmercury (mg methylmercury/kg fish). See Water Quality Criterion for the Protection of Human Health: Methylmercury (EPA-823-R-01-001, January 3, 2001) for how this value is calculated using the criterion equation in EPA's 2000 Human Health Methodology rearranged to solve for a protective concentration in fish tissue rather than in water.
Benzo(a)Pyrene	610/625	0.5 µg/L	1.0 µg/L	Water & Organisms 1.6E-05 µg/L Organisms Only 1.6E-05 µg/L
PCB	608	0.25 µg/L	0.5 µg/L	Water & Organisms 7E-06 µg/L Organisms Only 7E-06 µg/L This criterion applies to total PCBs (*e.g.,* the sum of all congener or isomer or homolog or Aroclor analyses).

3 Wastewater Characterization Description

This section describes the wastewater treatment discharge considered in this technology evaluation. Treated wastewater characteristics are described, including average and peak flow, effluent concentrations, and toxic compounds of concern.

3.1 Summary of Wastewater Characterization

A general wastewater treatment process with industry accepted wastewater characteristics was developed as the common baseline to represent a starting point for comparison with potential future advanced treatment technologies and improvements. The baseline included a secondary treatment process with disinfection sized for annual average flows of 5 mgd. Effluent limits for biochemical oxygen demand (BOD) and total suspended solids (TSS) were assumed to be between 10 to 30 mg/L from such a facility. No nutrient or human health toxics removal was assumed to be accomplished in the existing baseline treatment process.

3.2 Baseline Wastewater Treatment Facility

The first step in the process is to define the baseline wastewater treatment plant to be evaluated in this study. The goal is then to identify the additional technology needed to comply with revised toxic pollutant effluent limits. Rather than evaluating the technologies and costs to upgrade multiple actual operating facilities, the Study Partners specified that a generalized municipal/industrial wastewater treatment facility would be defined and used as the basis for developing toxic removal approaches. Characteristics of the facility's flows and effluent are described in Table 3-1.

Table 3-1. General Wastewater Treatment Facility Characteristics

Average Annual Wastewater Flow, mgd	Maximum Month Wastewater Flow, mgd	Peak Hourly Wastewater Flow, mgd	Effluent BOD, mg/L	Effluent TSS, mg/L
5.0	6.25	15.0	10 to 30	10 to 30

mgd = million gallons per day
mg/L = milligrams per liter

In the development of the advanced treatment technologies presented below, the capacities of major treatment elements are generally sized to accommodate the maximum month average wastewater loads with ability to accommodate peak hourly flows. Hydraulic elements, such as pumps and pipelines, were selected to accommodate the peak hourly wastewater flow.

The general treatment facility incorporates baseline treatment processes including influent screening, grit removal, primary sedimentation, suspended growth biological treatment (activated sludge), secondary clarification, and disinfection using chlorine. Solids removed during primary treatment and secondary clarification are assumed to be

thickened, stabilized, dewatered, and land applied to agricultural land. The biological treatment process is assumed to be activated sludge with a short SRT (less than 4-days). The baseline secondary treatment facility is assumed not to have processes dedicated to removing nutrients or toxics. However, some coincident removal of toxics will occur during conventional treatment.

3.3 Toxic Constituents

As described in Section 2.2, the expectation of more stringent HHWQC will eventually trigger regulatory demands for NPDES permittees to install advanced treatment technologies. The Study Group selected four specific toxic pollutants reflecting a range of toxic constituents as the basis for this study to limit the constituents and technologies to be evaluated to a manageable level.

The four toxic pollutants selected for review were as follows:

- Polychlorinated Biphenyls (PCBs)
- Mercury
- Arsenic
- BAP, a polycyclic aromatic hydrocarbon (PAH)

Mercury and arsenic are metals, and PCBs and PAHs are organic compounds. Technologies for removing metals and organic compounds are in some cases different. Key information on each of the compounds, including a description of the constituent, the significance of each constituent, proposed HHWQC based effluent limits, basis for the proposed criteria, typical concentration in both municipal and industrial secondary effluent, and current Washington state water quality criteria, are shown in Table 2-1. It is assumed that compliance with the proposed criteria in the table would need to be achieved at the “end of pipe” and Ecology would not permit a mixing zone for toxic constituents. This represents a “worst–case” scenario, but it is a plausible assumption about discharge conditions given that the HHWQ criteria are such low concentrations that ambient receiving waters may be near, or already exceed these levels, and not provide an opportunity for effluent dilution.

4 Treatment Approaches and Costs

Four advanced treatment process options for toxics removal were selected for further evaluation based on the characterization of removal effectiveness from the technical literature review and Study Group preferences. Four tertiary treatment options (RO or GAC based) with and without AOP were considered as follows (all options were added to the baseline secondary treatment):

- RO Based:
    - UF/RO
    - UF/AOP/GAC/RO
- GAC Based:
    - UF/GAC
    - UF/AOP/GAC

Based on the literature review, it is not anticipated that any of the treatment options will be effective in reducing all of the selected pollutants to below the anticipated water quality criteria. A summary of the capital and operations and maintenance costs for tertiary treatment is provided, as well as a comparison of the adverse environmental impacts for each advanced treatment alternative.

4.1 Constituent Removal – Literature Review

The evaluation of treatment technologies relevant to the constituents of concern was initiated with a literature review. The literature review included a desktop search using typical web-based search engines, and search engines dedicated to technical and research journal databases. Additionally, HDR's experience with the performance of treatment technologies specifically related to the four constituents of concern was used in evaluating candidate technologies. A summary of the constituents of concern and relevant treatment technologies is provided in the following literature review section.

4.1.1 Arsenic

The anticipated required HHWQC effluent limit for arsenic is 0.018 µg/L. A variety of treatment technologies can be applied to capture arsenic (Table 4-1). Most of the information in the technical literature and from the treatment technology vendors is focused on potable water treatment for compliance with a Safe Drinking Water Act (SDWA) maximum contaminant level (MCL) of 10 µg/L. The most commonly used arsenic removal method for a wastewater application (tertiary treatment) is coagulation/ flocculation plus filtration. This method by itself could remove more than 90 to 95 percent of arsenic. Additional post-treatment through adsorption, ion exchange, or reverse osmosis is required for ultra-low arsenic limits in the 0.018 µg/L range under consideration. In each case pilot-testing is recommended to confirm effluent quality performance of each selected technology.

Table 4-1. Summary of Arsenic Removal Technologies[1]

Technology	Advantages	Disadvantages
Coagulation/filtration	• Simple, proven technology • Widely accepted • Moderate operator training	• pH sensitive • Potential disposal issues of backwash waste • As^{+3} and As^{+5} must be fully oxidized
Lime softening	• High level of arsenic treatment • Simple operation change for existing lime softening facilities	• pH sensitive (requires post treatment adjustment) • Requires filtration • Significant sludge operation
Adsorptive media	• High As^{+5} selectivity • Effectively treats water with high total dissolved solids (TDS)	• Highly pH sensitive • Hazardous chemical use in media regeneration • High concentration SeO_4^{-2}, F^-, Cl^-, and SO_4^{-2} may limit arsenic removal
Ion exchange	• Low contact times • Removal of multiple anions, including arsenic, chromium, and uranium	• Requires removal of iron, manganese, sulfides, etc. to prevent fouling • Brine waste disposal
Membrane filtration	• High arsenic removal efficiency • Removal of multiple contaminants	• Reject water disposal • Poor production efficiency • Requires pretreatment

[1]Adapted from WesTech

The removal of arsenic in activated sludge is minimal (less than 30 percent) (Andrianisa et al. 2006; Ge et al., 2020), but biological treatment can control arsenic speciation during aerobic biological processes as As (III) is oxidized to As (V). Recent research suggests potential promise in increasing arsenic removal with aerobic granular sludge via biosorption and/or controlled conditions for potentially increasing such removals (Wang et al., 2018; Peng et al., 2018). Research by Ge et al. (2020) suggests that it is more effective to remove As downstream of biological treatment due to lower levels of dissolved organic matter and phosphate in the activated sludge process. Such removal

can occur downstream of activated sludge via coagulation/flocculation/filtration removal, as well as adsorption removal methods, which are more effective in removal of As(V) vs. As (III). A combination of activated sludge and post-activated sludge precipitation with a metal salt (e.g., alum or ferric chloride addition to MLSS and effluent)) can result in a removal efficiency of greater than 95 percent. This combination could decrease As levels from 200 µg/L to less than 5 µg/L (5,000 ng/L) (Andrianisa et al. 2008). Olujimi et al., (2012) found activated sludge could reduce As levels to a range of 0.64 to 2.2 µg/L. However, this is still at least an order-of-magnitude greater than the 0.018 µg/L proposed standard for arsenic.

Data from the West Basin Municipal Water District MF/RO/AOP suggests effluent performance in the range of 0.1 to 0.2 µg/L Effluent concentrations at West Basin could be lower since the analytical detection limit used at West Basin was 0.15 µg/L, however that is still an order of magnitude higher than the proposed HHWQC in Washington. Data from a confidential demonstration project facility using UF/RO/AOP suggests effluent performance as low as <0.036 µg/L. A range of expected enhanced removal rates might be assumed to be equivalent to that achieved at these UF/RO/AOP facilities in the 0.036 to 0.2 µg/L range.

Review of Specific Technologies for Arsenic Removal

Coagulation plus Settling or Filtration

Coagulation may remove more than 95 percent of arsenic through the creation of particulate metal hydroxides. Ferric sulfite is typically more efficient and applicable to most wastewater sources compared to alum. The applicability and extent of removal should be pilot-tested, since removal efficiency is highly dependent on the local water constituents and water characteristics (i.e., pH, temperature, solids).

Filtration can be added after settling to increase arsenic removal. Example treatment trains with filtration are shown in Figure 4-1 and , respectively.

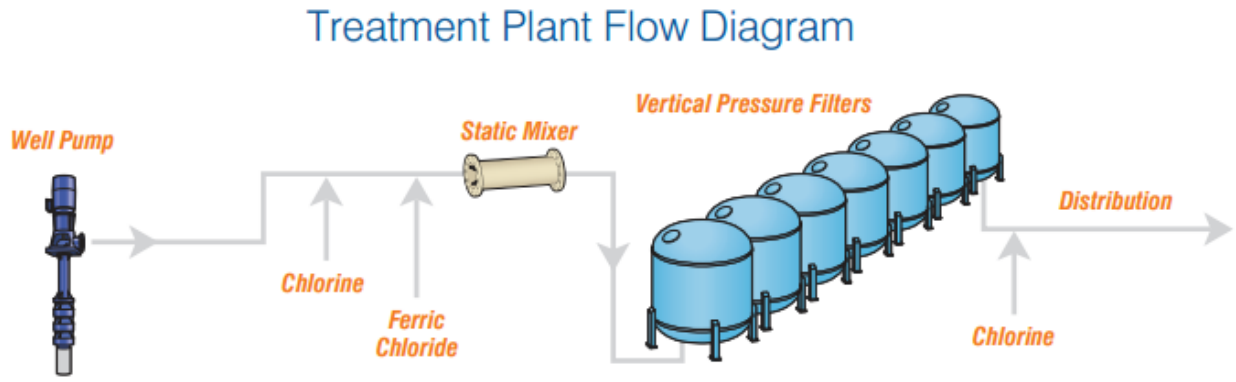

Figure 4-1. Water Treatment Configuration for Arsenic Removal (WesTech)

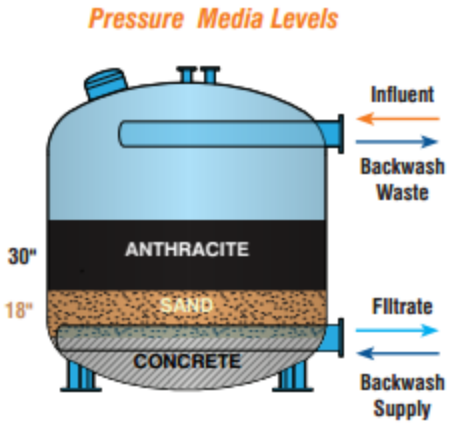

Figure 4-2. WesTech Pressure Filters for Arsenic Removal

One system for treatment of potable water with high levels of arsenic in Colorado (110 mg/L) consists of enhanced coagulation followed by granular media pressure filters that include anthracite/silica sand/garnet media (WesTech). The arsenic levels were reduced to less than the drinking water MCL, which is 10 µg/L (10,000 ng/L). The plant achieves treatment by reducing the pH of the raw water to 6.8 using sulfuric acid, and then adding approximately 12 to 14 mg/L ferric sulfate. The water is filtered through 16 deep bed vertical pressure filters, the pH is elevated with hydrated lime and is subsequently chlorinated and fed into the distribution system. (https://f.hubspotusercontent10.net/hubfs/541513/content/case-study/Case-Study-Fallon-NV-VPF-SuperSettler.pdf).

Softening (with lime)

Removes up to 90 percent arsenic through co-precipitation, but it requires the pH to be higher than 10.2.

Adsorption processes

Activated alumina is considered an adsorptive media, although the chemical reaction is an exchange of arsenic ions with the surface hydroxides on the alumina. When all of the surface hydroxides on the alumina have been exchanged, the media must be regenerated. Regeneration consists of backwashing, followed by sodium hydroxide, flushing with water and neutralization with a strong acid. Effective arsenic removal requires sufficient empty bed contact time. Removal efficiency can also be impacted by the water pH, with neutral or slightly acidic conditions being considered optimum. If As (III) is present, it is generally advisable to increase empty bed contact time, as As (III) is adsorbed more slowly than As (V). Alumina dissolves slowly over time due to contact with the chemicals used for regeneration. As a result, the media bed is likely to become compacted if it is not backwashed periodically.

Granular ferric hydroxide works by adsorption, but when the media is spent it cannot be regenerated and must be replaced. The life of the media depends upon pH of the raw water, the concentrations of arsenic and heavy metals, and the volume of water treated daily. Periodic backwashing is required to prevent the media bed from becoming compacted and pH may need to be adjusted if it is high, in order to extend media life. For

maximum arsenic removal, filters operate in series. For less stringent removal, filters can operate in parallel.

One type of adsorption media has been developed for application to non-drinking water processes for arsenic, phosphate and for heavy metals removal by sorption (Severn Trent Bayoxide® E IN-20). This granular ferric oxide media has been used for arsenic removal from mining and industrial wastewaters, selenium removal from refinery wastes and for phosphate polishing of municipal wastewaters. Valley Vista drinking water treatment with Bayoxide® E IN-20 media achieves removal from 31-39 µg/L (31,000-39,000 ng/L) to below 10 µg/L MCL (http://www.severntrentservices.com/News/Successful_Drinking_Water_Treatment_in_an_Arsenic__Hot_Spot__nwMFT_452.aspx).

Another adsorptive filter media is greensand. Greensand is available in two forms: as glauconite with manganese dioxide bound ionically to the granules and as silica sand with manganese dioxide fused to the granules. Both forms operate in pressure filters and both are effective. Greensand with the silica sand core operates at higher water temperatures and higher differential pressures than does greensand with the glauconite core. Arsenic removal by greensand requires a minimum concentration of iron. If a sufficient concentration of iron is not present in the raw water, ferric chloride is added.

WesTech filters with greensand and permanganate addition for drinking water systems can reduce As from 15 to 25 µg/L to non-detect. Sodium hypochlorite and/or potassium permanganate are added to the raw water prior to the filters. Chemical addition may be done continuously or intermittently, depending on raw water characteristics. These chemicals oxidize the iron in the raw water and also maintain the active properties of the greensand itself. Arsenic removal is via co-precipitation with the iron.

Ion Exchange

Siemens offers a potable ion exchange (PIX) arsenic water filtration system. PIX uses ion exchange resin canisters for the removal of organic and inorganic contaminants, in surface and groundwater sources to meet drinking water standards.

Filtronics also uses ion exchange to treat arsenic. The technology allows removal for below the SWDA MCL for potable water of 10 µg/L (10,000 ng/L).

Nanofiltration and Reverse Osmosis

Arsenic is effectively removed by RO when it is in an oxidative state As(V) to approximately 1 µg/L or less (Ning 2002). While effective, RO has its own inherent challenges when dealing with brine reject as discussed in this paper. A potentially attractive solution is the use of nanofiltration membranes (Worou et al., 2021). While still emerging, such nanofiltration membranes have shown promise as they have exhibited long-term efficiency, fouling reduction, cost reduction, and an increase in separation of multivalent ions, rejection performance, and high flux achievement compared to RO. This *Treatment Technology Review and Assessment* for the Northwest Pulp and Paper Association did not consider nanofiltration membranes as this is still an emerging technology for such applications.

Summary of Arsenic Technologies

The current state of the technology for arsenic removal is focused on satisfying the 10 µg/L SWDA MCL for arsenic in potable water. The current EPA maximum concentration level for arsenic in drinking water at 10 µg/L is much higher than 0.018 µg/L target for arsenic in this study for Washington. The majority of the treatment technologies discussed above are able to remove arsenic to either the SDWA maximum contaminant level, or to the analytical laboratory level of detection. The lowest detection limit of one of the EPA approved methods of arsenic measurements is 0.020 µg/L (Grosser, 2010), which is comparable to the 0.018 µg/L limit targeted in this study.

Combined processes for arsenic removal, such as MF or UF combined with RO and an AOP process, appear capable of arsenic removal to the same order of magnitude as the Washington HHWQC. Pilot tests would be required at individual treatment plants to determine the lowest concentration achievable on a sustainable and reliable basis. The feasibility of compliance would depend upon the formulation of effluent limits in discharge permits. Compliance with long term average mass loading limits might be feasible, however compliance with maximum day concentration limits would be unlikely.

4.1.2 Polycyclic Aromatic Hydrocarbons - Benzo(a)pyrene

The anticipated required HHWQC effluent limit for BAP is 0.000016 µg/L.

Benzo(a)pyrene During Biological Treatment

The partitioning behavior for BAPs is well understood with the lower molecular weight compounds primarily in the dissolved form, whereas the higher molecular weight compounds tend to be bound to organic-rich surfaces and/or solids (Schwartzenbach et al., 2003). This partitioning behavior applies to wastewater treatment, whereby BAPs which have a high molecular weight have been found to primarily bind to sludge (Melcer et al. 1993; Liu et al, 2017)). Primary and secondary processing could remove up to 69 percent of incoming PAHs and BAP in particular, mostly due to adsorption to sludge (Liu et al., 2017). Such removal levels are comparable with previous research by Kindaichi et al., NA; Wayne et al., 2009) that found removals by primary and secondary processes of up to 60 percent.

Biodegradation of BAP is expected to be very low since there are more than five benzene rings which are resistant to biological degradation. Biosurfactant addition to biological process could partially improve biodegradation, but only marginally (Sponza et al. 2010). Existing data from municipal treatment facilities in Washington state have influent and effluent concentrations of BAP of approximately <0.3 µg/L which suggests that current secondary treatment has limited effectiveness at BAP removal.

Activated Sludge has shown removals to below 0.0057 µg/L, however, this is still two orders-of-magnitude greater than the HHWQC of 0.000016 µg/L (Ecology 2010).

Methods to Enhance Biological Treatment of Benzo(a)pyrene

Ozonation prior to biological treatment could potentially improve biodegradability of BAP (Zeng et al. 2000; Yerushalmi et al., 2006). In the case of soil remediation, ozonation

before biotreatment improved biodegradation by 70 percent (Russo et al. 2012). The overall removal of BAP increased from 23 to 91 percent after exposure of water to 0.5 mg/L ozone for 30 minutes during the simultaneous treatment process and further to 100 percent following exposure to 2.5 mg/L ozone for 60 minutes during the sequential treatment mode (Yerushalmi et al. 2006). In general, to improve biodegradability of BAP, long exposure to ozone might be required (Haapea et al. 2006).

A literature review of treating BAP in various water environments support the combination of combined treatment methods, such as ozone followed by biological treatment, is essential for effective BAP removal (Mojiri et al., 2019). Other physical/chemical treatments of interest are sonication pre-treatment, electronic beam irradiation, or activated carbon (Gupta and Gupta, 2016). Such treatments (except activated carbon) break up PAHs into more bioavailable forms for subsequent biological degradation.

Recent studies suggest that a membrane bioreactor (MBR) is capable of removing PAHs from wastewater (Rodrigue and Reilly 2009; González et al. 2012). The removal mechanism in González et al. (2012) suggests a blend of sorption and air stripping with little or no biodegradation. As a result, an MBR would be unlikely to achieve any significant PAH removal at a full-scale facility.

Removal of Benzo(a)pyrene from Drinking Water

Activated Carbon and Biochar

Since BAP has an affinity to particulate matter, it has been found to be removed from drinking water sources by means of adsorption (e.g., granular activated carbon (GAC) (EPA)). Similarly, Oleszczuk et al. (2012) showed that addition of 5 percent activated carbon could remove 90 percent of PAHs from the wastewater. More recent research has focused on the use of biochar (Oleszczuk et al. (2014). The biochar results were more broadly \ ranging than with GAC (17 to 58 percent reduction of PAHs at 5 percent biochar) and highly dependent on feedstock, biochar particle size, and temperature. In contrast, biochar is promising to further evaluate as it lends itself to a circular economy of recycling.

Reverse Osmosis and Nanofiltration

Light (1981) studied dilute solutions of PAHs, aromatic amines, and nitrosamines and found rejections of these compounds in reverse osmosis to be over 99 percent for polyamide membranes. Bhattacharyya et al. (1987) investigated rejection and flux characteristics of FT30 membranes for separating various pollutants (PAHs, chlorophenols, nitrophenols) and found membrane rejections were high (>98 percent) for the organics under ionized conditions.

While treating landfill leachate, Smol and Włodarczyk-Makuła (2017) found that coagulation coupled with nanofiltration and RO resulted in 88 percent removal of PAHs. The coagulation and nanofiltration step removed up to 78 percent of the PAHs, which suggests the nanofiltration step removed the majority of the PAHs.

Summary of Benzo(a)pyrene Technologies

Current technologies show that BAP removal rates may be approximately 99 percent or greater with a single technology. The lowest detection reported for BAP is 0.0057 µg/L, which is also the secondary effluent BAP concentration assumed for this study (Ecology 2010). Even if it is assumed that an additional 99 percent removal can be achieved with post-secondary treatment, it is unlikely to comply with the HHWQC (99 percent removal of 0.0057 µg/L=0.00057 µg/L which still exceeds the HHWQC). Therefore, it appears that single advanced treatment technologies alone will not remove BAP to the proposed HHWQC levels. Multiple advanced technologies in series may have the ability to further reduce BAP concentrations, however no known processes exist which demonstrate this in testing or full-scale facilities.

4.1.3 Mercury

The range of potential water column concentrations for methylmercury associated with EPA's proposed 0.03 mg/kg tissue concentration are lower than the approved analytical methods in 40 CFR part 136 for Method 1631E with a quantitation level of 0.0005 µg/L. Consequently, treatment facilities would need to target non-detectable levels of effluent methylmercury less than 0.0005 µg/L. Therefore, a limit of 0.0005 µg/L is used for comparison to existing treatment plants and to values cited in literature.

It is well-documented that mercury removal from wastewater can be achieved using precipitation, adsorption, filtration, or a combination of these technologies (e.g., Hua et al., 2020). There is no available data to support that achieving ultra-low effluent mercury concentrations near 0.0005 µg/L is possible at full-scale. This review provides a summary of treatment technology options and anticipated effluent mercury concentrations.

Precipitation (and co-precipitation) involves chemical addition to form a particulate and solids separation, using sedimentation or filtration. Precipitation includes the addition of a chemical precipitant and pH adjustment to optimize the precipitation reaction. Chemicals can include metal salts (ferric chloride, ferric sulfate, ferric hydroxide, or alum), pH adjustment, lime softening, or sulfide. A common precipitant for mercury removal is sulfide, with an optimal pH between 7 and 9. The dissolved mercury is precipitated with the sulfide to form an insoluble mercury sulfide that can be removed through clarification or filtration. One disadvantage of precipitation is the generation of a mercury-laden sludge that will require dewatering and disposal. The mercury sludge may be considered a hazardous waste and require additional treatment and disposal at a hazardous waste site. The presence of other compounds, such as other metals, may reduce the effectiveness of mercury precipitation/co-precipitation. For low-level mercury treatment requirements, several treatment steps will likely be required in pursuit of very low effluent targets.

EPA compiled a summary of facilities that are using precipitation/co-precipitation for mercury treatment (EPA, 2007). Three of the full-scale facilities were pumping and treating groundwater and the remaining eight facilities were full-scale wastewater treatment plants. One of the pump and treat systems used precipitation, carbon

adsorption, and pH adjustment to treat groundwater to mercury effluent concentrations of 0.3 µg/L or less.

Adsorption treatment can be used to remove inorganic mercury from water. While adsorption can be used as a primary treatment step, it is frequently used for polishing after a preliminary treatment step (EPA, 2007). One disadvantage of adsorption treatment is that when the adsorbent is saturated, it either needs to be regenerated or disposed of and replaced with new adsorbent. A common adsorbent is GAC. There are several patented and proprietary adsorbents on the market for mercury removal. Adsorption effectiveness can be affected by water quality characteristics, including high solids and bacterial growth, which can cause media blinding. A constant low flow rate to the adsorption beds increases effectiveness (EPA, 2007). The optimal pH for mercury adsorption on GAC is pH 4 to 5; therefore, pH adjustment may be required.

EPA compiled a summary of facilities that are using adsorption for mercury treatment (EPA, 2007). Some of the facilities use precipitation and adsorption as described above. The six facilities summarized included two groundwater treatment and four wastewater treatment facilities. The reported effluent mercury concentrations were all less than 2 µg/L (EPA 2007).

Membrane filtration can be used in combination with a preceding treatment step. The upstream treatment is required to precipitate soluble mercury to a particulate form that can be removed through filtration. According to the EPA summary report, ultrafiltration is used to remove high-molecular weight contaminants and solids (EPA, 2007). The treatment effectiveness can depend on the source water quality since many constituents can cause membrane fouling, decreasing the effectiveness of the filters. One case study summarized in the EPA report showed that treatment of waste from a hazardous waste combustor treated with precipitation, sedimentation, and filtration achieved effluent mercury concentrations less than the detection limit of 0.2 µg/L.

Bench-scale research performed at the Oak Ridge Y-12 Plant in Tennessee evaluated the effectiveness of various adsorbents for removing mercury to below the NPDES limit of 0.012 µg/L and the potential revised limit of 0.051 µg/L (Hollerman et al., 1999). Several proprietary adsorbents were tested, including carbon, polyacrylate, polystyrene, and polymer adsorption materials. The adsorbents with thiol-based active sites were the most effective. Some of the adsorbents were able to achieve effluent concentrations less than 0.051 µg/L but none of the adsorbents achieved effluent concentrations less than 0.012 µg/L. Subsequent research on ultrafiltration pore size membranes using polyvinylamine coating membrane suggests removals as high as 99 percent (Huang et al., 2015). However, coating the membrane with polyvinylamine reduced the water flux significantly so a balance is required between removal rates and full-scale applicability.

Other mercury removal bench-scale and pilot-scale tests have been performed on refinery wastewater to determine treatment technology effectiveness for meeting very low mercury levels (Urgun-Demirtas et al., 2012; 2013). The Urgun-Demirtas paper found, at bench-scale, that MF membranes could achieve mercury concentrations of 0.00055 µg/L and reported UF membranes could achieve levels as low as 0.00014 µg/L using EPA Method 1631E. However, while EPA Method 1631E has a method detection limit (MDL) of 0.00005 µg/L, versus its ML of 0.0005 µg/L, detection limit means the

minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero as determined by the procedure given in 40 CFR part 136, Appendix B. The quantitation level, also known as minimum level of quantitation (ML), is the lowest level at which the entire analytical system must give a recognizable signal and acceptable calibration point for the analyte. It is equivalent to the concentration of the lowest calibration standard, if the laboratory has used all method-specified sample weights, volumes, and cleanup procedures. Therefore, while the report lists a level below the ML for UF membranes, the ML is the minimum value that is considered a reliable measurement, and the value of 0.00014 µg/L should be understood to indicate that there was 99 percent confidence that there was a greater than zero mercury level, but not taken as a reliable measurement.

The Great Lakes Initiative water quality criterion for mercury is less than 0.0013 µg/L for municipal and industrial wastewater plants in the Great Lakes region. This research included an initial bench scale test including microfiltration, ultrafiltration, nanofiltration, and reverse osmosis to meet the mercury water quality criterion. The nanofiltration and reverse osmosis required increased pressures for filtration and resulted in increased mercury concentrations in the permeate. Based on this information and the cost difference between the filtration technologies, a pilot-scale test was performed. The 0.04 µm PVDF GE ZeeWeed 500 series membranes were tested. The 0.0013 µg/L water quality criterion for the Great Lakes Region was met under all pilot study operating conditions. The mercury in the refinery effluent was predominantly in particulate form which was well-suited for removal using membrane filtration.

Other emerging technologies for mercury removal/management are being developed, such as the use of carbon nanotubes (CNTs) (e.g., Verma et al., 2019) and the use of wetlands with biochar (Chang et al., 2022). CNTs are gaining traction as they allow user specific surface chemistries to target specific compounds, such as mercury. As for wetlands and biochar, such configurations offer a means to balance natural treatment with mercury management. While both are attractive, they are still emerging for mercury management and thus not considered further as candidate treatment trains in this study.

Based on available data, it appears that existing municipal treatment facilities can reduce effluent mercury to near EPA Method 1631E's minimum level of quantification (ML) of 0.0005 µg/L, but not meet it on non-detect levels. As stated previously, levels below the ML would be needed to satisfy the fish tissue criteria of 0.03 mg/kg. Average effluent mercury is in the range of 0.0012 to 0.0066 µg/L for existing facilities with secondary treatment and enhanced treatment with cloth filters and membranes. The Spokane County plant data range is an average of 0.0012 µg/L to a maximum day of 0.003 µg/L. Addition of advanced treatment processes such as GAC or RO would be expected to enhance removal rates. Data from the West Basin treatment facility in California suggests that at a detection limit of 0.00799 µg/L, mercury is not detected in the effluent from this advanced process train. It is important to note that industrial plants may have higher existing mercury levels and thus the effluent quality that is achievable at an industrial facility may be of lower quality depending upon site specific circumstances.

Summary of Mercury Technologies

The literature review revealed one paper on mercury removal technologies near or below the revised effluent target/quantitation limit of 0.0005 µg/L. The value of 0.00055 µg/L was achieved by MF membranes, and a value of 0.00014 µg/L was reported using UF membranes. However, as stated previously, this should be seen as an indication that there was a non-zero amount of mercury remaining in the effluent and not an accurate measurement of the actual remaining mercury concentration. Further, these were both from bench-scale testing and not full scale treatment facilities.

4.1.4 Polychlorinated Biphenyls

The EPA proposed HHWQC for PCBs is 0.000007 µg/L. PCBs are persistent organic pollutants that can be difficult to remove in treatment. PCB treatment in wastewater can be achieved using oxidation with peroxide, UV + peroxide, filtration, biological treatment, or a combination of these technologies. There is limited information available about achieving ultra-low effluent PCB concentrations near the 0.000007 µg/L range under consideration in the proposed rulemaking process. Dischargers along the Spokane River have been actively developing a technical support document for PCB variances for river discharges (Ecology, Draft 2020). The draft Ecology report suggests removals for various dischargers along the Spokane River remove 65 to 99 percent of PCBs, dependent on treatment technologies in place and other variables (e.g., feed loads). This review provides a summary of treatment technology options and anticipated effluent PCB concentrations.

Research on the effectiveness of ultraviolet (UV) light and peroxide on removing PCBs was tested in bench scale batch reactions (Yu, Macawile, Abella, & Gallardo 2011). The combination of UV and peroxide treatment achieved PCB removal greater than 89 percent, and in several cases exceeding 98 percent removal. The influent PCB concentration for the batch tests ranged from 50 to 100 micrograms per liter (µg/L). The final PCB concentration (for the one congener tested) was <10 µg/L (10,000 ng/L) for all tests and <5 µg/L (5,000 ng/L) for some tests. The lowest PCB concentrations in the effluent occurred at higher UV and peroxide doses.

Pilot testing was performed to determine the effectiveness of conventional activated sludge and a membrane bioreactor to remove PCBs (Bolzonella et al. 2010). EPA Method 1668 was used for the PCB analysis (detection limit of 0.000010 µg/L per congener). Influent to the pilot system was a combination of municipal and industrial effluent. The detailed analysis was for several individual congeners. Limited testing using the Aroclor method (total PCBs) was used to compare the individual congeners and the total concentration of PCBs. Both conventional activated sludge and UF membrane bioreactor (MBR) systems removed PCBs. The effluent UF MBR concentrations ranged from <0.00001 µg/L to 0.00004 µg/L compared to <0.00001 µg/L to 0.00088 µg/L for conventional activated sludge. The pilot testing showed that increased SRT and higher mixed liquor suspended solids concentrations in the MBR system led to increased removal in the liquid stream. More recent studies by Rodenburg et al. (2022) found that membrane filtration resulted in PCB load reductions by approximately 55 percent at

municipal wastewater treatment plants in the Spokane River. However, the UF MBR effluent was still two orders-of-magnitude greater than the proposed HHWQC.

Bench scale studies were completed to test the effectiveness of GAC and biological activated carbon (BAC) for removing PCBs (Ghosh, Weber, Jensen, & Smith 1999). The effluent from the GAC system was 0.800 µg/L. The biological film in the BAC system was presumed to support higher PCB removal with effluent concentrations of 0.200 µg/L. High suspended sediment in the GAC influent can affect performance. It is recommended that filtration be installed upstream of a GAC system to reduce solids and improve effectiveness.

The City of Coeur d'Alene, Idaho operates an Advanced Wastewater Treatment Facility (AWTF) with Tertiary Membrane Filtration (TMF) that discharges to the Spokane River. The TMF facility was designed for achieving low levels of effluent phosphorus, ammonia, and BOD using 0.04 µm nominal pore size PVDF GE ZeeWeed 500 series ultrafiltration (UF) membranes with coagulant addition (alum, polymer). The City's NPDES discharge permit includes Section II.I that requires Best Management Practices for polychlorinated biphenyl (PCB) congeners, in addition to permit required influent, effluent, and receiving water monitoring using EPA Method 1668 (EPA 2013). Laboratory analysis must target MDLs no greater than the MDLs listed in Table 2 of EPA Method 1668 Revision C (EPA-820-R-10-005), for each of the 209 individual PCB congeners. Each congener has an MDL ranging from 7 to 77 pg/L with a median of 14.5 pg/L (or 0.0000145 µg/l). The method reporting limits for PCB congeners in water is 10 to 1,000 picogram/liter (pg/L) (or 0.00001 to 0.0001 µg/l).

The City has collected 7 years of effluent PCB monitoring data with 32 individual sampling events. The PCB totals, both blank corrected and unaltered, were evaluated (Coeur d'Alene 2021). Sample results were "corrected" to account for laboratory contamination. If a sample result is within a certain factor of the laboratory blank, it is removed from the total sum of PCB congener concentrations based on the presumption that the analytical results may not be valid. A "10X" blank correction identifies congeners that are less than ten times the associated blank result and counts these congeners as zero when totaling. Equipment blanks were also run for the effluent sampler and corrected at the 10X level. The range of congener concentrations in the blanks was 0.2 pg/L to 1,170 pg/L with a median of 1.88 pg/L.

Using the City's sampling results dataset, the median concentration of samples gathered from January-February 2015 through September-October 2021 was calculated. The median was selected as a statistical representation of the central tendency to dampen the effect of outlying samples. Whereas the average or mean may be skewed by higher concentrations and the mode may not be appropriate for a small dataset. The sum of the median effluent PCB congener concentrations for uncorrected laboratory results and blank corrected results were 278 pg/L and 117 pg/L respectively (or 0.000278 and 0.000117 µg/l).

Based on limited available data, it appears that existing municipal secondary treatment facilities in Washington state can reduce effluent PCBs to the range of approximately 0.00010 to 0.0015 µg/L. It appears that the best performing existing municipal treatment facility in Washington state with an ultrafiltration membrane can reduce effluent PCBs to

the range of approximately 0.00019 to 0.00063 µg/L. This is based on a limited data set and laboratory blanks covered a range that overlapped with the effluent results (blanks 0.000058 to 0.00061 µg/L).

Addition of advanced treatment processes would be expected to enhance PCB removal rates, but the technical literature does not appear to provide definitive information for guidance for achieving effluent concentrations as low as proposed HHWQC. A range of expected enhanced removal rates may be assumed to vary widely from the level of the reference ultrafiltration MBR of <0.00001 to 0.0004 µg/L.

Summary of PCB Technologies

The literature review revealed that there are viable technologies available to reduce PCBs to very low concentration levels <0.00001 µg/L, but no research was identified with treatment technologies capable of meeting the HHWQC for PCBs of 0.000007 µg/L. Based on this review, a tertiary process was selected to biologically reduce PCBs and separate the solids using tertiary filtration. Alternately, GAC was investigated as an option to reduce PCBs, although it is not proven that it will meet the effluent limits.

4.2 Unit Processes Evaluated

Based on the results of the literature review, a wide range of technologies were evaluated for toxic constituent removal. A listing of the technologies is as follows:

- Chemically enhanced primary treatment (CEPT). This physical and chemical technology is based on the addition of a metal salt to precipitate particles prior to primary treatment, followed by sedimentation of particles in the primaries. This technology has been shown to effectively remove arsenic but there is little data supporting the claims. As a result, the chemical facilities are listed as optional.
- Activated sludge treatment (with a short SRT of approximately 4 days or less). This biological technology is commonly referred to as secondary treatment. It relies on converting dissolved organics into solids using biomass. Having a short SRT is effective at removing degradable organics referred to as BOD compounds for meeting existing discharge limits. Dissolved constituents with a high affinity to adsorb to biomass (e.g., metals, high molecular weight organics, and others) will be better removed compared to smaller molecular weight organics and recalcitrant compounds which will have minimal removal at a short SRT.
- Enhanced activated sludge treatment (with a long SRT of >8 days). This builds on secondary treatment by providing a longer SRT, which enhances sorption and biodegradation. The improved performance is based on having more biomass coupled with a more diverse biomass community, especially nitrifiers, which have been shown to assist in removal of some of the more recalcitrant constituents not removed with a shorter SRT (e.g., lower molecular weight PAHs). There is little or no data available on the effectiveness of this treatment for removing BAP.
- Additional benefits associated with having a longer SRT are as follows:
    - Lower BOD and TSS discharge loads to receiving water

  - Improved water quality and benefit to downstream users
  - Lower effluent nutrient concentrations which reduce algal growth potential in receiving waters
  - Reduced receiving water dissolved oxygen demand due to ammonia removal
  - Reduced ammonia discharge, which is toxic to aquatic species
  - Improved water quality for habitat, especially as it relates to biodiversity and eutrophication
  - Secondary clarifier effluent more conditioned for filtration and disinfection
  - Greater process stability from the anaerobic/anoxic zones serving as biological selectors

- Coagulation/Flocculation and Filtration. This two-stage chemical and physical process relies on the addition of a metal salt to precipitate particles in the first stage, followed by the physical removal of particles in filtration. This technology lends itself to constituents prone to precipitation (e.g., arsenic).
- Lime Softening. This chemical process relies on increasing the pH to either volatilize dissolved constituents or inactivate pathogens. Given that none of the constituents being studied are expected to volatilize, this technology was not carried forward.
- Adsorptive Media. This physical and chemical process adsorbs constituents to a combination of media and/or biomass/chemicals on the media. There are several types of media, with the most proven and common being GAC. GAC can also serve as a coarse roughing filter.
- Ion Exchange. This chemical technology exchanges targeted constituents with a resin. This technology is common with water softeners where the hard divalent cations are exchanged for monovalent cations to soften the water. Recently, resins that target arsenic and mercury removal, including activated alumina and granular ferric hydroxides, have been developed. The resin needs to be cleaned and regenerated, which produces a waste slurry that requires subsequent treatment and disposal. As a result, ion exchange was not considered for further.
- Membrane Filtration. This physical treatment relies on the removal of particles larger than the membranes pore size. There are several different membrane pore sizes as categorized below.
  - Microfiltration (MF): nominal pore size range typically between 0.1 to 1 micron. This pore size targets particles, both inert and biological, and bacteria. If placed in series with coagulation/flocculation upstream, dissolved constituents precipitated out of solution and bacteria can be removed by the MF membrane.
  - Ultrafiltration (UF): nominal pore size range of typically between 0.010 to 0.1 micron. This pore size targets those solids removed with MF

(particles and bacteria) plus viruses and some colloidal material. If placed in series with coagulation/flocculation upstream, dissolved constituents precipitated out of solution can be removed by the UF membrane.

- Nanofiltration (NF): nominal pore size range of typically between 0.001 to 0.010 micron. This pore size targets those removed with UF (particles, bacteria, viruses) plus colloidal material. If placed in series with coagulation/flocculation upstream, dissolved constituents precipitated out of solution can be removed by the NF membrane.

- Membrane Bioreactor (MBR) (with a long SRT). This technology builds on secondary treatment whereby the membrane (microfiltration) replaces the secondary clarifier for solids separation. As a result, the footprint is smaller, the mixed liquor suspended solids concentration can be increased to about 5,000 – 10,000 mg/L, and the physical space required for the facility reduced when compared to conventional activated sludge. As with the activated sludge option operated at a longer SRT, the sorption and biodegradation of organic compounds are enhanced in the MBR process. The improved performance is based on having more biomass coupled with a more diverse biomass community, especially nitrifiers which have been shown to assist in removal of persistent dissolved compounds (e.g., some PAHs). There is little or no data available on effectiveness at removing BAP. Although a proven technology, MBRs were not carried further in this technology review since they are less likely to be selected as a retrofit for an existing activated sludge (with a short SRT) secondary treatment facility. The MBR was considered to represent a treatment process approach more likely to be selected for a new, greenfield treatment facility. Retrofits to existing secondary treatment facilities can accomplish similar process enhancement by extending the SRT in the activated sludge process followed by the addition of tertiary membrane filtration units.

- Reverse Osmosis (RO). This physical treatment method relies on the use of sufficient pressure to osmotically displace water across the membrane surface while simultaneously rejecting most salts. RO is very effective at removing material smaller than the size ranges for the membrane filtration list above, as well as salts and other organic compounds. As a result, it should be more effective than filtration and MBR methods described above at removing dissolved constituents. Although effective, RO produces a brine reject water that must be managed and disposed of separately.

- Advanced Oxidation Processes (AOPs). This broad term considers all chemical and physical technologies that create strong hydroxyl-radicals. Examples of AOPs include Fenton's oxidation, ozonation, ultraviolet/hydrogen peroxide (UV-H_2O_2), and others. The radicals produced are rapid and highly reactive at breaking down recalcitrant compounds. AOPs were carried forward because they are expected to break down PCBs and BAP and potentially contribute to enhancing removals when combined with other technologies.

Based on the technical literature review discussed above, a summary of estimated contaminant removal rates by unit treatment process is presented in Table 4-2.

Table 4-2. Contaminants Removal Breakdown by Individual Unit Process

Unit Process	Arsenic	BAP	Mercury	PCBs
Activated Sludge - Short SRT	28-90% removal; final effluents concentrations ranging from 0.64 – 2.2 µg/L[h]	Partial removal by partitioning <0.0057 ug/L[m]	>92% removal by adsorption of mercury onto activated sludge flocs and subsequent settling[g]	80% removal; effluent <0.00088 µg/L 93% removal; average effluent as low as .000660 µg/L[c]
Activated Sludge - Long SRT	28-90% removal; final effluents concentrations ranging from 0.64 – 2.2 µg/L[h] Potential bio-oxidation of arsenite to arsenate[j]	Partial removal by partitioning and/or partial biodegradation; MBR could potentially remove most of BAP <0.0057 ug/L[m]	>92% removal by adsorption of mercury onto activated sludge flocs and subsequent settling[g]	>93% removal with a membrane bioreactor, <0.00001 to 0.00004 µg/L (includes membrane filtration)[k]
Ultrafiltration (UF)*	More than 90% removal (rejection of bound arsenic)	90% removal; effluent of 0.1 µg/L (includes sand prefiltration before ultrafiltration)[d]	Effluent of 0.00055 µg/L with microfiltration.[f] Effluent of 0.00014 µg/L with ultrafiltration.[f]	>93% removal with a UF membrane bioreactor, <0.00001 to 0.00004 µg/L[k] 98% removal; average effluent as low as .0002 µg/L[c,d] Median 0.000278 µg/L uncorrected and 0.000117 µg/L blank corrected [u]
Reverse Osmosis (RO)	More than 90% removal (rejection of bound arsenic and removal of soluble arsenic)[o]	More than 98% removal[p,q]	80% removal; effluent of 0.0011 µg/L[f]	Expected to have greater removal than Microfiltration or Ultrafiltration
AOP	No removal; potential chemical oxidation of arsenite to arsenate[i]	More than 99% removal[a]	No removal	As much as 98% removal (<0.99 µg/L)[b]
Granular Activated Carbon (GAC)	No removal, removal only when carbon is impregnated with iron	90% removal	<0.300 µg/L (precipitation and carbon adsorption)[s] <0.051 µg/L (GAC)[t]	<0.800 µg/L. Likely requires upstream filtration[r]
Disinfection	--	--	--	--

Unit Process	Arsenic	BAP	Mercury	PCBs
Combined Processes	UF/RO/AOP: Effluent of <0.036 µg/L Confidential demonstration project[n]			
Lowest Cited Concentration Removal Method	UF/RO/AOP: Effluent of <0.036 µg/L Confidential demonstration project[n]	Activated Sludge: <0.0057 µg/L	Microfiltration: 0.00055 µg/L[f]	UF Membrane Bioreactor: Best: <0.00001 µg/L Average: < 0.0002 µg/L
Required HHWQC based Effluent Quality	0.018 µg/L	0.000016 µg/L	0.0005 µg/L	0.000007 µg/L[d]

* Values given are for Microfiltration. Actual performance may be better with UF.

a. Ledakowicz et al., 1999. Note this is for lab conditions, not WWTP performance
b. Yu et al., 2011. Note this is for lab conditions, not WWTP performance
c. Rodenburg et al., 2022. Interference/contamination issues were cited for measuring PCBs at this ultra-low level EPA method 1668.
d. Rodenburg et al., 2022. Note that membrane pore size is not given.
e. Smol and Wlodarkczyk-Makula 2012
f. Urgun-Demirtas et al., 2012. Note that EPA Method 1631E was used for detection. This has a minimum level of quantitation (ML) of 0.0005 µg/L. EPA Method 1631E has a method detection limit (MDL) of 0.00005 µg/L. Detection level or *detection limit* means the minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is *greater than zero* as determined by the procedure given in 40 CFR part 136, Appendix B. The *quantitation level*, also known as minimum level of quantitation (ML), is the lowest level at which the entire analytical system must give a recognizable signal and acceptable calibration point for the analyte. It is equivalent to the concentration of the lowest calibration standard, if the laboratory has used all method-specified sample weights, volumes, and cleanup procedures. Therefore, while the report lists a level below the ML for UF membranes, the ML is the minimum value that is considered a reliable measurement, and the value of 0.00014 µg/L should be understood to indicate that there was 99 percent confidence that there was a greater than zero mercury level, but not taken as a reliable measurement. Hence the value from MF of 0.0055 is a value that can be considered potentially reliable. Additionally, Mercury removal was operating pressure dependent, with higher operating pressure generally resulting in poorer removal of mercury. Note that these were bench-scale test results, not full-scale plant results.
g. Brown and Lester, 1979. Adsorption of mercury is a hypothesized removal mechanism. Note that operating SRT for the activated sludge process was not specified.
h. Olujimi et al., 2012. Note that operating SRT for the activated sludge process was not specified.
i. Pettine et al., 1999. Note this is for lab conditions, not WWTP performance.
j. Andrianisa et al., 2008. Bench-scale study, not WWTP performance.
k. Bolzonella et al., 2010
l. UF/NF/ and RO all produced mercury levels of <0.0013 µg/L
m. Ecology 2010
n. Data from a confidential demonstration project facility using UF/RO/AOP. The filtration process includes MF and UF in parallel, after which the filtrate from each is combined. Degree of removal from each individual process cannot be determined as only influent and final effluent samples were taken for arsenic.
o. Ning, 2002
p. Light, 1981
q. Bhattacharyya et al., 1987
r. Ghosh et al., 1999
s. EPA, 2007
t. Hollerman et al., 1999
u. City of Coeur d'Alene

4.3 Unit Processes Selected

The key conclusion from the literature review was that there is limited, to no evidence, that existing treatment technologies are capable of simultaneously meeting all four of the revised standards for the toxics under consideration. Advanced treatment using RO or GAC is expected to provide the best overall removal of the constituents of concern. It is unclear whether these advanced technologies can meet revised effluent limits based on HHWQC, however these processes may achieve the best effluent quality of the technologies reviewed. This limitation in the findings is based on a lack of an extensive dataset on treatment removal effectiveness in the technical literature for the constituents of interest at the low levels relevant to the proposed criteria, which approach or exceed the limits of reliable removal performance for the technologies and analytical methods. As Table 4-2 highlights, certain unit processes are capable of removing a portion, or all, of an individual constituent in each technology. The removal performance for each constituent will vary from facility to facility and require a site-specific, detailed evaluation because the proposed criteria are for such low concentrations. In some cases, a facility may only have elevated concentrations of a single constituent of concern under consideration in this study. In other cases, a discharger may have elevated concentrations of the four constituents identified in this study, as well as others not identified in this study, but subject to revised water quality criteria. This effort is intended to describe a planning level concept of what treatment processes are required to comply with discharge limits for all four constituents. Based on the literature review of unit processes above, four different treatment trains were developed for the analysis that are compared against a baseline of secondary treatment as follows:

- Baseline: Conventional secondary treatment is the baseline that is most commonly employed nationwide at wastewater treatment plants. A distinguishing feature for this treatment is the short solids retention time (SRT) (<4 days) in activated slugged that is focused on removal of BOD with minimal removal of the toxic constituents of concern in this study.
- Advanced Treatment – UF/RO: This alternative builds on baseline treatment with the implementation of a longer SRT (>8 days) and the addition of UF and RO. The longer SRT removes not only BOD, but it also has the capacity to remove nutrients and a portion of the toxic constituents of concern. This alternative requires a RO brine management strategy which will be discussed in sub-sections below.
- Advanced Treatment – UF/GAC: This alternative provides a different approach to advanced treatment by using GAC and avoiding the RO reject brine water management concern. Similar to the UF/RO process, this alternative incorporates the longer SRT (>8 days) with the capacity to remove BOD, nutrients, and a portion of the toxic constituents of concern. As a result, the decision was made to develop costs for advanced treatment options using both RO and GAC.
- Advanced Treatment – UF/AOP/GAC: This alternative provides an additional step to advanced treatment with UF/GAC to further enhance effluent quality by

including AOP to break down PCBs and PAH prior to filtration with GAC. Similar to the UF/GAC and UF/RO process options, this alternative includes the longer SRT (>8 days) with the capacity to remove BOD, nutrients, and a portion of the toxic constituents of concern.

- Advanced Treatment – UF/AOP/GAC/RO: This alternative provides two additional steps to advanced treatment with UF/GAC to enhance effluent quality even further by including AOP to break down PCBs and PAH prior to filtration with GAC by adding a final step with RO. Similar to the UF/GAC and UF/RO processes, this alternative also includes the longer SRT (>8 days) with the capacity to remove BOD, nutrients, and a portion of the toxic constituents of concern.

The process flowsheets for each alternative are presented in Figure 4-3 to Figure 4-7, beginning with the baseline secondary treatment process in Figure 4-3, followed by the 4 advanced treatment alternatives. Table 4-3 presents a summary of unit process descriptions for the individual elements of each alternative treatment process train. Appendix A presents a summary of the sizing criteria for each of the unit treatment processes.

Table 4-3. Unit Processes Description for Each Alternative

Unit Process	Baseline	Advanced Treatment – UF/GAC	Advanced Treatment – UF/AOP/GAC	Advanced Treatment – UF/RO	Advanced Treatment – UF/AOP/GAC/RO
Influent Flow	5 mgd				
CEPT; Optional	--	Metal salt addition (alum) upstream of primaries			
Activated Sludge	• HRT: 4 hrs. • Short SRT: <8 days	• HRT: 9 hrs. (Requires more tankage than the Baseline) • Long SRT: >8 days (Requires more tankage than the Baseline)			
Secondary Clarifiers	Hydraulically Limited				
Ultrafiltration (UF)	--	Membrane Filtration to Remove Particles, Bacteria, Viruses, and some Colloids			
AOP	--	--	Breaks down PCBs and BAPs	--	Breaks down PCBs and BAPs
Reverse Osmosis (RO)	--	--		RO treats 50% of flow to remove metals and dissolved constituents. Sending 50% of flow through the RO and blending it with the balance of plant flows ensures a stable, non-corrosive, non-toxic discharge.	
Reverse Osmosis Brine Reject Mgmt	--	--		Several Options (All Energy or Land Intensive)	
Granular Activated Carbon (GAC)	--	Removes Dissolved Constituents		--	Removes Dissolved Constituents
Disinfection	Not shown to remove any of the constituents				

4.3.1 Baseline Treatment Process

A flowsheet of the baseline treatment process is provided in Figure 4-3. The baseline treatment process assumes the current method of treatment commonly employed by wastewater dischargers. For this process, water enters the headworks and undergoes primary treatment, followed by conventional activated sludge (short SRT) and disinfection. The excess solids wasted from the activated sludge process are thickened, followed by mixing with primary solids prior to entering the anaerobic digestion process for solids stabilization. The digested biosolids are dewatered to produce a cake and hauled off-site. Since the exact process for each facility in Washington is unique, this secondary treatment process was used to establish the baseline capital and O&M costs. The baseline costs will be compared against the advanced treatment alternatives to illustrate the magnitude of the increased costs and environmental impacts.

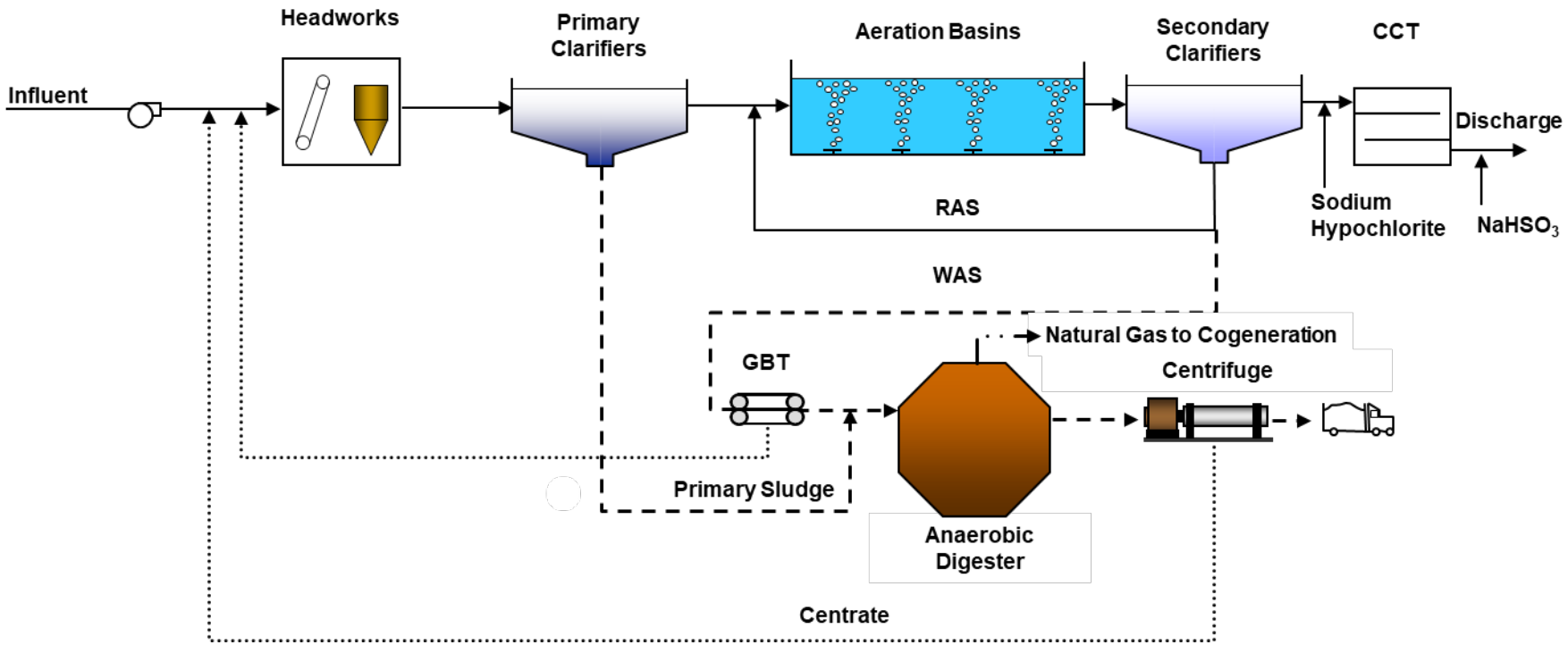

Figure 4-3. Baseline Flowsheet – Conventional Secondary Treatment

4.3.2 Advanced Treatment – Tertiary UF/RO

A flowsheet for the advanced treatment Tertiary UF/RO alternative is provided in Figure 4-4. This alternative builds on the baseline secondary treatment facility, whereby the SRT is increased in the activated sludge process, and UF and RO are added prior to disinfection and discharge. The solids treatment train does not change with respect to the baseline. Additionally, a brine management strategy must be included for RO reject.

The longer SRT in an activated sludge plant provides the following benefits:

- Lower effluent BOD and TSS discharge load
- Higher removal of recalcitrant constituents and heavy metals
- Improved water quality and benefit to downstream users
- Less downstream algal growth
- Reduced receiving water dissolved oxygen demand due to ammonia removal
- Reduced ammonia discharge loads, which is toxic to several aquatic species
- Improved water quality for habitat, especially as it relates to biodiversity and eutrophication
- Secondary clarifier effluent more conditioned for filtration and disinfection
- Greater process stability from the anaerobic/anoxic zones serving as a selector

The RO process concentrates contaminants into a smaller volume reject stream. Disposing of the RO reject stream can be challenging because of the potentially large volume of water involved and the concentration of contaminants contained in the brine. For reference, a 5 mgd process wastewater flow might result in 1 mgd of brine reject requiring further management. The available treatment/handling options for RO reject are as follows:

- Brine Recovery Systems
- Surface water discharge
- Ocean discharge
- Haul and discharge to coastal location for ocean discharge
- Sewer discharge
- Deep well injection
- Evaporate in a pond
- Solar pond concentrator

Many of the RO brine reject management options above result in returning the dissolved solids to a “water of the state” such as surface water, groundwater, or marine waters. Past rulings in Washington State have indicated that once pollutants are removed during treatment they are not to be re-introduced to a water of the state. As a result, these

methods for disposal were not considered viable options for management of RO reject water in Washington.

Membrane filtration is a proven technology demonstrated over 35 years of operations. The key technical and operational challenges associated with the tertiary add-on membrane filtration units are as follows:

- Membrane durability is dependent on feed water quality. The feed water quality is facility specific.
- Membranes are sensitive to particles, so upstream screening is critical. The newer generations of membranes have technical specifications that require a particular screen size.
- Membrane area requirements may be based on peak flows as water must pass through the membrane pores. Additionally, membranes struggle with variable hydraulic loading. Flow equalization upstream can greatly reduce the required membrane surface area and provide uniform membrane loading. Flow equalization was assumed for this analysis, however, at certain plants, flow equalization may not be possible and the cost for UF, AOP, GAC, and RO systems will increase significantly as a result.
- Membrane tanks can exacerbate foam related issues from the upstream biological process. Foam entrapment in the membrane tank from the upstream process can reduce membrane filtration capacity and in turn result in a plant-wide foam accumulation problem.
- Reliable access to the membrane modules is key to practical operation and maintenance. Once the automated programmable logical control (PLC) system is functioning properly, overall maintenance requirements for sustained membrane operation are relatively modest.
- Membranes are maintained through frequent membrane relaxation, or back pulses, combined with a periodic deep chemical clean in place (CIP) process.
- Sizing of membrane filtration facilities is governed by hydraulic flux. Municipal wastewater applications are typically based on flux rates that range from about 20 to 40 gallons per square foot per day (gfd) under average annual conditions. The flux associated with industrial applications is wastewater specific.

Brine Recovery System

A Brine Recovery System (BRS) produces little or no liquid brine residual, but rather leaves a dried residual salt material or low moisture content cake solids to be disposed of in some way. This process improves the water recovery of the RO system by reducing the volume of brine that must be treated and disposed of in some manner. BRS options include intermediate treatment, thermal-based technologies, pressure driven membranes electric potential driven membranes, and other alternative approaches.

Summary

There are many techniques which can be used to manage reject brine water associated with RO treatment. The selection of an appropriate alternative is primarily governed by geography and local constraints. A comparison of the various brine management methods and relative potential costs are provided in Table 4-4.

Table 4-4. Brine Disposal Method Relative Cost Comparison

Disposal Method	Description	Relative Capital Cost	Relative O&M Cost	Comments
Brine Recovery System (BRS)	Further concentrates brine reject for further downstream processing	High	High	This option is preferred as an intermediate step. This rationale is based on the reduction in brine reject volume to handle following BRS: RO reject stream volume is reduced on the order of 50-90%.
Surface Water Discharge	Brine discharge directly to surface water. Requires an NPDES permit.	Lowest	Lowest	Capital and O&M costs are heavily dependent on the distance from brine generation point to discharge. Not a viable option given that brine contains constituents to be removed from surface waters.
Ocean Discharge	Discharge through a deep ocean outfall. Requires an NPDES permit.	Medium	Low	Capital cost depends on location and availability of existing deep water outfall, or viability of permitting a new marine outfall.
Sewer Discharge	Discharge to an existing sewer pipeline for treatment at a wastewater treatment plant.	Low	Low	Both capital and O&M costs heavily dependent on the brine generation point to discharge distance. Higher cost than surface water discharge due to ongoing sewer connection charges. Viability depends upon whether discharge to another facility is acceptable.
Deep Well Injection	Brine is pumped underground to an area that is isolated from drinking water aquifers.	Medium	Medium	Technically sophisticated discharge and monitoring wells required. O&M cost highly variable based on injection pumping energy.
Evaporation Ponds	Large, lined ponds are filled with brine and as water evaporates, a a concentrated salt remains.	Low – High	Low	Capital cost highly dependent on the amount of brine, climate conditions, and the availability and cost of land.
Salinity Gradient Solar Ponds (SGSP)	SGSPs harness solar power from pond to power an evaporative unit.	Low – High	Lowest	Same as evaporation ponds plus added cost of heat exchanger and pumps. Lower O&M cost due to electricity production.

Of the brine management options, BRS was considered as the most viable approach for this analysis to RO reject water management. Two BRS options were examined: a thermal concentrator and a membrane concentrator, both with the same size evaporation pond following BRS. Capital expenditures for the two are similar, but the thermal concentrator has far higher O&M costs. The membrane option was chosen because of more reasonable costs, and because it will require similar maintenance to the RO system itself. The strength in this combination is that BRS reduces the brine reject volume, which in turn reduces the required evaporation pond footprint size. The disadvantage is that evaporation ponds, compared to several other options, require a substantial amount of physical space, which may not be available at existing treatment plant sites. To further reduce pond size, BRS was evaluated assuming the use of mechanical evaporators, resulting in a total pond area of 4 acres for all advanced treatment scenarios utilizing RO. The incorporation of mechanical evaporators is especially important for the state of Washington due to seasonal variations in weather, relatively low evaporation rates, and high precipitation rates in parts of the state. It is also important to recognize that the greenhouse gas (GHG) emissions vary widely for the eight brine management options listed above based on energy and chemical intensity.

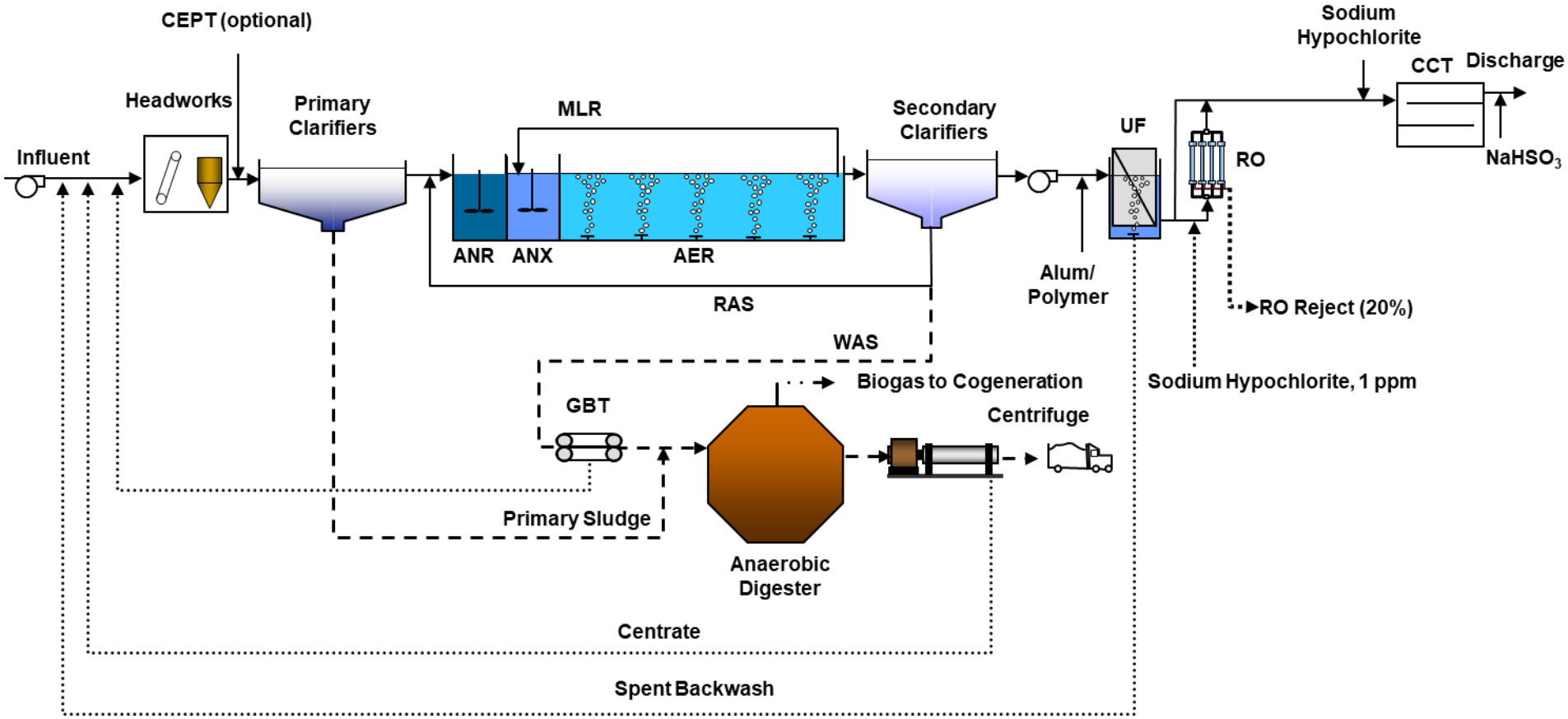

Figure 4-4. Advanced Treatment Flowsheet – Tertiary UF/RO

4.3.3 Advanced Treatment – Tertiary UF/GAC Alternative

A flowsheet for the advanced treatment Tertiary UF/GAC alternative is provided in Figure 4-5. Following the UF technology, a GAC contactor and media are required. This alternative was developed as an option that does not require a brine management technology for comparison to the advanced treatment Tertiary UF/RO alternative. However, this treatment alternative does require new or regenerated GAC, and disposal/hauling of spent GAC. A baseline secondary treatment facility can be retrofitted for UF/GAC. The long SRT in an activated sludge plant provides the following benefits, as previously stated:

- Lower effluent BOD and TSS discharge load
- Higher removal of recalcitrant constituents and heavy metals
- Improved water quality and benefit to downstream users
- Less downstream algal growth
- Reduced receiving water dissolved oxygen demand due to ammonia removal
- Reduced ammonia discharge loads, which is toxic to several aquatic species
- Improved water quality for habitat, especially as it relates to biodiversity and eutrophication
- Secondary clarifier effluent more conditioned for filtration and disinfection
- Greater process stability from the anaerobic/anoxic zones serving as a selector

The key technical and operational challenges associated with the tertiary add-on membrane filtration units are as follows:

- Membrane durability is dependent on feed water quality. The water quality is facility specific.
- Membranes are sensitive to particles, so upstream screening is critical. The newer generations of membranes have technical specifications that require a particular screen size.
- Membrane area requirements may be based on peak flows as water must pass through the membrane pores. Additionally, membranes struggle with variable hydraulic loading. Flow equalization upstream can greatly reduce the required membrane surface area and provide uniform membrane loading. Flow equalization was assumed for this analysis, however at certain plants, flow equalization may not be possible and the cost for UF, AOP, GAC, and RO systems will significantly increase.
- Membrane tanks can exacerbate any foam related issues from the upstream biological process. Foam entrapment in the membrane tank from the upstream process can reduce membrane filtration capacity and in turn result in a plant-wide foam problem.

- Once the automated programmable logical control (PLC) system is functioning, overall maintenance requirements for sustained membrane operation are relatively modest.
- Membranes are maintained through frequent membrane relaxation, or back pulses, combined with a periodic deep chemical clean in place (CIP) process.
- Sizing of membrane filtration facilities is governed by hydraulic flux. Municipal wastewater characteristics result in flux values that range from about 20 to 40 gallons per square foot per day (gfd) under average annual conditions. The flux associated with industrial applications may vary and is wastewater specific.

Following the UF membranes are the activated carbon facilities. There are two kinds of activated carbon used in treating water: powdered activated carbon (PAC) and GAC. PAC is finely-ground, loose carbon that is added to water, mixed for a short period of time, and removed. GAC is larger than PAC, is generally used in beds or tanks that permit higher adsorption and easier process control than PAC allows and is replaced periodically. PAC is not selective, and therefore, will adsorb all active organic substances making it an impractical solution for a wastewater treatment plant. As a result, GAC was considered for this analysis. The type of GAC (e.g., bituminous and subbituminous coal, wood, walnut shells, lignite or peat), gradation, and adsorption capacity are determined by the size of the largest molecule/contaminant that is being filtered (AWWA, 1990).

GAC is employed in two fashions, either in gravity contact basins, or in pressurized tanks. Pressurized tanks are more commonly used in polishing applications, such as the removal of trace amounts of our constituents of concern.

As water flows through the carbon bed, contaminants are captured by the surfaces of the pores until the carbon is no longer able to adsorb new molecules. The concentration of the contaminant in the treated effluent increases over time. Once the contaminant concentration in the treated water reaches an unacceptable level (called the breakthrough concentration), the carbon is considered "spent" and must be replaced by virgin or reactivated GAC.

The capacity of spent GAC can be restored by thermal reactivation. Some treatment facilities have the ability to regenerate GAC on-site, but generally small systems haul the spent GAC away for off-site regeneration (EPA 1993). For this study, off-site disposal was assumed.

The basic facilities and unit processes included in this treatment process alternatives with GAC are as follows:

- GAC supply and delivery
- GAC influent feed (Secondary Effluent) pumping
    - Low head feed pumping
    - High head feed pumping (assumed for this study for pre-engineered pressure GAC contactors)
- Contactors and backwash facilities
    - Custom gravity GAC contactor

    - Pre-engineered pressure GAC contactor (assumed for this study)
    - Backwash pumping
- Storage facilities
    - Steel tanks
    - Concrete tanks (assumed for this study; larger plants would typically select concrete tanks)
- Spent carbon regeneration
    - On-site GAC regeneration
    - Off-Site GAC regeneration/disposal (disposal assumed for this study)

The GAC contactor provides a 25-minute empty bed contact time (EBCT) for maximum month conditions. The GAC media must be regenerated/changed out about twice per year in a furnace. The constituents sorbed to the GAC media are removed during the regeneration process. A typical design has full redundancy and additional storage tankage for spent and virgin GAC. Facilities that use GAC need to decide whether they will regenerate GAC on-site or off-site. Due to challenges associated with receiving air emission permitting for new furnaces, it was assumed that off-site regeneration/disposal was the more likely option and included for this analysis.

The key technical and operational challenges associated with the tertiary add-on GAC units are as follows:

- Nearest vendor to acquire virgin GAC supplies. Frequency of virgin GAC delivery and hauling costs.
- Contactor selection is typically based on existing treatment plant equipment, as well as available operator expertise and labor-hours. Concrete gravity contactors are not typically used for polishing applications compared with pre-engineered pressure filters, and pressure filters can handle a wider range of flows. Gravity concrete filters may be feasible when converting pre-existing conventional filters at a treatment plant, but otherwise take longer to design and construct. Furthermore, gravity concrete filters require far greater operations and maintenance effort compared to pressure contactors for a variety of reasons; gravity GAC contactors are subject to biological growth issues, have a more complex media replacement process, and are more difficult to repair. Installment of prefabricated pressure vessels is simpler, and because they are standard across most installations, they require less operator training. For these reasons, the gravity GAC contactor was not used for this evaluation.
- Periodic backwashing is critical for maintaining the desired hydraulics and to control biological growth.
- Off-site GAC regeneration/disposal appears more viable due to the challenges with air emissions permitting and was assumed for this study

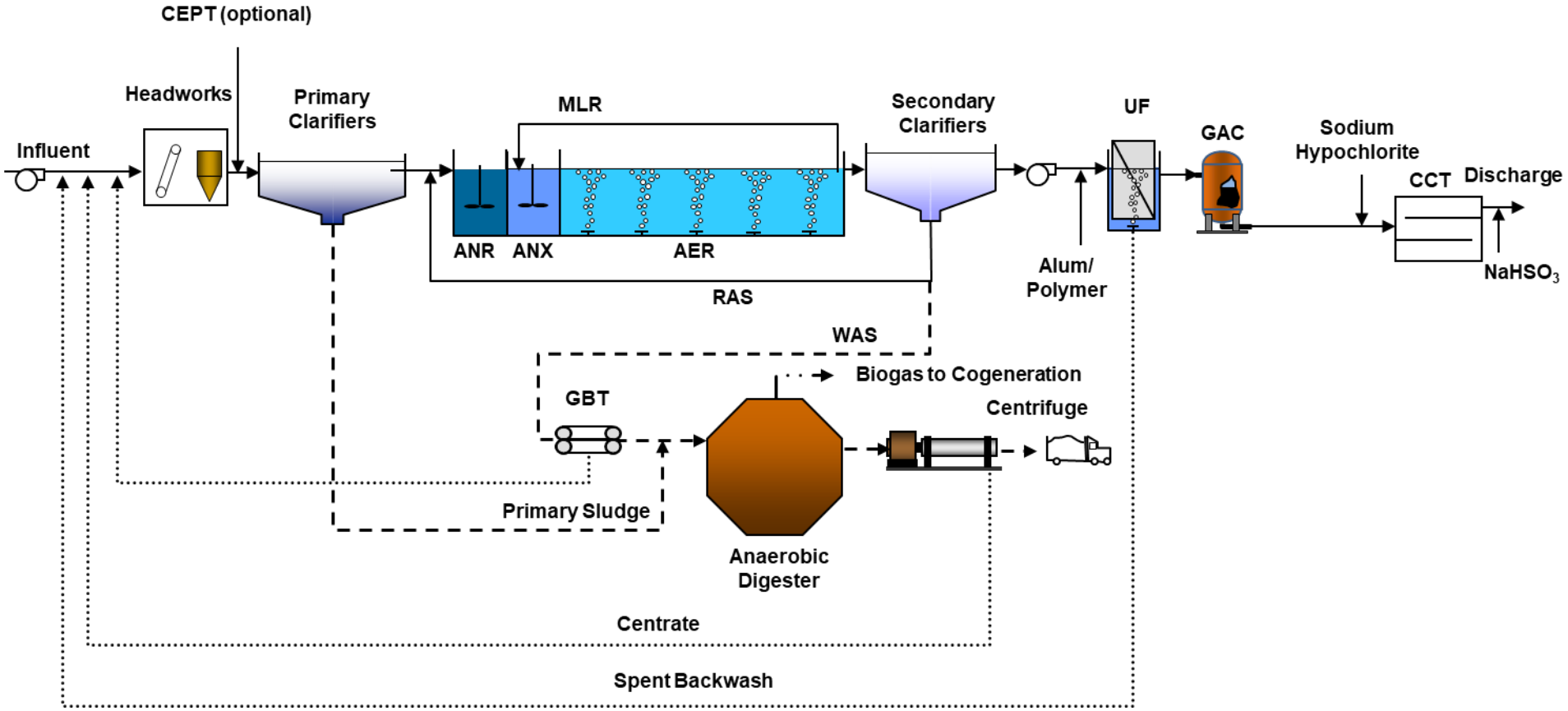

Figure 4-5. Advanced Treatment Flowsheet – Tertiary UF/GAC

4.3.4 Advanced Treatment – Tertiary UF/AOP/GAC

A flowsheet of the advanced treatment Tertiary UF/AOP/GAC alternative is provided in Figure 4-6. Following the UF technology, AOP is used for breakdown of PCBs and BAPs, followed by GAC pressure contactors to remove the remaining contaminants. This alternative was developed in order to focus on further reduction of PCBs and BAPs to levels lower than possible with UF and GAC alone, by breaking down the contaminants and adsorbing the remnants in GAC.

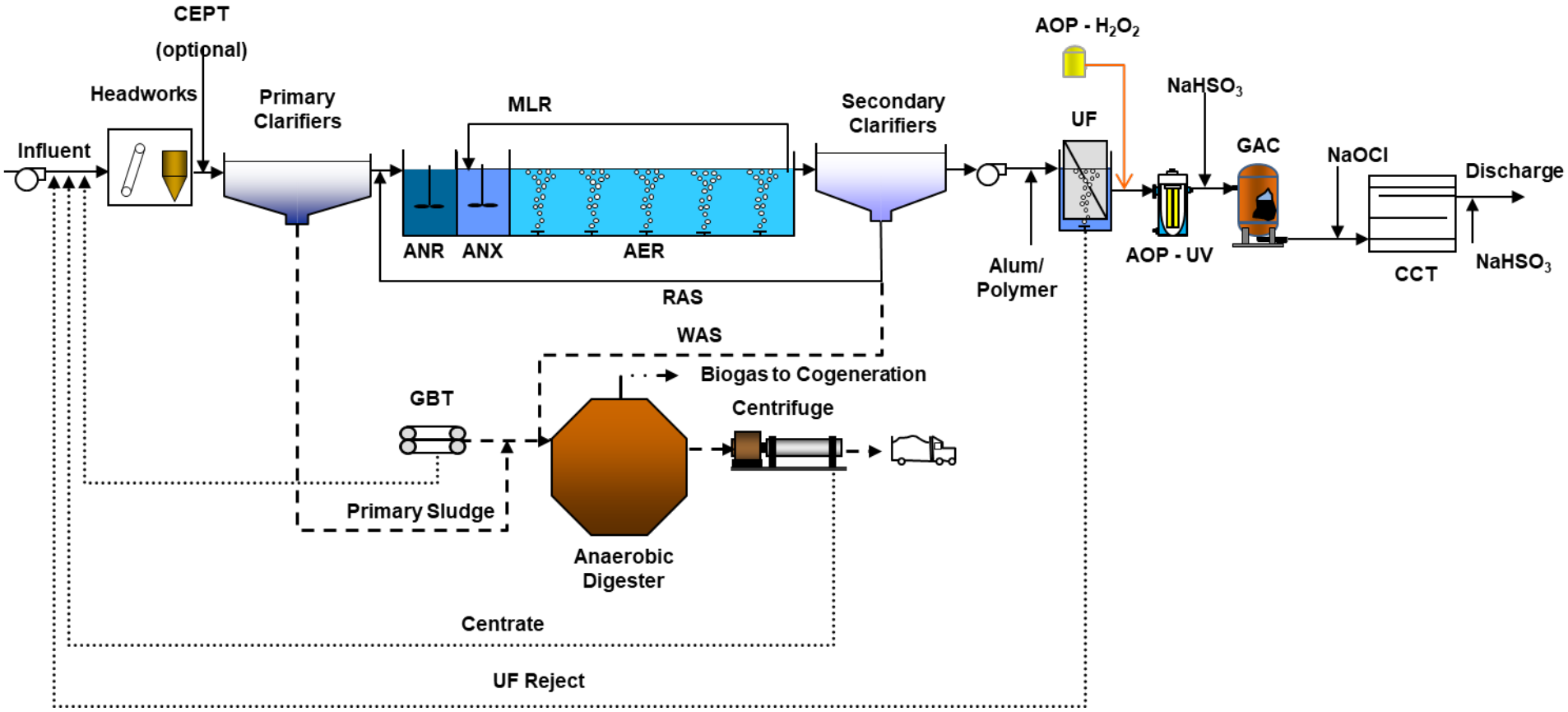

Figure 4-6. Advanced Treatment Flowsheet – Tertiary UF/AOP/GAC

4.3.5 Advanced Treatment – Tertiary UF/AOP/GAC/RO

A flowsheet of the advanced treatment Tertiary UF/AOP/GAC/RO alternative is provided in Figure 4-7. Following the UF technology, AOP is used for breakdown of PCBs and BAPs, followed by GAC pressure contactors to remove the remaining contaminants. RO is added to this process train in order to further reduce all targeted contaminants: Arsenic, BAP, Mercury and PCBs. This alternative was developed in order to reduce PCBs and BAPs to lower levels than possible with UF, AOP and GAC, by breaking down the contaminants and removing them in GAC with further final filtration through RO.

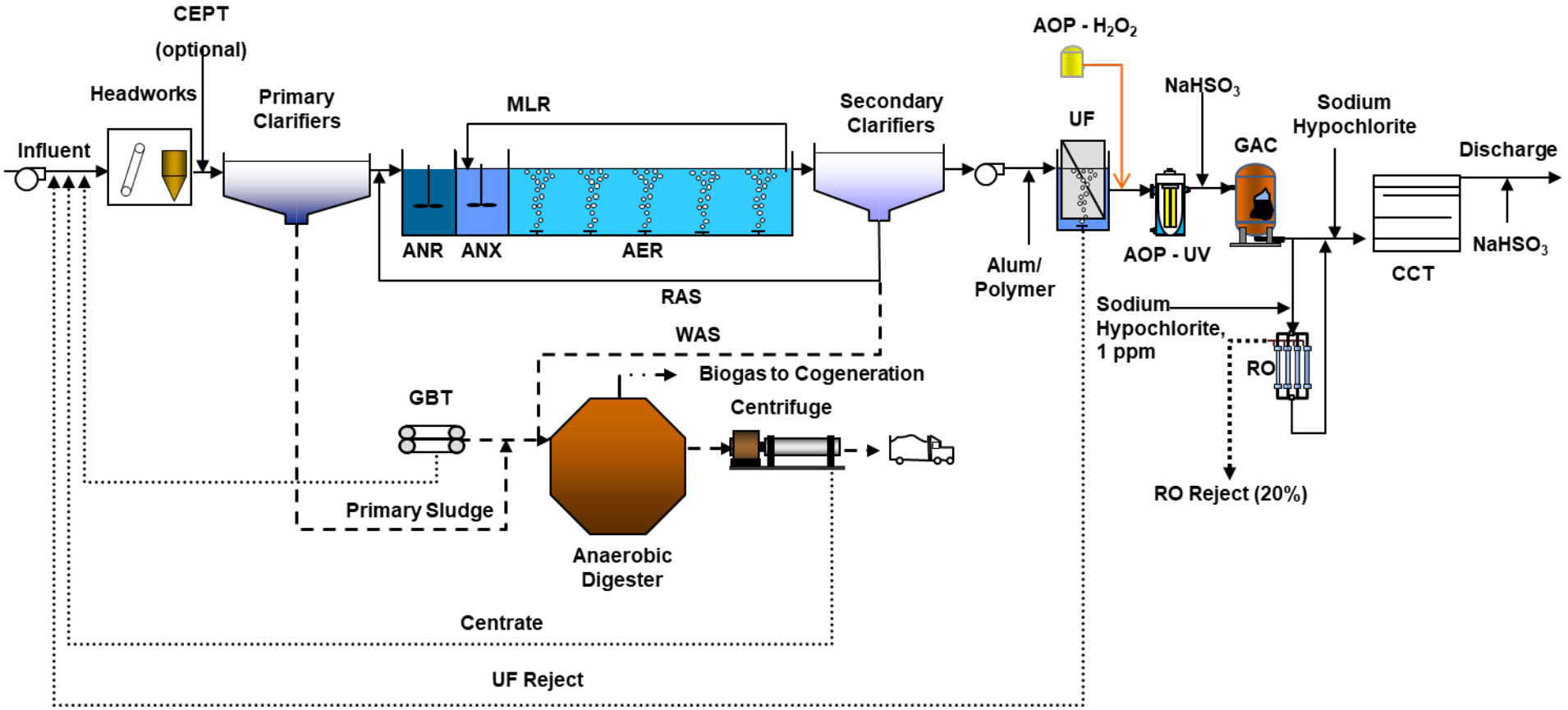

Figure 4-7. Advanced Treatment Flowsheet – Tertiary UF/AOP/GAC/RO

4.4 Steady-State Mass Balance

A steady-state mass balance program was used to calculate the flows and loads within the candidate advanced treatment processes in order to size facilities. The design of wastewater treatment facilities is generally governed by steady-state mass balances. For a steady-state mass balance, the conservation of mass is calculated throughout the entire wastewater treatment facility for defined inputs. Dynamic mass balance programs exist for designing wastewater facilities, but for a planning level study such as this, a steady-state mass balance program is adequate. A dynamic program is generally used for detailed design and is site-specific with associated requirements for more detailed wastewater characterization.

The set of model equations used to perform a steady-state mass balance are referred to as the model. The model equations provide a mathematical description of various wastewater treatment processes, such as an activated sludge process, that can be used to predict unit performance. The program relies on equations for each unit process to determine the flow, load, and concentration entering and leaving each unit process.

An example of how the model calculates the flow, load, and concentration for primary clarifiers is provided below. The steady-state mass balance equation for primary clarifiers has a single input and two outputs as shown in the simplified Figure 4-8. The primary clarifier feed can exit the primary clarifiers as either effluent or sludge. Solids not removed across the primaries leave as primary effluent, whereas solids captured leave as primary sludge. In this example, scum is not accounted for.

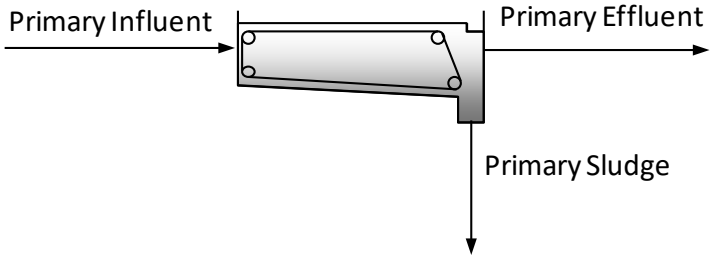

Figure 4-8. Primary Clarifier Inputs/Outputs

The mass balance calculation for a primary clarifier requires the following input:

- Solids' removal percentage across the primaries (based on average industry accepted performance)
- Primary solids thickness (i.e., percent solids) (based on average industry accepted performance)

The steady-state mass balance program provides a reasonable first estimate for the process performance, and an accurate measure of the flows and mass balances at various points throughout the plant. The mass balance results were used for sizing the facility needs for each alternative. A listing of the unit process sizing criterion for each unit process is provided in Appendix A. By listing the unit process sizing criteria, a third-

party user can replicate the analysis and arrive at comparable results. The key sizing criteria that differ between the baseline and treatment alternatives are as follows:

- Aeration basin size for baseline was based on MLSS whereas for advanced treatment alternatives it is based on oxygen uptake rate (OUR).
- The UF/GAC, UF/AOP/GAC, UF/RO and UF/AOP/GAC/RO sizing is only required for the respective advanced treatment alternatives.

4.5 Adverse Environmental Impacts Associated with Advanced Treatment Technologies

The transition from the baseline (conventional secondary treatment) to the advanced treatment alternatives has some environmental impacts that merit consideration, including the following:

- Land area for additional system components (which for constrained facility sites may necessitate land acquisition and encroachment into neighboring properties with associated issues and challenges, etc.).
- Increased energy use and atmospheric emissions of greenhouse gases and criteria air contaminants associated with power generation to meet new pumping requirements across the membrane filter systems (UF and RO) and GAC.
- Increased chemical demand associated with membrane filters (UF and RO).
- Increased chemical demand associated with AOP
- Energy and atmospheric emissions associated with granulated charcoal regeneration.
- RO brine reject disposal. The brine recovery systems are energy intensive and increase atmospheric emissions as a consequence of the electrical power generation required for removing water content from brine reject.
- Increase in sludge generation from transitioning from the baseline to the advanced treatment alternatives. There will be additional sludge captured with the chemical addition to the primaries and membrane filters (UF and RO). Additionally, the GAC units will capture more solids.
- Benefits to receiving water quality by transitioning from a short SRT (<4 days) in the baseline to a long SRT (>8 days) for the advanced treatment alternatives (as previously stated):
    - Lower BOD and TSS discharge loads
    - Higher removal of recalcitrant constituents and heavy metals
    - Improved water quality and benefit to downstream users
    - Reduced nutrient loadings to receiving waters and lower algal growth potential

- Reduced in receiving water body's dissolved oxygen depression due to ammonia removal
- Reduced ammonia discharge loads, which is toxic to aquatic species
- Improved water quality for aquatic habitat, especially as it relates to biodiversity and eutrophication
- Secondary clarifier effluent better conditioned for subsequent filtration and disinfection
- Greater process stability from the anaerobic/anoxic zones serving as biological selectors

GHG emissions were calculated for the baseline and advanced treatment alternatives. The use of GHG emissions is a tool to normalize the role of energy, chemicals, biosolids hauling, and fugitive emissions (e.g., nitrous oxide and methane) in a single unit. The mass balance results were used to quantify energy demand and the corresponding GHG emissions for each alternative. Energy demand was estimated from preliminary process calculations.

A listing of the energy demand for each process stream, the daily energy demand, and the unit energy demand is presented in Table 4-5. The negative energy demand for the solids stream in Table 4-5 represents the recovery of biogas from the anaerobic treatment process and utilization for as fuel for cogeneration of electrical power and heat. The 1,110 kWh/MG treated for the baseline is relatively close to other industry unit energy benchmarks (Gu et al., 2017). An adapted plot from the Gu et al. (2017) study is provided in Figure 4-9, which suggests that a 5 mgd plant with activated sludge requires on the order of 1,500 kWh/MG treated. The difference between the two estimates is likely attributed to a lack of anaerobic digestion and cogeneration for a 5 mgd plant and other miscellaneous differences as captured in the Gu et al. (2017) study. If Gu et al. (2017) study excluded such facilities, the unit energy demand would be on the order of 1,300 kWh/MG treated.

The advanced treatment options energy demand ranges from 2.0 to 2.8 times greater than the baseline. This large increase in energy demand is attributed to the energy required to pass water through the membrane barriers and/or the granular activated carbon. This increase aligns with findings from both Falk et al. (2011) and USEPA (2021) that evaluated various tiers of nutrient levels with the results also suggesting increases 2+ times with the most stringent requiring advanced treatment (e.g., RO). Additionally, there is energy required to handle the constituents removed as either regenerating/disposing of the GAC or handling the RO brine reject water. This additional energy required to treat the removed constituents is presented in Table 4-5.

Details on the assumptions used to convert between energy demand, chemical demand and production, as well as biologically-mediated gases (i.e., CH_4 and N_2O) and GHG emissions are provided in Appendix B.

A plot of the GHG emissions for each alternative is shown in Figure 4-10. The GHG emissions increase from the baseline to progressively higher levels for each of the advanced treatment alternatives. The GHG emissions increase approximately 100

percent with respect to baseline for the UF/GAC alternative process and over 116 percent for the UF/RO alternative.

Table 4-5. Energy Breakdown for Each Alternative (5 mgd design flow)

Parameter	Units	Baseline	Advanced Treatment – Tertiary UF/GAC	Advanced Treatment – Tertiary UF/AOP/GAC	Advanced Treatment – Tertiary UF/RO	Advanced Treatment – Tertiary UF/AOP/ GAC/RO
Daily Liquid Stream Energy Demand	MWh/d	6.5	12.2	12.9	13.0	16.8
Daily Solids Stream Energy Demand[a]	MWh/d	-1.0	-0.9	-0.9	-0.9	-0.9
Daily Energy Demand	MWh/d	5.6	11.3	12.1	12.1	15.9
Unit Energy Demand	kWh/MG Treated	1,100	2,300	2,400	2,400	3,200

[a] The solids stream energy results in a net production of energy from anaerobic digestion cogeneration.

MWh/d = megawatt hours per day
kWh/MG = kilowatt hours per million gallons

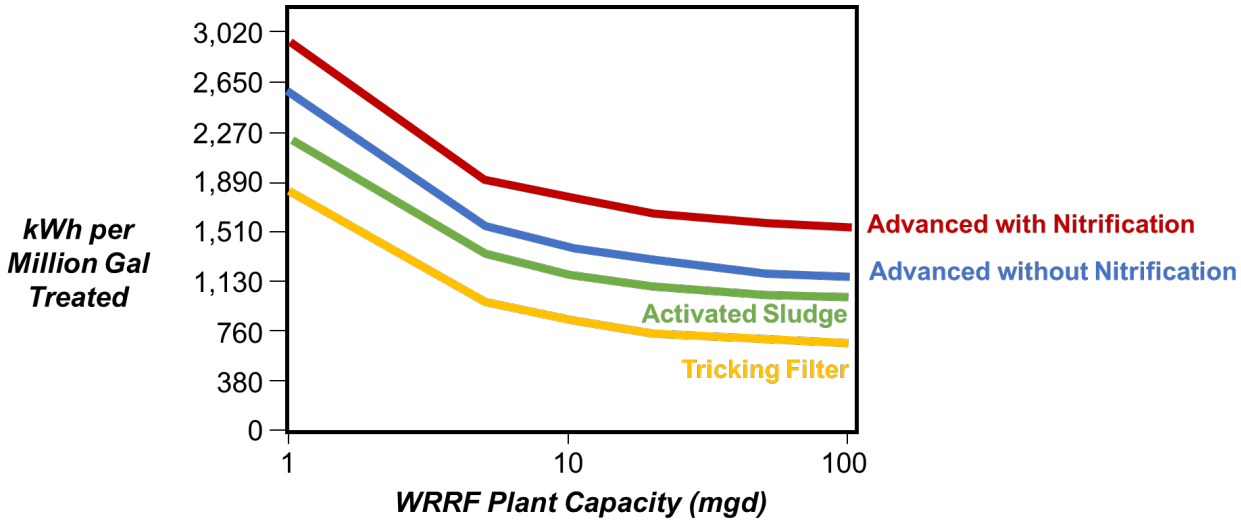

Figure 4-9. Example of an Energy Benchmark (Source: Gu et al., 2017)

The UF/GAC energy demand would be larger if GAC regeneration was performed on-site at the treatment facility versus off-site regeneration/disposal at a vendor's facility located elsewhere. The GHG emissions presented in Figure 4-10 do not include the energy or air emissions that result from off-site GAC regeneration. Only the hauling associated with

transporting the spent GAC is included. The energy associated with operating the spent carbon regeneration furnace would exceed the GHG emissions from hauling spent GAC to a remote site for regeneration.

The BRS liquid discharge portion of GHG emissions alone in the UF/RO and UF/AOP/GAC/RO alternatives are comparable to the baseline level of GHGs. This contribution to increased GHG emissions by the BRS highlights the importance of the challenges associated with managing brine reject.

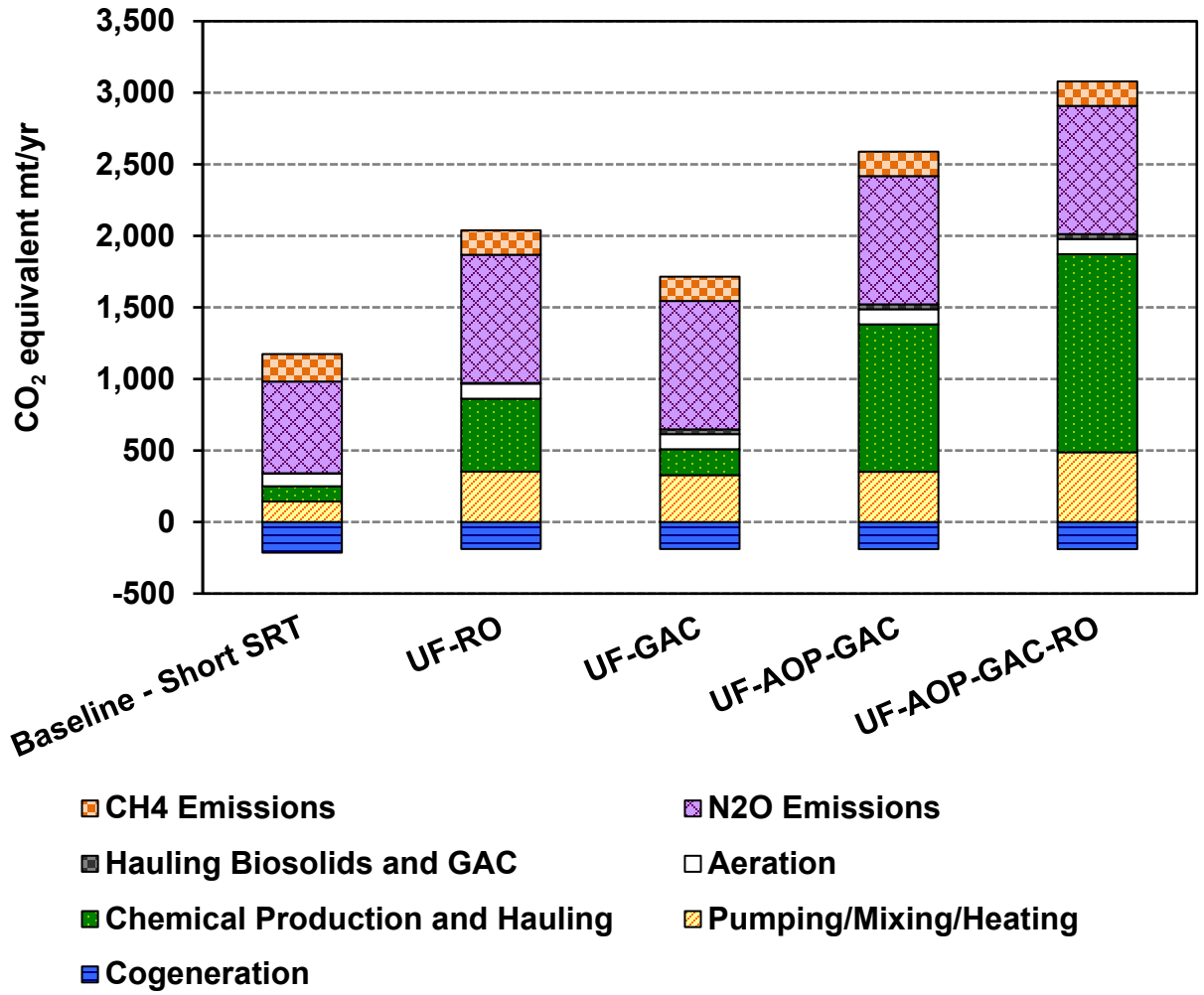

Figure 4-10. Greenhouse Gas Emissions for Each Alternative

The use of GHG emissions as a measure of sustainability does not constitute a complete comparison between the baseline and advanced treatment alternatives. Rather, it is one metric that captures the impacts of energy, chemical demand, and production, as well as biologically mediated gases (i.e., CH_4 and N_2O). The GHG emissions results suggests that careful consideration should be given to the benefits from advanced treatment compared to the potential adverse environmental impacts and economic costs.

An example list of other potential environmental impacts to consider are as follows based on the Tool for the Reduction and Assessment of Chemical and Environmental Impacts (TRACI; Bare et al., 2003; Bare, 2011) as described in a recent EPA publication (EPA, 2021):

- Eutrophication potential
- Cumulative energy demand
- Global warming potential via GHG emissions (as presented in this effort)
- Acidification potential
- Fossil depletion
- Smog formation potential
- Human health – particulate matter formation
- Ozone depletion potential
- Water depletion
- Human health toxicity – cancer potential
- Human health toxicity – noncancer potential
- Ecotoxicity potential

This effort excluded the majority of these considerations since this planning level evaluation focused on the energy and chemical impacts via demands, costs, and GHG emissions. The incorporation of such parameters to inform decision-making might be worthwhile if dischargers are required to move forward with such treatment considerations.

4.6 Costs

Total project costs, along with the operations and maintenance costs, were developed for each advanced treatment alternative for a comparison with baseline secondary treatment.

4.6.1 Approach

The cost estimates presented in this report are planning level opinions of probable construction costs for a nominal 5 mgd treatment plant design flow representing a typical facility without site specific details about local wastewater characteristics, physical site constraints, existing infrastructure, receiving waters, etc. The cost estimates are based on wastewater industry cost references, technical studies, actual project cost histories, and professional experience. The costs presented in this report are considered planning level estimates. A more detailed development of the advanced treatment process alternatives and site-specific information would be required to further refine the cost estimates. Commonly, this is accomplished in the preliminary design phase of project development for specific facilities following planning phases.

The cost opinion includes a range of costs associated with the level of detail used in this analysis. Cost opinions based on preliminary engineering can be expected to follow the Association for the Advancement of Cost Engineering (AACE International) Recommended Practice No. 17R-97 Cost Estimate Classification System estimate Class 5. A Class 5 estimate is based upon a 0 to 2 percent project definition, commensurate with a master plan of concept design. A Class 5 estimate has an expected accuracy range of -35 to 60 percent. It is considered an “order-of-magnitude estimate.” The life-cycle costs were prepared using the net present value (NPV) method.

The cost associated for each new unit process is based on a unit variable, such as required footprint, volume, demand (e.g., lb O_2/hr), and others. This approach is consistent with the approach developed for the EPA document titled “Estimating Water Treatment Costs: Volume 2-Cost Curves Applicable to 1 to 200 mgd Treatment Plants” dated August 1979. The approach has been updated since 1979 to account for inflation and competition, but the philosophy for estimating costs for unit processes has not changed. For example, the aeration system sizing/cost is governed by the maximum month airflow demand. Additionally, the cost associated with constructing an aeration basin is based on the volume. The cost estimates consider economies of scale.

The O&M cost estimates were calculated from preliminary process calculations. The operations cost includes energy, chemical demand, and labor. For example, a chemical dose was assumed based on industry accepted dosing rates and the corresponding annual chemical cost for that chemical. The maintenance cost values account for labor, equipment replacement, and in particular membrane and UV lamp replacement for the advanced treatment alternatives.

4.6.2 Unit Cost Values

The life-cycle cost evaluation was based on using the economic assumptions shown in Table 4-6. The chemical costs were based on actual values from other projects. To perform detailed cost evaluations, each selected technology would need to be arranged on a site-specific facility plan based on the location of the existing piping, channels, and other necessary facilities.

Table 4-6. Economic Evaluation Variables

Item	Value
Nominal Discount Rate	5%
Financial Parameters:	
Base Year	2022
Project Life	20 years
Energy	$0.10/kWh
Natural Gas	$9/1000 ft^3
Chemicals:	
Alum (44-49%)	$0.87/gal
Ferric Chloride	$1,218/ton
Sodium Hypochlorite (12.5%)	$1.4/gal
Sodium Bisulfite (25%)	$1.53/gal
Hydrogen Peroxide (50%)	$2.50/Gal
Anti-Scalant	$2.90/lb
Salt	$0.05/lb
Sulfuric Acid (93%)	$0.05/lb
Caustic (50%)	$0.15/lb
Hauling:	
Biosolids Hauling Distance	100 miles (one way)
Biosolids Truck Volume	6,000 gal/truck
Biosolids Truck Hauling	$100 service fee + $3.50/mile
GAC Virgin Media Cost	$45.51/CF
GAC Exchange Cost (removal, disposal, install new media)	$8.43/CF
kWh= kilowatt hours; lbs=pounds; GAC=granulated activated carbon; gal=gallon	

4.6.3 Net Present Value of Total Project Costs and Operations and Maintenance Cost in 2022 Dollars

An estimate of the net present value for the baseline treatment process and the incremental costs to implement the advanced treatment alternatives is shown in Table . The cost for the existing baseline treatment process was estimated based on new construction for the entire conventional secondary treatment process (Figure 4-3). For comparison with other references, Falk et al. (2011) identified the cost for baseline and advanced treatment with tertiary UF/RO as $12/gpd and $29/gpd respectively for a 10 mgd facility in 2020 dollars. These unit cost values would be expected increase from a 10 to a 5 mgd facility as economies of scale are reduced, resulting in higher costs for the 5 mgd facility. The incremental cost to expand from existing baseline secondary treatment to advanced treatment was calculated by taking the difference between the baseline and the advanced treatment alternatives. These values serve as a benchmark for understanding the prospective cost for constructing advanced treatment at the planning level of process development.

Table 4-7. Treatment Technology Total Project Costs in 2022 Dollars for a 5 mgd Facility

Alternative	Total Construction Cost ($ Million)	O&M Net Present Value ($ Million)**	Total Net Present Value ($ Million)	NPV Unit Cost, ($/gpd)
Baseline (Conventional Secondary Treatment)	72 - 178	8 - 19	80 - 197	16 - 39
Advanced Treatment - UF/RO*				
Baseline (from the top of the table)	72 - 178	8 - 19	80 - 197	16 - 39
Additional Cost (beyond Baseline) for UF/RO*from Baseline	75 - 185	21 - 51	96 - 237	19 - 47
Total Cost (includes Baseline): Advanced Treatment - UF/RO*	148 - 364	29 - 70	176 - 434	35 - 87
Advanced Treatment - UF/GAC				
Baseline (from the top of the table)	72 - 178	8 - 19	80 - 197	16 - 39
Additional Cost (beyond Baseline) for UF/GAC	52 - 128	22 - 54	74 - 182	15 - 36

Alternative	Total Construction Cost ($ Million)	O&M Net Present Value ($ Million)**	Total Net Present Value ($ Million)	NPV Unit Cost, ($/gpd)
Total Cost (includes Baseline): Advanced Treatment - UF/GAC	125 - 307	29 - 72	154 - 379	31 - 76
Advanced Treatment - UF/AOP/GAC				
Baseline (from the top of the table)	72 - 178	8 - 19	80 - 197	16 - 39
Additional Cost (beyond Baseline) for UF/AOP/GAC	66 - 162	31 - 76	97 - 239	19 - 48
Total Cost (includes Baseline): Advanced Treatment - UF/AOP/GAC	138 - 340	39 - 95	177 - 435	35 - 87
Advanced Treatment - UF/AOP/GAC/RO*				
Baseline (from the top of the table)	72 - 178	8 - 19	80 - 197	16 - 39
Additional Cost (beyond Baseline) for UF/AOP/GAC/RO*	117 - 289	47 - 116	164 - 405	33 - 81
Total Cost (includes Baseline): Advanced Treatment - UF/AOP/GAC/RO*	190 - 467	55 - 135	244 - 602	49 - 120

*Assumes BRS for RO brine management, followed by evaporation ponds. Other options are available as listed in Section 4.3.2

**Includes the cost for labor.

mgd=million gallons per day
MG=million gallons
MF/RO=membrane filtration/reverse osmosis
MF/GAC=membrane filtration/granulated activated carbon
O&M=operations and maintenance
Net Present Value = total financed cost assuming a 5 percent nominal discount rate over an assumed 20-year equipment life.

4.6.4 Unit Cost Assessment

Costs presented above are based on a treatment capacity of 5.0 mgd, however, existing treatment facilities range dramatically across Washington in size and flow treated. Table 4-10 indicates that the unit capital cost for baseline conventional secondary treatment for 5 mgd ranges between $16 to $39 per gallon per day of treatment capacity. The unit cost for the advanced treatment alternatives increases the range from the low $30's to $120 on a $/gpd of treatment capacity. The increase in cost for the advanced treatment alternatives is discussed in the sub-sections below.

Advanced Treatment – Tertiary UF/RO

The advanced treatment Tertiary UF/RO alternative has a total NPV unit cost range of $35 to $87 per gallon per day of capacity. This translates to an incremental cost increase with respect to the baseline of $19 to $47 per gallon per day treatment capacity. The key differences in cost between the baseline and the advanced treatment Tertiary UF/RO are as follows:

- Larger aeration basins than the baseline to account for the longer SRT (<4 days versus >8 days).
- Additional pumping stations to pass water through the membrane facilities (UF and RO). These are based on max month flows.
- Equalization Basin.
- Membrane facilities (UF and RO; equipment, tanks chemical feed facilities, pumping, etc.) and replacement membrane equipment.
- Additional energy and chemical demand to operate the membrane facilities (UF and RO).
- Brine Recovery System facilities to further concentrate the brine reject.
- Brine Recovery System facilities are energy/chemically intensive and they require membrane replacement every few years due to the brine reject water quality.
- An evaporation pond to handle the brine reject that has undergone further concentration by the Brine Recovery System.

The advanced treatment Tertiary UF/RO assumes that 100 percent of the flow is treated by UF, followed by 50 percent of the flow treated with RO. Sending a portion of flow through the RO and blending it with the balance of plant flows ensures a stable water (e.g. balanced mineral and chemical content) to discharge to surface waters. The RO brine reject (about 1.0 mgd) undergoes BRS pre-treatment that further concentrates the brine reject to about 0.01 to 0.1 mgd. The recovery for both RO and BRS processes is highly dependent on water quality (e.g., silicate levels).

BRS technologies are effective at concentrating brine reject, but it comes at a substantial cost ($15 per gallon per day at maximum month influent flow (6.25 mgd)). The ability to further concentrate brine reject was critical from a management standpoint. Although 8

different options were presented for managing brine reject in Section 4.3.1, none of them is an attractive approach for handling brine reject except for BRS. BRS provides a viable pre-treatment step that requires subsequent downstream treatment to further reduce volumes. Evaporation ponds following BRS were used for this study. Without BRS, the footprint space requirements would be much greater.

Approximately 4 acres of evaporation ponds, or more, may be required to handle the BRS concentrate, depending upon concentrator effectiveness, local climate conditions, residuals accumulation, residual removal, etc. Precipitation throughout Washington is highly variable, which can greatly influence evaporation pond footprint space requirements.

Past discussions with an industry installing evaporation ponds revealed that they will use mechanical evaporators to enhance evaporation rates. The use of mechanical evaporators was included in this study and the costs are included in the BRS estimates. Since evaporation rates vary in Washington and are low or vary seasonally, the need for mechanical evaporators will depend on facility location.

Advanced Treatment – Tertiary UF/GAC

The advanced treatment Tertiary UF/GAC alternative has a total NPV unit cost range of $31 to $76 per gallon per day capacity. This translates to an incremental cost increase with respect to the baseline of $15 to $36 on a per gallon per day of treatment capacity basis. The key differences in cost between the baseline and the advanced treatment Tertiary UF/GAC are as follows:

- Larger aeration basins than the baseline to account for the longer SRT (<4 days versus >8 days).
- Additional pumping stations to pass water through the UF membrane and GAC facilities. These are based on max month flows.
- Equalization Basin.
- GAC facilities (equipment, pre-engineered pressure contact tanks, pumping, GAC media, etc.)
- Additional energy to feed and backwash the GAC facilities.
- GAC media replacement was the largest contributor of any of the costs.
- Additional hauling and fees to regenerate/dispose of GAC off-site.

The advanced treatment Tertiary UF/GAC assumes that 100 percent of the flow is treated by UF, followed by 100 percent of the flow treated with GAC. The GAC technology is an established technology. The costing approach was in accordance with EPA guidelines developed in 1998.

The critical issue in estimating the cost of the GAC technology is whether a GAC vendor regeneration facility is located within the region. On-site regeneration is an established technology with a furnace, however there are several concerns as listed in Section 4.3.3:

- Ability to obtain an air emissions permit

- Additional equipment to operate and maintain
- Energy and air emissions to operate a furnace on-site
- Operational planning to ensure that furnace is operating 90 to 95 percent of the time. Otherwise, operations will be constantly starting/stopping the furnace which is energy intensive and deleterious to equipment
- If not operated properly, the facility has the potential to create hazardous/toxic waste to be disposed

If located within a couple of hundred miles, off-site GAC regeneration is preferred. For this study, off-site disposal and virgin media replacement was assumed at a cost of $45.51/cf for new media and $8.43/cf for removal, disposal, and installation of the new media.

Advanced Treatment – Tertiary UF/AOP/GAC

The advanced treatment Tertiary UF/AOP/GAC alternative has a total NPV unit cost range of $35 to $87 per gallon per day capacity. This translates to an incremental cost increase with respect to the baseline of $19 to $48 per gallon per day of treatment capacity basis. As this alternative includes a treatment process added on to the UF/GAC option, the key differences between baseline and the UF/GAC option also apply here but are not listed; the following key differences in cost between UF/GAC and UF/AOP/GAC are as follows:

- Additional chemical feed facilities for Hydrogen Peroxide and Sodium Bisulfite
- Enclosed UV reactors, electrical equipment, and additional piping

The advanced treatment Tertiary UF/AOP/GAC assumes that 100 percent of the flow is treated by the UF, AOP and GAC.

Advanced Treatment – Tertiary UF/AOP/GAC/RO

The advanced treatment Tertiary UF/AOP/GAC/RO alternative has a total present worth unit cost range of $49 to $120 per gallon per day capacity. This translates to an incremental cost increase with respect to the baseline of $33 to $81 per gallon per day of treatment capacity basis. As this alternative combines GAC and RO and includes an AOP, the key differences between baseline and the UF/GAC and UF/RO options also apply here but are not listed. The key differences in cost between UF/AOP/GAC and UF/AOP/GAC/RO are as follows:

- Additional pumping stations to pass water through the RO membranes. These are based on maximum month flows.
- RO membrane facilities: equipment, tanks chemical feed facilities, pumping, etc., and replacement membrane equipment.
- Additional energy and chemical demand to operate the RO membranes.
- Brine Recovery System facilities to further concentrate the brine reject.

- Brine Recovery System facilities are energy/chemically intensive and they require membrane replacement every few years due to the brine reject water quality.
- An evaporation pond to handle the brine reject that has undergone further concentration by the Brine Recovery System.

The advanced treatment Tertiary UF/AOP/GAC/RO assumes that 100 percent of the flow is treated by the UF, AOP and GAC, and 50 percent of the flow is treated by the RO and then recombined with the remainder of GAC effluent. Sending a portion of flow through the RO and blending it with the balance of plant flows ensures a stable water to discharge to surface waters. The RO brine reject (about 1.0 mgd) undergoes BRS pre-treatment that further concentrates the brine reject to about 0.01 to 0.1 mgd. The recovery for both RO and BRS processes is highly dependent on water quality (e.g., silicate levels).

Incremental Treatment Cost

The difference in costs between the baseline and the advanced treatment alternatives is listed in Table 4-8. The incremental cost to retrofit the baseline facility to the advanced treatment was calculated by taking the difference between the four alternatives. These values serve as a planning level benchmark for understanding the potential cost for retrofitting a particular facility. However, the actual incremental cost will be unique to a particular facility. Several reasons for the wide range in cost in retrofitting a baseline facility to advanced treatment are summarized as follows:

- Physical plant site constraints. A particular treatment technology may or may not fit within the constraints of a particular plant site. A more expensive technology solution that is more compact may be required. Alternately, land acquisition may be necessary to enlarge a plant site to allow for the addition of advanced treatment facilities. An example of the former is stacking treatment processes vertically to account for footprint space constraints. This is an additional financial burden that would not be captured in the incremental costs presented in Table 4-8. Yard piping. Site specific conditions may prevent the most efficient layout and piping arrangement for an individual facility. This could lead to additional piping and pumping to convey the wastewater through the plant. This is an additional financial burden that would not be captured in the incremental costs presented in Table 4-8.
- Pumping stations. Each facility has a unique hydraulic profile that might require additional pumping stations not captured in this planning level analysis. This is an additional financial burden that would not be captured in the incremental costs presented in Table 4-8.

An assessment was completed to compare costs for facilities with lower capacity (0.5 mgd) as presented in Table 4-8, as well as at a higher capacity (25 mgd) as presented in Table 4-9. It is well-documented that wastewater projects are impacted by economies of scale, whereby the unit costs (e.g., $/gpd) typically decrease as facilities increase in size. To account for such, the capital costs were adjusted based on non-linear scaling equations with scaling exponents. The scaling exponent values were based on HDR

experience. In contrast, O&M costs were adjusted with linear scaling. These two scaled costs were combined to calculate total NPV costs and NPV unit costs.

The NPV unit cost for Baseline treatment for 0.5 mgd ranges between $38 to $93 per gallon per day, and the incremental cost between Baseline and Advanced Treatment ranges from $31 to $168 per gallon per day.

Table 4-8. Treatment Technology Total Project Costs in 2022 Dollars for a 0.5 mgd Facility

Alternative	Total Construction Cost ($ Million)	O&M Net Present Value ($ Million)	Total Net Present Value ($ Million)	NPV Unit Cost ($/gpd)
Baseline (Conventional Secondary Treatment)	18 - 45	1 - 2	19 - 29	38 - 93
Advanced Treatment – Tertiary UF/RO*				
Baseline (from the top of the table)	18 - 45	1 - 2	19 - 29	38 - 93
Additional Cost (beyond Baseline) for UF/RO	19 - 47	2 - 5	21 - 32	42 - 103
Total Cost (includes Baseline): Advanced Treatment - UF/RO*	37 - 91	3 - 7	40 - 61	80 - 197
Advanced Treatment – Tertiary UF/GAC				
Baseline (from the top of the table)	18 - 45	1 - 2	19 - 29	38 - 93
Additional Cost (beyond Baseline) for UF/GAC	13 - 32	2 - 5	15 - 24	31 - 75
Total Cost (includes Baseline): Advanced Treatment - UF/GAC	31 - 77	3 - 7	34 - 53	68 - 169
Advanced Treatment – Tertiary UF/AOP/GAC				
Baseline (from the top of the table)	18 - 45	1 - 2	19 - 29	38 - 93
Additional Cost (beyond Baseline) for UF/AOP/GAC	17 - 41	3 - 8	20 - 30	39 - 97
Total Cost (includes Baseline): Advanced Treatment - UF/AOP/GAC	35 - 86	4 - 10	39 - 59	77 - 190

Alternative	Total Construction Cost ($ Million)	O&M Net Present Value ($ Million)	Total Net Present Value ($ Million)	NPV Unit Cost ($/gpd)
Advanced Treatment – Tertiary UF/AOP/GAC/RO				
Baseline (from the top of the table)	18 - 45	1 - 2	19 - 29	38 - 93
Additional Cost (beyond Baseline) for UF/AOP/GAC/RO	29 - 73	5 - 12	34 - 53	68 - 168
Total Cost (includes Baseline): Advanced Treatment - UF/AOP/GAC/RO	48 - 117	5 - 13	53 - 82	106 - 262
* Assumes Brine Recovery System for RO brine management, followed by evaporation ponds. Other options are available as listed in Section 4.3.2.				

The NPV unit cost for Baseline treatment for 25 mgd ranges between $9 to $22 per gallon per day and the incremental cost between Baseline and Advanced Treatment ranges from $18 to $74 per gallon per day.

The larger 25 mgd plant is not as expensive on a unit cost basis ($/gpd) of treatment capacity. This dissimilarity in the unit costs ($/gpd) between the 0.5 and 25 mgd of treatment capacity is attributed to economies of scale. Cost curve comparisons (potential total construction cost and total net present value) for the baseline and the four tertiary treatment options (UF/RO, UF/GAC, UF/AOP/GAC and UF/AOP/GAC/RO) are shown in Figure 4-11 and Figure 4-12. It is important to note that while the economies of scale suggest lower incremental costs for the larger size facilities, some aspects of the advanced treatment processes may become infeasible at larger capacities due to factors such as physical space limitations and the large size requirements for components such as RO reject brine management.

Table 4-9. Treatment Technology Total Project Costs in 2022 Dollars for a 25 mgd Facility

Alternative	Total Construction Cost ($ Million)	O&M Net Present Value ($ Million)	Total Net Present Value ($ Million)	NPV Unit Cost ($/gpd)
Baseline (Conventional Secondary Treatment)	190 - 468	38 - 94	228 - 351	9 - 22
Advanced Treatment – Tertiary UF/RO*				
Baseline (from the top of the table)	190 - 468	38 - 94	228 - 351	9 - 22

Alternative	Total Construction Cost ($ Million)	O&M Net Present Value ($ Million)	Total Net Present Value ($ Million)	NPV Unit Cost ($/gpd)
Additional Cost (beyond Baseline) for UF/RO	370 - 910	142 - 349	512 - 787	20 - 50
Total Cost (includes Baseline): Advanced Treatment - UF/RO*	388 - 955	143 - 351	530 - 816	21 - 52
Advanced Treatment – Tertiary UF/GAC				
Baseline (from the top of the table)	190 - 468	38 - 94	228 - 351	9 - 22
Additional Cost (beyond Baseline) for UF/GAC	309 - 761	146 - 359	455 - 700	18 - 45
Total Cost (includes Baseline): Advanced Treatment - UF/GAC	327 - 805	147 - 361	474 - 729	19 - 47
Advanced Treatment – Tertiary UF/AOP/GAC				
Baseline (from the top of the table)	190 - 468	38 - 94	228 - 351	9 - 22
Additional Cost (beyond Baseline) for UF/AOP/GAC	345 - 849	192 - 473	537 - 827	21 - 53
Total Cost (includes Baseline): Advanced Treatment - UF/AOP/GAC	363 - 894	193 - 475	556 - 856	22 - 55
Advanced Treatment – Tertiary UF/AOP/GAC/RO				
Baseline (from the top of the table)	190 - 468	38 - 94	228 - 351	9 - 22
Additional Cost (beyond Baseline) for UF/AOP/GAC/RO	480 – 1,182	273 - 672	753 – 1,159	30 - 74
Total Cost (includes Baseline): Advanced Treatment - UF/AOP/GAC/RO	498 – 1,226	274 - 674	772 – 1,188	31 - 76

* Assumes Brine Recovery System for RO brine management, followed by evaporation ponds. Other options are available as listed in Section 4.3.2.

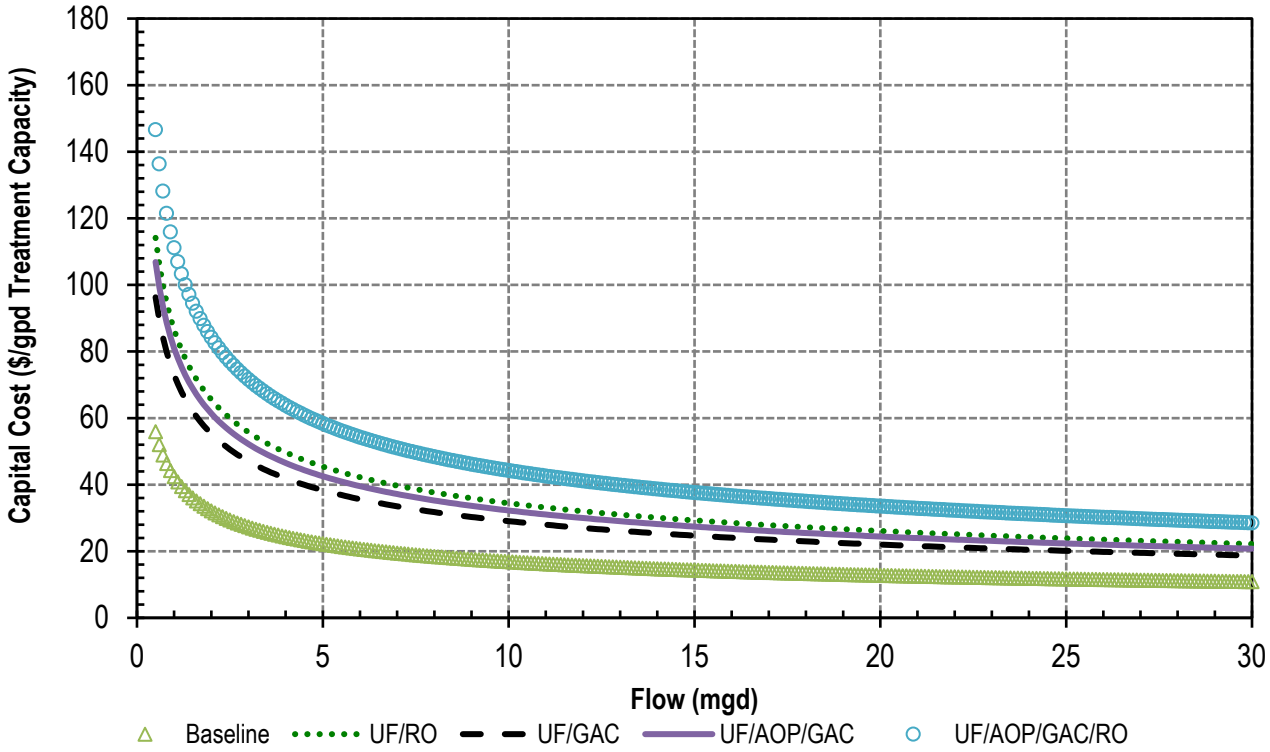

Figure 4-11. Capital Cost Curve Comparison for Baseline Treatment, UF/RO, UF/GAC, UF/AOP/GAC, and UF/AOP/GAC/RO

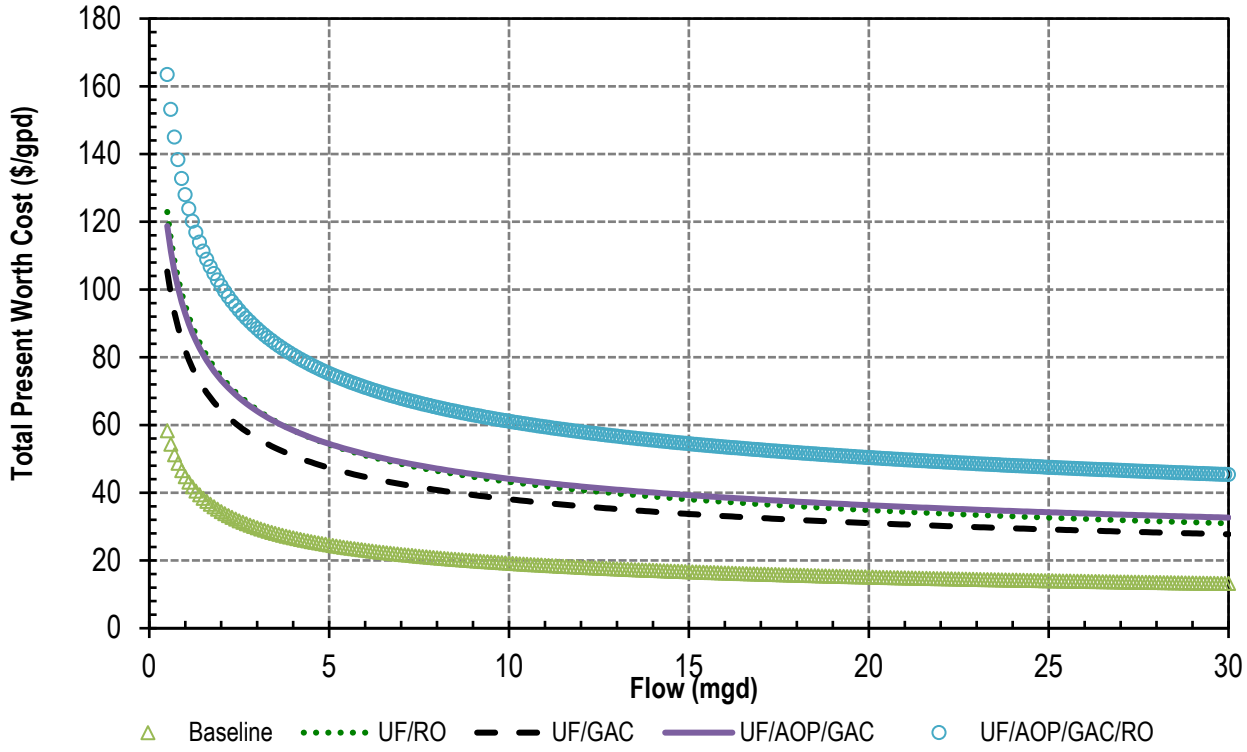

Figure 4-12. NPV Cost Curve Comparison for Baseline Treatment, UF/RO, UF/GAC, UF/AOP/GAC, and UF/AOP/GAC/RO

4.7 Pollutant Mass Removal

An estimate of the projected mass load reduction for the four constituents of concern was developed and is presented in Table 4-10. The current secondary effluent and advanced treatment effluent data is based on the information available from municipal treatment plant facilities. Effluent data is limited for advanced treatment facilities such as UF/RO, UF/GAC, UF/AOP/GAC and UF/AOP/GAC/RO at concentrations as low as the human health water quality criteria for Washington. Due to this lack of effluent performance data, advanced treatment was assumed to remove an additional 50 to 95 percent of the constituents, resulting in the range of potential effluent concentration values presented in Table 4-10. It is important to note that these estimates are based on limited data and are presented here simply for the purpose of quantifying potential mass removals. Current secondary effluent for industrial facilities would likely be greater than the data presented here for municipal wastewater facilities. As a result, the projected effluent concentrations and loads for industrial facilities would likely be higher.

Table 4-10. Pollutant Mass Removal by Contaminant for a 5 mgd Facility

Component	Arsenic	BAP	Mercury	PCBs
Required HHWQC based Effluent Quality (µg/L)	0.018	0.000016	0.0005	0.000007
Current Secondary Effluent Concentration (µg/L)*	5	0.006	0.025	0.002
Projected Effluent Quality (µg/L) from Advanced Treatment*	0.25 - 2.5	0.0003 - 0.003	0.00125 - 0.0125	0.0001 - 0.001
Mass Removed (mg/d)**	47,300 – 89,930	57 – 108	240 - 450	19 – 36
Mass Removed (lb/d)**	0.104-0.198	0.00013 – 0.00024	0.00052 – 0.00099	0.00004 – 0.00008

* Estimated at 50-95 percent removal of Current Secondary Effluent Concentration.
** 1 lb = 454,000 mg
HHWQC=human health-based water quality criteria
MF/RO=membrane filtration/reverse osmosis
MF/GAC=membrane filtration/granulated activated carbon
µg/L=micrograms per liter
mg/d=milligrams per day
lb/d=pounds per day

Unit costs were developed based on required mass removal from a 5 mgd facility for each of the four constituents of concern to reduce discharges from current secondary effluent quality to the assumed required effluent quality (HHWQC). It important to note that this study concludes it is unclear if existing technology can meet the required effluent quality, however, the information presented in Table 4-11 assumes HHWQC would be met for developing unit costs and uses the costs for UF/RO as an example. The unit

costs are expressed as dollars in NPV (over a 20-year period) per pound of constituent removed over the same 20-year period as seen in the equation below:

$$(Current\ Secondary\ Effluent\ Concentration - Required\ HHWQC\ based\ Effluent\ Quality) * 8.34 * 5\ mgd * 365\ days * 20\ years$$

The current secondary effluent quality data presented are based on typical secondary effluent quality expected for a municipal/industrial discharger. Table 4-11 suggests unit costs are most significant in meeting the PCB, BAP, and mercury required effluent quality.

Table 4-11. Unit Cost by Contaminant for a 5 mgd Facility Implementing Advanced Treatment using UF/RO

Component	Arsenic	BAPs	Mercury	PCBs
Required HHWQC based Effluent Quality (µg/L)	0.018	0.000016	0.0005	0.000007
Current Secondary Effluent Concentration (µg/L)*	5	0.006	0.025	0.002
Total Mass Removed (lb) over 20-year Period**	1,517	1.82	7.5	0.61
Unit Cost (NPV $/lb removed over 20-years)**	$201,000	$170,000,000	$41,000,000	$500,000,000

* Derived from data presented in Table 4-10.
** 20-year NPV of $305,000,000, the average of the range presented in Table 4-7 for advanced treatment using UF/RO.
NPV=net present value
HHWQC=human health-based water quality criteria
µg/l=micrograms per liter

4.8 Sensitivity Analysis

The ability of dischargers to meet a HHWQC one order of magnitude less stringent than the HHWQC presented in Table 2-1 was considered. The same advanced treatment technologies using UF/RO, UF/GAC, UF/AOP/GAC, or UF/AOP/GAC/RO would be applied to meet revised effluent quality one order-of-magnitude less stringent. Based on available data for estimated effluent quality, it appears the arsenic and mercury limits may be met at a less stringent HHWQC, depending upon how effluent limits were structured in discharge permits. Compliance may be feasible with effluent limits based on long term average mass loadings, while successful compliance with maximum day concentration limits is unlikely. Compliance with one order-of-magnitude less stringent BAP and PCB concentration limits would still be unlikely. It is important to note that a discharger's ability to meet these less stringent limits depends on existing secondary effluent characteristics and is facility specific. Facilities with higher secondary effluent constituent concentrations will have greater difficulty meeting HHWQC.

5 Summary and Conclusions

This study evaluated treatment technologies potentially capable of meeting revised effluent discharge limits associated with revised HHWQC. A literature review of potential technologies was conducted to evaluate and screen treatment methods for meeting revised effluent limits for four constituents of concern: arsenic, BAP, mercury, and PCBs. Four alternatives were selected to compare against a secondary treatment baseline, including enhanced secondary treatment with UF/RO, UF/GAC, UF/AOP/GAC, or UF/AOP/GAC/RO. Capital and operating costs were estimated, and a net present value (NPV) was calculated for each alternative, including the incremental cost to add advanced treatment to an existing secondary treatment facility.

The following conclusions can be made from this study.

- Revised HHWQC based on EPA's proposed Human Health Criteria for Washington (Federal Register 2022) will result in very low water quality criteria for toxic constituents.
- There are limited "proven" technologies available for dischargers to meet all required effluent quality limits that would be derived from revised HHWQC.
- Current secondary wastewater treatment facilities provide high degrees of removal for toxic constituents; however, they will not be capable of compliance with all water quality-based NPDES permit effluent limits derived from EPA's proposed HHWQC for Washington.
- Advanced treatment technologies have been investigated and candidate process trains have been conceptualized for toxics removal.
- Advanced wastewater treatment technologies may enhance toxics removal rates; however, they will not be capable of compliance with HHWQC based effluent limit for PCBs. The lowest levels achieved based on the literature review were between <0.00001 and 0.0002 µg/L, two orders-of-magnitude greater than the proposed HHWQC of 0.000007 µg/L.
- Compliance with a HHWQC for arsenic of 0.018 µg/L is questionable, even for the most elaborate treatment process trains, because little performance data is available from facilities operating at these low concentrations. Most treatment technology performance information available in the literature is based on drinking water treatment applications targeting a much higher Safe Drinking Water Act (SDWA) Maximum Contaminant Level (MCL) of 10 µg/L. Data from a confidential demonstration project using UF/RO/AOP shows performance to the same order-of-magnitude at <0.036 µg/L versus the proposed HHWQC 0.018 µg/L. It is possible this demonstration project is producing effluent near proposed HHWQC for arsenic.
- Compliance with EPA's proposed methylmercury tissue concentration criteria of 0.03 mg/kg appears unlikely. The range of potential water column concentrations for methylmercury associated with EPA's proposed 0.03 mg/kg tissue

concentration are lower than the approved analytical methods in 40 CFR part 136 for Method 1631E with a quantitation level of 0.0005 µg/L. Consequently, treatment facilities would need to target non-detectable levels of effluent methylmercury less than 0.0005 µg/L.

- Little information is available to assess the potential for advanced technologies to comply with revised BAP criteria, but compliance appears unlikely. A municipal wastewater treatment plant study reported both influent and effluent BAP concentrations of <0.0057 µg/L, two orders-of-magnitude greater than the proposed HHWQC of 0.000016 µg/L (Ecology, 2010).
    - Some technologies may be effective at treating identified constituents of concern to meet revised limits while others may not. It is therefore even more challenging to identify a technology that can meet all constituent limits simultaneously. Multiple technologies paired together may be necessary.
    - A HHWQC that is one order-of-magnitude less stringent might be satisfied for arsenic and mercury, however compliance with less-stringent BAP and PCB limits would still be unlikely.
- Advanced treatment processes incur significant capital and operating costs.
    - Advanced treatment processes to remove additional arsenic, BAP, mercury, and PCBs would combine enhancements to secondary treatment with ultrafiltration membranes, an advanced oxidation process, reverse osmosis or granular activated carbon and increase the estimated capital cost of treatment from $16 to $39 to up to $31 to $120 $/gpd of treatment capacity (based on a 5.0-million-gallon-per-day (mgd) facility).
    - The operation and maintenance NPV costs for the advanced treatment process train will be substantially higher, between $29 and $135 million versus $8 to $19 million, over 20 years.
- Implementation of additional treatment will result in additional collateral impacts including:
    - High energy consumption.
    - Increased greenhouse gas emissions.
    - Increase in solids production from chemical addition to the primaries. Additionally, the membrane and GAC facilities will capture more solids that require processing and utilization or disposal.
    - Increased physical space requirements at treatment plant sites for advanced treatment facilities and residuals management, including reverse osmosis reject brine processing.
- It appears advanced treatment technology alone would not be capable of compliance with potential water quality based effluent limits resulting from the proposed HHWQC and that alternative compliance tools, such as variances, would be necessary for discharger compliance.

- Implementation flexibility will be necessary to reconcile the difference between the capabilities of treatment processes and the potential for HHWQC driven water quality based effluent limits to be lower than attainable with current technology.

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7 Appendices

Appendix A - Unit Process Sizing Criteria

Appendix B - Greenhouse Gas Emissions Calculation Assumptions

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Appendix A. Unit Process Sizing Criteria

Table A-1. Unit Processes Sizing Criteria for Each Alternative

Unit Process	Units	Baseline Treatment	Advanced Treatment	Comment
Influent Pumping Station	mgd	15	15	Sized for Peak Hour Flow
Screening	mgd	15	15	Sized for Peak Hour Flow
Grit	mgd	15	15	Sized for Peak Hour Flow
Ferric Dose for CEPT (optional)	mg/L	20	20	This is the metal salt upstream of the primaries
Primary Clarifiers	gpd/sf	1,000/2000	1,000/2000	1,000 is for Average Annual; 2,000 is for Peak Hour. Peak Hour controls for the flows in this report
Primary Solids Pumping Station	mgd	6.25	6.25	Sized for the solids produced from clarifiers at an influent Maximum Month Flow (6.25 mgd)
Aeration System Oxygen Uptake Rate (OUR)	mg/L/hr	30	30	Average annual OUR is used in tandem with mixed liquor to determine the required aeration basin volume (the limiting parameter governs the activated sludge basin volume)
Aeration Basin Mixed Liquor	mg/L	1,250	2,500	Average annual mixed liquor is used in tandem with OUR (see previous row) to determine the required aeration basin volume (the limiting parameter governs the activated sludge basin volume)
Secondary Clarifiers Hydraulic Loading	gpd/sf	1200	1200	Applied to Peak Hour Flow, as clarifiers governed by hydraulic loading rate
Return Activated Sludge (RAS) Pumping Station	mgd	6.25	6.25	RAS must have capacity to meet 100% influent Max Month Flow
Waste Activated Sludge (WAS) Pumping Station	mgd	6.25	6.25	Sized for the solids produced from clarifiers at the Maximum Month Flow (6.25 mgd)
Flow Equalization Tank	mgd	--	6.25	EQ tank sized to trim any flow between Max Month Flow (6.25 mgd) and Peak hour flow (15 mgd) down to Max month flow
Alum Addition pre UF	mg/L	--	20	at Average Annual Flow
Ultrafiltration (UF) Flux	gallon per square foot per day (gfd)	--	25	At Average annual Flow
Pre-RO Chlorine Feed	mg/L	--	1	At Maximum Month Flow

Unit Process	Units	Baseline Treatment	Advanced Treatment	Comment
Reverse Osmosis (RO)	gallon per square foot per day (gfd)	--	10	At Average Annual Flow
RO Reject	%	--	20	This represents the percentage of feed flow that is rejected as brine and used to size the Brine Recovery System
GAC Pump Station	mgd	--	6.25	Sized for Maximum Month Flow
GAC Pressure Filters	Empty Bed Contact Time (minutes)	--	25	
GAC Pressure Filters	mgd	--	6.25	Sized for Maximum Month Flow
GAC Spent Media Storage	MG	--	Volume of Filters	Equal to the volume of all filters
GAC Virgin Media Storage	MG	--	Volume of Filters	Equal to the volume of all filters
Chlorination Dose	mg/L	10	10	At Peak Hour Flow (15 mgd)
Chlorination Storage Capacity	days	14	14	At Average Annual Conditions
Chlorine Contact Tank	min	15	15	This is for Peak Hour conditions.
Dechlorination Dose	mg/L	10	10	At Peak Hour Flow (15 mgd)
Dechlorination Storage Capacity	days	14	14	At Average Annual Conditions
Gravity Thickener	mgd	6.25	6.25	Sized for the WAS Flow from Secondary clarifiers at Maximum Month Flow (6.25 mgd)
Sludge Holding Tank	days	2	2	Sized for total sludge flow from Primary and Secondary Clarifiers at Max Month Flow (6.25 mgd)
Anaerobic Digestion	Hydraulic residence time (HRT days)	18	18	This is for average annual conditions
Dewatering Centrifuge	gpm	12	13	Sized based on solids produced from Anaerobic Digestion at Maximum Month Flows

gpd=gallons per day; sf=square feet; gpm=gallons per minute

Appendix B. Greenhouse Gas Emissions Calculation Assumptions

The steady state mass balance results were used to calculate GHG emissions. The assumptions used to convert between energy demand, chemical demand and production, as well as biologically-mediated gases (i.e., CH4 and N2O) and GHG emissions are provided in Table B-1. Methane and nitrous oxide emissions are included as they are thought to dominate direct carbon footprint emissions from wastewater treatment plants (Valkova et al., 2021). The assumptions are based on EPA (2020) values for energy production, the latest monitoring trends on N2O emissions (Valkova et al., 2021), Intergovernmental Panel on Climate Change (IPCC) (2006; 2013; 2019) for conversions and fugitive CH4 emissions, and various resources for chemical production and hauling from production to the wastewater treatment plant (WWTP). N2O emissions benchmarking in wastewater is hindered by non-standard reporting (Vasilaki et al, 2019). Rather than rely on theoretical methods, data from on-site N2O measurements was used (Valkova et al., 2021). While there is more confidence in the data for on-site measurements, this is an area with potential for considerable variability from plant to plant as the on-site data measurements is limited. The data collected to date suggests that N2O emissions potential is inversely related to total nitrogen load reduction across the treatment plant. Additionally, the biogas produced during anaerobic digestion that is used as a fuel source is converted to energy with MOP8 (WEF 2009) recommended waste-to-energy values.

Table B-1. Greenhouse Gas Emissions Assumptions

Parameters	Units	Value	Source
N_2O to CO_2 Conversion	lb CO_2/lb N_2O	265	IPCC, 2013
CH_4 to CO_2 Conversion	lb CO_2/lb CH_4	28	IPCC, 2013
Energy Production			
CO_2	lb CO_2/MWh	211.9	USEPA (2020)
N_2O	lb N_2O/MWh	0.003	USEPA (2020)
CH_4	lb CO_2/MWh	0.020	USEPA (2020)
Sum Energy Production	lb CO_2/MWh	213.3	USEPA (2020)
GHGs per BTU Natural Gas			
CO_2	lb CO_2/MMBTU Natural Gas	117	USEPA (2014)
N_2O	lb N_2O/MMBTU Natural Gas	0.0002	USEPA (2014)
CH_4	lb CH_4/MMBTU Natural Gas	0.0022	USEPA (2014)
Sum Natural Gas	lb CO_2/MMBTU Natural Gas	117.1	USEPA (2014)

Parameters	Units	Value	Source
Non-BNR N_2O Emissions	% Mass N_2O/ Mass influent Total Nitrogen	1.4%	Valkova et al. (2021)
BNR N_2O Emissions	% Mass N_2O/ Mass influent Total Nitrogen	1.0%	Valkova et al. (2021)
CH_4 Emissions (from Liquid Stream; excludes digestion)	g CH4/g BOD	0.03	IPCC (2019)
Biogas Purity	% Methane	65	WEF, 2009
Biogas to Energy	BTU/cf CH4	550	WEF, 2009
Digester Gas to Electrical Energy Transfer Efficiency	%	32	HDR Data
Chemical Production			
Alum	lb CO_2/lb Alum	0.28	SimaPro 6.0 - BUWAL250, Eco-indicator 95
Polymer	lb CO_2/lb Polymer	1.18	Owen (1982)
Sodium Hypochlorite	lb CO_2/lb Sodium Hypochlorite	1.07	Owen (1982)
Sodium Bisulfite	lb CO2/lb Sodium Bisulfite	1.19	City of Winnipeg (2012)
Hydrogen Peroxide	lb CO2/lb Hydrogen Peroxide	1.19	USEPA (2017)
Building Energy Efficiency	kBTU/sf/yr	62	Median for the various listed buildings (Energy Star (2021))
Hauling Distance		-	
Local	miles	100	-
Hauling Emissions			
Fuel Efficiency	miles per gallon	8	
CO_2	kg CO_2/gal diesel	10.2	CA Climate Action Registry Reporting Tool (2008)
N_2O	kg N_2O/gal diesel	0.0001	CA Climate Action Registry Reporting Tool (2008)
CH_4	kg CH_4/gal diesel	0.003	CA Climate Action Registry Reporting Tool (2008)
Sum Hauling Fuel	kg CO_2/gal diesel	10.2	CA Climate Action Registry Reporting Tool (2008)

GWh = Giga Watt Hours

MWh = Mega Watt Hours
MMBTU = Million British Thermal Units
BTU = British Thermal Unit
PE = Population Equivalents
kBTU/sf/yr = 1,000 British Thermal Units per Square Foot per Year
cf = cubic feet
lb = pound
kg = kilogram
gal = gallon

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COMMENTS ON BEHALF OF

THE NORTHWEST PULP & PAPER ASSOCIATION,
AMERICAN FOREST & PAPER ASSOCIATION,
WASHINGTON FARM BUREAU,
ASSOCIATION OF WASHINGTON BUSINESS,
WESTERN STATES PETROLEUM ASSOCIATION,
WESTERN WOOD PRESERVERS INSTITUTE,
TREATED WOOD COUNCIL,
INLAND EMPIRE PAPER COMPANY,
NIPPON DYNAWAVE PACKAGING,
PACKAGING CORPORATION OF AMERICA,
PORT TOWNSEND PAPER COMPANY, AND
GREATER SPOKANE, INC.

ON THE EPA PROPOSED HUMAN HEALTH WATER QUALITY CRITERIA FOR THE STATE OF WASHINGTON, 87 Fed. Reg. 19046 (April 1, 2022)

Docket ID No. EPA-HQ-OW-2015-0174

May 31, 2022

Prepared by James Tupper and Lynne Cohee, Tupper Mack Wells PLLC

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The Northwest Pulp & Paper Association, American Forest & Paper Association, Washington Farm Bureau, Association of Washington Business, Western States Petroleum Association, Western Wood Preservers Institute, Treated Wood Council, Inland Empire Paper Company, Nippon Dynawave Packaging, Packaging Corporation of America, Port Townsend Paper Company, and Greater Spokane, Inc. submit the following comments on the Environmental Protection Agency (EPA) proposed revision to certain federal water quality criteria applicable to the State of Washington announced in 87 Fed. Reg. 19046 (April 1, 2022).

These comments include the attachments identified in the table of contents as well as the documents contained in the Supporting Documents Files submitted with these comments. Documents in the Supporting Documents File are identified by page number within parentheses in footnote citations. We request that the comment letter, attachments, and Supporting Documents File be included in the rulemaking docket.

Introduction

Maintaining and improving water quality in the state of Washington is our shared goal. We support sustainable water quality standards that result in cleaner water, preserve aquatic life, and protect human health. To be effective in reaching these goals, the adopted standards must be based on accurate and complete data, recognized scientific principles, and prudent risk management calculations. Most of all, water quality standards must reflect the important balance between protection and attainability to justify significant public and private investments necessary to meet the standards.

Unfortunately, EPA's proposed human health water quality criteria (HHWQC) fail to meet these principles for sustainable regulation. If adopted, the resulting standards will be completely unattainable even with cost-prohibitive water treatment technologies.

It is important to recognize the unintended consequences of the proposed rule. Faced with the inability to meet an unattainable standard and the resulting permit uncertainty, employers are less likely to invest in newer water treatment technologies or other upgrades to modernize and expand their operations. This lack of investment will put at risk important family-wage jobs, including union jobs and those bringing critical economic activity to rural areas.

Similarly, local governments across Washington state will be required to invest untold millions of dollars in new technology even though these investments will not result in compliance with the EPA standards. Those costs will have to be passed on to the citizens of the state in the form of higher utility and tax rates at a time when many are already facing economic challenges. This added burden would compound the skyrocketing cost of living for Washingtonians due to record inflation driving up the costs of housing, food, fuel, and other essentials. These burdens will fall heaviest on the citizens of our state who can least afford another increase in their costs of living.

EPA's proposal to impose unattainable water quality standards stands in contrast to the thorough rulemaking process employed by the State of Washington Department of Ecology (Ecology) when it adopted state water quality standards in 2016. Those state standards, among the most restrictive human health criteria ever adopted under the Clean Water Act (CWA), were based on years of work by Ecology with all stakeholders, a deep consideration of the available

science, and conscientious risk management determinations. In announcing these 2016 standards, Washington state officials voiced justifiable pride in the thorough process used by Ecology and the resulting protections the standards would afford the people of Washington.

For example, in a November 15, 2016, statement issued by Ecology, then-director Maia Bellon publicly expressed disappointment with EPA's rejection of the state HHWQC proposal:

We're disappointed that Washington state's approach wasn't accepted in its entirety. We worked hard to craft new water quality standards that were balanced and made real progress – improving environmental protection and human health while helping businesses and local governments comply.

We were always clear in our goal –to meet EPA's requirements and tailor our proposal to work for Washington state. We believe we did that with the clean water standards we adopted…[1].

As members of Washington's regulated community, we have consistently maintained our commitment to improving water quality. We recognized that while these standards were some of the most protective standards adopted by any state in the nation, they provided a legitimate, if challenging, path to compliance.

In 2016, EPA rejected the state-adopted standards and replaced them with its own, more restrictive, and unattainable standards, which we viewed as arbitrary and capricious. We filed our 2017 petition for rulemaking and reconsideration in the hope of advancing sustainable regulations that balance protection and attainability. In that filing, we did not seek to review the factors used by the state in creating its rule because those standards were the result of many years of discussions among stakeholders and reflected the State of Washington's best judgment on risk management decisions. Instead, we asked that EPA reconsider and accept the approach Ecology had employed in setting standards.

When EPA agreed with that request, the standards developed by Ecology went into effect and are protecting Washington's resources and residents today.

There is no real question as to whether these standards, developed and adopted by state officials after more than four years of analysis, are effectively protecting all consumers, including highly exposed populations, such as tribal members in Washington who consume greater amounts of fish and shellfish.

In contrast to the thorough and inclusive process employed by Ecology to develop its standards, EPA has not conducted independent analyses or developed a meaningful record for its proposed rulemaking. Instead, it has cherry-picked some elements and factors that the state specifically chose, after years of in-depth discussions, for its overall risk management decisions. For instance, the use of 175 g/day fish consumption rate by Ecology is more than adequately protective of all Washington consumers of fish and shellfish, when considered in the broader context of the state's other risk management decisions regarding the risk factor, relative source

[1] Ecology, "Ecology Director Maia Bellon responds to EPA's announcement on Washington's water quality standards Department of Ecology News Release," (November 15, 2016)(07960-07961).

contribution, and bioconcentration issues. EPA should not disregard these other determinations while accepting the fish consumption rate, as all were inter-related components of the state's risk management decision. EPA has not independently justified its decisions to reject Ecology's consideration of the factors, including the state's fish consumption rate, that drive the proposed federal standards.

EPA's position regarding standards for polychlorinated biphenyls (PCBs) is especially egregious, given the intra-agency conflict between the stringent level in the proposed water quality standard and the relatively lax level under the Toxic Substance Control Act (TSCA), the law responsible for federal regulation of chemicals in products. The water quality standard EPA is proposing would limit discharge of PCBs to 7 parts per quadrillion—the equivalent of one drop from a standard eye dropper dissolved in the water of 2,859 Olympic-sized swimming pools. In contrast, EPA's standards for allowable levels of PCBs in new products is 50,000,000,000 parts per quadrillion, a figure more than 7,000,000,000 times higher than the proposed HHWQC. We support pollution prevention opportunities and believe EPA's approach to set an unattainable limit for pollutants such as PCBs through the CWA, while not using TSCA or other tools to address much greater PCB risks, places an unfair and unnecessary burden on both private employers and local governments within the state of Washington.

In the proposal, EPA contends that its PCB standard will not impact facilities operating under CWA permits in Washington. This contention is based on the premise that the only EPA-approved method to test for PCBs is not sensitive enough to measure compliance at such miniscule concentrations. In fact, EPA assigns zero costs to the proposal based on this and other considerations. This is demonstrably not the case. As explained later in this comment letter, EPA is currently placing maximum pressure on Ecology and facilities in Washington to use an unapproved test method for PCBs as the basis to design and install new treatment systems in an effort to achieve its anticipated and unattainable PCB standard. Despite extraordinary costs, the public and private segments of Washington's regulated community still will not achieve compliance.

Additionally, EPA is required to fully assess the potential impact and costs associated with its proposed rule. The potential economic impacts on Washington communities and businesses over the next five to fifteen years are staggering. These impacts will be felt in permit compliance, public and private capital funding, and diversion of resources to address standards that offer no meaningful additional protection for public health. EPA's cursory review of costs was insufficient and contrary to Supreme Court precedent requiring meaningful cost-benefit analysis.

As a result of these shortcomings, EPA's aspirations for the benefits of this rule are just that: aspirational. The water quality standards simply cannot be achieved, and there are legitimate questions regarding whether they can even be accurately measured. This is not a sustainable regulatory framework that will drive meaningful investments in treatment technology or meaningful improvements in water quality.

Finally, EPA's unfortunate decision to ignore and abandon the detailed analysis, diverse stakeholder engagement, and sound decision-making that went into the state of Washington's human health water quality criteria submitted in 2016 violates the basic tenets of the CWA. The CWA and EPA guidance vests responsibility for risk management determination for human

health water quality criteria with the state. EPA's decision in 2019 to confirm the state's proposed rule reflected the respective roles of the state and federal governments as contained under the CWA. In contrast, the current effort seeks to replace the science-based state standards with new EPA criteria based solely on EPA's views on how the state should manage risks—despite the fact that this is unquestionably the state's prerogative. The Federal Register statement by EPA fails to demonstrate why the state risk management decisions are in any way inconsistent with the CWA, EPA regulations, and EPA guidance.

EPA should reconsider this rulemaking and reaffirm its approval of the stringent state human health criteria adopted by the state in 2016 and already protecting Washington waters and residents.

Comment No. 1: EPA has wrongly and unlawfully determined that the State of Washington human health water quality criteria adopted in 2016 and approved by EPA in 2019 are deficient under the Clean Water Act.

Congress established a federal-state partnership for implementing the CWA. *PUD No. 1 of Jefferson Cnty. v. Wash. Dept. of Ecology*, 511 U.S. 700, 703-04, 114 S.Ct. 1900 (1994); *City of Abilene v. U.S. E.P.A.*, 325 F.3d 657, 659 (5th Cir. 2003) (quoting *Arkansas v. Oklahoma*, 503 U.S. 91, 101, 112 S.Ct. 1046 (1992)). The U.S. Supreme Court has described the CWA as "a program of cooperative federalism." *New York v. United States,* 505 U.S. 144, 167, 112 S.Ct. 2408 (1992). States are principally responsible for implementing much of the statute. 33 U.S.C. § 1251(b) ("It is the policy of Congress to recognize, preserve, and protect the primary responsibilities and right of States to prevent, reduce, and eliminate pollution.").

The CWA accordingly assigns to the states the primary authority for adopting water quality standards. 33 U.S.C. § 1313(a), (c). State water quality standards submitted to EPA must protect all designated beneficial uses, be based on sound scientific rationale and contain sufficient parameters or constituents to protect the designated uses. 40 C.F.R. §131.11(a). When establishing criteria, states are encouraged to base numeric values on guidance adopted by EPA pursuant to CWA § 304(a) ("304(a) Guidance"); 304(a) Guidance modified to reflect site-specific conditions; or other scientifically defensible methods. 40 C.F.R. § 131.11(b). The standards must include the six elements set out in 40 C.F.R. § 131.6, including use designations consistent with the CWA, the methods used and analyses conducted to support the WQS, and water quality criteria sufficient to protect the designated uses.[2]

Once adopted by a state, EPA's role is to review the standards for consistency with the CWA, and either approve or disapprove the standards. 33 U.S.C. § 1313(c)(2)(A); 40 C.F.R. § 131.5(a). EPA's review is not open-ended or discretionary. Rather, it reviews the standards with reference to five different factors set out in 40 C.F.R. § 131.5(a). If EPA determines that the standards are consistent with these factors, EPA must, within 60 days of the date of submission, approve the standards. 33 U.S.C. §1313(c)(3); 40 C.F.R. § 131.5(b). If EPA determines that the state-submitted standards are not consistent with these five factors, then EPA has 90 days in

[2] 40 C.F.R. § 131.20(c) further delineates the information, analyses, methodologies, and policies that states must submit to EPA along with the water quality standards.

which to notify the state and specify the changes necessary to meet the CWA's requirements. *Id.* If the state fails to adopt the changes within 90 days of notification by the EPA, then EPA must promulgate a water quality standard for the state. 33 U.S.C. §§ 1313(c)(3), (c)(4).

Where a state has adopted water quality standards *that have been approved by EPA*—as is the case here—EPA may only impose new standards on the state if EPA has adopted new water quality standards generally. 40 CFR 131.1 ("A State or authorized Tribe's applicable water quality standard for purposes of the Act remains the applicable standard until EPA approves a change, deletion, or addition to that water quality standard, or until EPA promulgates a more stringent water quality standard.") The Act does not anticipate that EPA will impose its policy preferences on a state after approving the state's water quality standards unless EPA has adopted new water quality standards, generally, subsequent to approving the state's standards. Here, EPA has entirely ignored this aspect of the CWA.

EPA cannot lawfully disregard the risk management decisions made by Ecology to base its human health criterion based on 175 g/day fish consumption rate (FCR) and risk factor of 1 x 10^{-6} for carcinogens other than PCBs where the state adopted a 2.3 x 10^{-5} risk factor coupled with the additional risk management decision to not adopt a criterion for PCBs less stringent than the NTR criterion for PCBs. The resulting standards in Washington are protective of the general population consumption rates within a range of risk factors from 10^{-6} and 10^{-5} while protecting tribal consumption rates at better than 10^{-4}. No state, including Washington, is required to apply a 10^{-6} risk factor appropriate for the general population to more highly exposed sub-populations such as tribal consumers. EPA established this as a matter of law in *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995).[3]

There is no question that the state standards are based on sound scientific rationale consistent with EPA guidance, and comply with all CWA requirements. Nonetheless, EPA rejects the state criterion for PCBs on the basis that the state PCB standard is based on a risk factor less stringent than 10^{-6} or 10^{-5}. In fact, as EPA concedes in its own rulemaking, the state standard protects a high tribal consumption rate, 175 g/day, to one in 43,478 for a high tribal fish consumption rate. 87 Fed. Reg. at 19053. This is more protective than EPA guidance which deems standards as protective of human health where median exposure for more highly exposed populations are protected to at least 10^{-4}. By extension, the state PCB standard is protective to a risk level of approximately 76 g/day at 10^{-5}. This is well above the 95th percentile of general population fish consumption rates in Washington for **all sources** at 57 g/day.[4] There is no basis for EPA to claim that state PCB criterion is inconsistent with EPA guidance based on the risk factor and FCR employed by Ecology for the current PCB criterion.

Ecology additionally provided a sound basis for the use of factors for relative source contribution (RSC), and bioconcentration factors (BCF). Moreover, it is the State of Washington's prerogative, not EPA's, to decide whether the risk factor adopted should be 10^{-5} or 10^{-6}. EPA is ignoring the long-standing principle under its own guidance that it is first and

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[3] EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994)(00899-00967).

[4] Ecology, Fish Consumption Rates: Technical Support Document Version 2.0, 40-44, Table 37 (January 2013)(Ecology Publication No. 12-09-058)(05398-05591 at 05459-05463 and 05514). 57 g/day is presented at the 95th percentile consumption rate for the general population based on the NCI methods.

foremost the prerogative of states to make risk management decisions for human health criteria. Through the National Toxic Rule (NTR) process, EPA offered states the option of human health criteria calculated based on either a 10^{-6} or 10^{-5} risk level for the general population.

It is not appropriate, and indeed arbitrary and capricious, to vary any one factor in the derivation of the standards without affording the state an opportunity to make a decision on the appropriate risk factor to be applied in Washington. This is essential under the concepts of shared responsibilities under the CWA and was part of the NTR—each state was afforded the discretion to make is own risk management decision as to the risk factor applied to the human health criteria applicable in its state. Washington opted to use a 10^{-6} risk level prior to 2016.[5] Washington continued that approach on a chemical-specific basis coupled with other risk management decisions that EPA is now ignoring.

In the State of Washington, the risk management decision as to the risk factors used to derive human health criteria is made through rulemaking in accordance with the state Administrative Procedures Act (APA). Ch. 34.05 RCW. The determination cannot be made on an ad hoc basis by the director of Ecology, the Attorney General, or the Governor. To the extent EPA is relying on the ad hoc representations of the state through press releases, consultations, or comments by the state on the proposed rule, any such statements on behalf of the state constitute unlawful rulemaking. They are actionable in state court for violations of the APA and cannot be relied on by EPA. The people of the state are entitled under the state APA for notice and opportunity to comment on a state administrative rule and further entitled to assurances that Ecology has complied with the significant legislative rule requirements under the state APA that apply to all rule making by Ecology. RCW 34.05.328. An end-run around this process by EPA would be unlawful.

It is also inappropriate for EPA to pick and choose between factors used by the State of Washington to derive its human health criteria, which already resulted in conservative risk levels in the current standards. Washington made a risk management decision to use a high consumption rate, in most cases a high risk factor, and state specific RSC values and BCF values. If EPA varies these assumptions, it should rely on the only available general population fish consumption data that is scientifically defensible and defer to the state as to the appropriate risk factor to be applied—either 10^{-6} or 10^{-5}. To do otherwise creates standards that are unduly and unnecessarily conservative. As described by Arcadis:

> Water quality criteria based on a high-end fish consumption rate (e.g., 175 g/day) and an excess lifetime cancer risk of $1x10^{-6}$ present a risk that is far more protective than the acceptable range as defined by USEPA (2000) for both the general population and highly exposed subpopulations, such as Native Americans. Why? Because conservative assumptions add up. If a decision maker chooses a conservative value for every variable in a risk calculation, the results will be far more protective than intended. Consider the hypothetical example of a risk assessment that is based on three independent and log-normally distributed parameters. In the case of a fish consumption calculation, those parameters might be the amount of fish eaten each day, the source of the fish, and the number of

[5] National Toxic Rule ("NTR"), 57 Fed. Reg. 60848-608923 at 60868 (00768-00847 at 00792); 40 C.F.R. §131.36(b)(14)(iii)(00848-00860).

years over the course of a lifetime that people live in a certain place and eat fish from a local source. Each value represents the 95th percentile, or in other words that 9,500 out of 10,000 people have a lower exposure: they eat less fish, do not only eat fish from local waters, or do not eat local fish for their entire life, for example. Combining those three variables would result in a risk estimate that would fall at the 99.78th percentile of the resulting distribution. The risk to 9,978 out of 10,000 people would be lower than the allowable risk level used to establish the standard. So, if $1x10^{-6}$ was selected as the allowable risk level for a criterion based on those assumptions, 9,978 people would have a risk less than $1x10^{-6}$ and only 22 would have a risk greater than $1x10^{-6}$. Decisions made on the basis of this hypothetical calculation, which compounds conservative factors, are far more protective than intended if the goal was to protect the average member of the population (or the 90th percentile or even the 95th percentile of the population) at the selected allowable risk level. Additionally, USEPA's proposed criteria go beyond the type of compounded conservatism of exposure assumptions described above and designate Native Americans as the general population and then apply acceptable risk levels previously used for the general population to the Native American subpopulation. The effect of this designation is to add an additional level of conservatism such that the general population and high-end consumers such as Native Americans, are protected at levels far greater than required by USEPA guidance cited above (2000).

This may look like an academic calculation. Some readers may think that overestimating risks is a good thing because it allows us to be extra-cautious, and that regulatory decisions based on risk estimates should be as conservative and protective as possible. But the consequences of such choices also need to be considered. There's a cost to reducing the levels of chemicals in the environment to meet more-stringent limits, a cost that may be measured in dollars, energy usage and therefore carbon dioxide (CO2) emissions exacerbating climate change, or the risk of injury to workers who have the job of reducing the levels of those chemicals. Chemicals may be used to treat wastewater to meet lower standards, for example, and the sludge that results has to be trucked to a landfill or incinerated. Generating the power used to operate the wastewater treatment plant uses natural resources and creates air emissions. Each of these aspects of the life cycle of wastewater treatment operations, and their related risks, should be weighed against the value of regulatory decisions based on the combination of several conservative assumptions, referred to as compounded conservatism. In addition, although more difficult to qualify, communicating overestimated risks to the public can lead to unnecessary psychological stress in community members that can contribute to real (as opposed to predicted) adverse human health effects (USEPA 2003).

Compounding conservative values for multiple variables (including a high fish consumption rate, long duration of residence, and upper percentile drinking water rate) to estimate risks with a low target excess lifetime cancer risk will have an unintended consequence. It will result in HHWQC that are far more protective of the vast majority of the population than reflected by the target excess lifetime cancer risk. That additional degree of protection must be weighed against the risks

and environmental impacts, as well as increased public utility treatment costs borne by ratepayers and financial implications on private industry, that would result from the additional treatment needed to meet such criteria.[6]

Comment No. 2: The proposed rule conflicts with EPA's long-standing policy on acceptable risk levels.

In rejecting the State of Washington's risk management decisions EPA misstates its guidance and supporting science for deriving human health water quality criteria. EPA fails to acknowledge that its 2000 Human Health Methodology provides for risk-based criteria using a risk level of 10^{-6} or 10^{-5} for the 90th percentile consumption rate for the general population as long as the **median** consumption rate for highly exposed populations is protected to a level of 10^{-4}. [7] The 2000 Human Health Methodology is clear that EPA deems both 10^{-6} and 10^{-5} risk levels as acceptable, [8] so long as the selection provides at least a 10^{-4} risk level for the highest consumers of fish.

- "EPA generally regulates pollutants treated as carcinogens in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations."[9]
- "EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} level."[10]

EPA guidance addresses the need to consider the impact of criteria on sensitive and subsistence populations. This guidance is reflected in the preference for local data over EPA default values for fish consumption rates.[11] That does not mean, however, that a 10^{-6} risk level becomes a maximum risk level for all population exposures. The EPA guidance directs that more specific information on consumption rates should be used to ensure that the criteria are within the protective range of EPA risk policy guidance:

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[6] ARCADIS, Derivation of Alternative Human Health Risk-Based Ambient Water Quality Criteria Using Probabilistic Methods for the State of Washington (May 2022), Attachment A at 6-7.

[7] NTR, 57 Fed. Reg. 60848-608923 at 60855 (00779).

[8] EPA asked states covered by the NTR to tell EPA if they preferred the human health criteria for the state be applied at a risk level of 10^{-5}. *See* NTR at 60864 (00788). In general, the NTR established AWQC for states based on a 10^{-6} risk level. *Id*. at 60860 (00784). A state could ask EPA to remove the state from the rule, and adopt human health criteria for a carcinogen at a 10^{-5} risk level. *Id*. If a state convinced EPA a 10^{-5} risk level was appropriate, public notice and comment would not be required "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." *Id*.

[9] NTR at 60855 (00779); *see also* 65 FR 31682, 31699 (May 18, 2000)(00861-00898).

[10] EPA, Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health ("EPA, 2000 Human Health Methodology"), EPA-822-B-00-004 at 1-12 (October 2000)(00074-0258 at 00104); *see also* NTR at 60848, 60863 (describing 10^{-5} level as "adequately protective")(00768, 00787).

[11] EPA, 2000 Human Health Methodology at 1-12, 4-25 (00104, 00184).

> EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen.[12]

EPA's justification for disregarding the 2000 Human Health Methodology is that it "did not consider how CWA decisions should account for applicable reserved fishing rights." This is patently not true. The Columbia River Inter-Tribal Fish Commission submitted a written comment on the draft 2000 guidance that raised treaty and trust obligations under the CWA.[13] As seen in the above quoted passage from the guidance, consumption patterns among subsistence populations and within a given tribal jurisdiction were considered by EPA when developing the 2000 Human Health Methodology.

Moreover, EPA has updated and amended this guidance numerous times since its publication in 2002 as documented on the EPA web site.[14] EPA actively considered tribal fishing rights in parallel CWA proceedings in 2001 and 2002 that were nearly contemporaneous to the 2000 guidance and predate each of its updates.[15]

EPA should acknowledge that the PCB risk factor adopted by the state is consistent with EPA guidance. Protecting a high tribal fish consumption rate of 175 g/day is well above the 90th percentile for tribal consumption, and results in a risk of 1 in 44,000, which is more protective than the applicable risk level of 1 in 10,000. Translated to an equivalent risk level at 1 in 100,000, or 1 x 10^{-5}, the existing state standard is protective to a fish consumption rate of 76 g/day. Based on the only scientifically valid fish consumption rate for the general population in Washington, this is well above the 95th percentile consumption rate Attachment A, at 56 g/day. Attachment A, Table 8a. EPA is simply incorrect in stating that the state risk management decision for Washington is not consistent with EPA policy.

EPA's rationale for the proposed rule—that "EPA often uses 10^{-6} as a *de minimis* risk level"—misstates EPA's long-standing policy on *de minimis* risk (note that, even if the statement were correct, it does not provide a legal basis to impose water quality standards on the State of Washington). EPA, across its environmental programs, the FDA and other federal agencies have consistently deemed 10^{-4} as a *de minimis* risk level when applied to a highly exposed subpopulation. EPA has provided no explanation or justification why this long-standing national

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[12] *Id.* at 2-6 (00112).

[13] EPA, Fish Consumption and Environmental Justice, at 58 (November 2002)[referencing Columbia River Inter-Tribal Fish Commission, Comments to Administrator Browner on the Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (1999)(00268-0452 at 00341).

[14] http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/index.cfm.

[15] EPA, Meeting Summary of the Executive Council of the National Environmental Justice Advisory Council December 3, 4, and 6, 2001 (06107-06157); *see also* EPA, Fish Consumption and Environmental Justice, A Report from the National Environmental Justice Advisory Council Meeting of December 3-6, 2001 (November 2002 revised)(00268-00452).

consensus is no longer applicable as a matter of science and public health to deriving water quality standards in Washington.

Rather than apply its own guidance and recognize the current Washington standards as legally compliant, EPA has once again cobbled together rationale that treaty rights afford some *de minimis* level of exposure and that must mean that tribal consumption rates have to be applied to a one in one million risk level to afford that *de minimis* risk protection. In doing so, EPA does not acknowledge the inconsistency with the long standing position of EPA and FDA programs that consider any exposure within a range of 10^{-6} to 10^{-4} to be a *de minimis* risk and a level of risk that is acceptable and insignificant for setting human health standards, including water quality standards.

In support of its position, EPA has cited one scientific study that appeared in the 2015 Federal Register, 80 Fed. Reg. at 55068, n. 26: "Castorina, Rosemary and Tracey J. Woodruff (sic), *Assessment of Potential Risk Levels Associated with the U.S. EPA Reference Values*, ENVIRONMENTAL HEALTH PERSPECTIVES, Vol. 111, No. 10, page 1318." This article, which is about air quality and not water quality standards, does not support the implication in the Federal Register that EPA considers a 10^{-6} risk level to be a bright line standard for *de minimis* risk. The authors in fact state, "As a point of comparison, The U.S. EPA has defined 1 in 1,000,000 excess cancer risk as a *de minimis* risk level for cancer (Caldwell et al. 1998; Clean Air Act Amendments 1990; Fiori and Meyeroff, 2002; U.S. EPA 1991), **although regulatory actions are sometimes limited to instances where risk exceeds 1 in 100,000**." (Emphasis added.)

"Fiori and Meyeroff, 2002[16]," one of the references cited in support of the quoted statement in the Castorina article is a proposal for a risk management approach for exposure to mutagens that applies a *de minimis* risk standard. The article provides a short but instructive summary of "regulatory precedents for negligible carcinogenic risk":

> Acceptable risk is a concept that is required because of the adoption of the no threshold theory of carcinogenicity. Setting the acceptable risk level is a risk management decision….When EPA sets an acceptable risk for the general population (as for drinking water standards), the upper bound risk level of one excess cancer per 1 million people (i.e., 10^{-6}) is used. (EPA, 1991).[17]

The "EPA 1991" reference in the two articles relied on by EPA is the draft NTR.[18] EPA states in the draft NTR that its risk based criteria are consistent with EPA guidelines that assume carcinogenicity is a "non-threshold phenomenon" and that there is no "safe" or "no-effect levels" of exposure.[19] Consistent with this guidance, EPA elected to use a "relatively stringent" cancer risk level of 10^{-6} as applied to the general population and deemed that protective of "subsistence

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[16] Fiori and Meyeroff, Extending the Threshold of Regulation Concept: *De Minimis* Limits for Carcinogens and Mutagens, 35 REGULATORY TOXICOLOGY AND PHARMACOLOGY, 209-16 (April 2002)(06355-06362).

[17] *Id.* at 210 (06356).

[18] EPA, Amendments to the Water Quality Standards Regulation to Establish the Numeric Criteria for Priority Toxic Pollutants Necessary to Bring All States into Compliance with Section 303(c)(2)(B), 56 Fed. Reg. 58420 (November 19, 1991)(06471-06529).

[19] *Id.* at 58434 (06485).

fishermen" who are more exposed than the general population.[20] It was the position of EPA then, based on the law and best available science, that the use of a 10^{-6} risk level "is in part addressing the potential that highly exposed subpopulations exist by selecting a relatively stringent cancer risk level (10^{-6}) for use in deriving State-wide criteria for carcinogens."[21]

The EPA guidance also illustrates why protecting the highest subpopulation exposure at 10^{-6} would be over-protective of designated uses:

> It is important to understand that criteria for carcinogens are based on chosen risk levels that inherently reflect, in part, the exposure parameters used to derive those values. Therefore, changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are *relative*, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6}, those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level). (Note: Fish consumers of up to 1,750 gm/day would not exceed the 10^{-4} risk level.) If a criterion were based on high-end intake rates and the relative risk of 10^{-6}, then an average fish consumer would be protected at a cancer risk level of approximately 10^{-8}. The point is that the risks for different population groups are not the same.[22]

EPA's 2000 Human Health Methodology clearly describes an "accepted risk range" of 10^{-4} to 10^{-6}, and provides that states may adopt a cancer risk level of either 10^{-5} or 10^{-6} for the general population, as long as "the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} level."[23] Remarkably, EPA's only reference in the proposed rule to this long held policy and practice of addressing the unique health risks to high consuming subpopulations is found in a footnote. 87 Fed. Reg. at 19048 n. 9. Rather than acknowledging that its proposed rule is not justified based on the 2000 Guidance, EPA simply states "EPA notes that states and authorized tribes can also choose a more stringent risk level." *Id.* at 19048 (§III.B.a).

The current rulemaking disregards the 2000 guidance. In the Federal Register statement for the draft Washington water quality rule in 2015 similarly disregarded that the federal government has consistently deemed a 10^{-4} risk level to result in a *de minimis* risk when applied to more exposed subpopulations when deriving human health criteria under the CWA. EPA again fails to acknowledge that across EPA and FDA programs exposures at the level of risk

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[20] *Id.* at 58435 (06486).

[21] *Id.*

[22] EPA, 2000 Human Health Methodology at 2-7 (00113).

[23] *Id*. at 1-12 (00104).

between 10^{-6} and 10^{-4} are deemed acceptable because they represent an insignificant and essentially zero increased risk of cancer.[24] EPA continues in the current rulemaking to misinterpret the scientific and public health consensus regarding the application of risk factors in setting human health standards.

"*De minimis"* is a term of art taken from the principle in common law of *de minimis non curat lex* meaning roughly that the "the law does not concern itself about trifles."[25] EPA disregards decades of scientific research and sound public policy by implying that highly exposed populations will not be as well protected if their exposure risk is at a risk level of 10^{-4}. On the contrary, it has been well understood prior to today that "if only a small population would be at greatest risk, the expected number of excess cancers corresponding to individual risks at the *de minimis* level of 10^{-4} would still be zero."[26] In actual practice, federal agencies across at least 132 regulatory decisions concluded that for small populations the *de minimis* lifetime risk was considered to be 10^{-4}.[27] These regulatory decisions include actions by the Consumer Product Safety Commission, the Food and Drug Administration, the Occupational Safety and Health Administration and EPA programs for water quality, air, pesticide use, drinking water, toxic substances and radiation.[28] A survey of these decisions concluded that "for small-population effects, regulatory action was never taken for individual risk levels below 10^{-4}.[29]

The accepted range of risk levels from 10^{-6} to 10^{-4} reflects a broader regulatory consensus that this range more than adequately protects human health to an insignificant level of risk that is essentially a zero increased risk of incurring cancer.[30] The abiding principle in the regulation of exposure to carcinogens was that there should be no exposure—that there is no safe level or threshold for exposure. An early expression of this principle is found in the 1954 Delaney Clause regulating chemicals in animal feed on the basis that there should be no toxins in toxic amounts.[31] It was apparent that health and environmental regulation would be impossible under the literal application of this concept. It is impossible to regulate to a zero standard.[32] This led to adoption by EPA and FDA of the Mantel-Bryan equation which is an early precursor to the current methodology for deriving risk based criteria under EPA guidance for human health criteria. Mantel-Bryan proposed using risk levels based at levels of insignificance that would

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[24] *See* Attachment A at 12.

[25] BLACK'S LAW Dictionary 524 (2009).

[26] J. Louch, V. Tatum, and P. Wiegand (NACASI, Inc.), E. Ebert (Integral Corp.), K. Conner and P. Anderson (ARCADIS-US), A Review of Methods for Deriving Human Health-Based Water Quality Criteria with Consideration of Protectiveness (August 2012), Attachment B at 18 (*quoting* D. Kocher, Criteria for Establishing *de minimis* Level of Radionuclides and Hazardous Chemicals in the Environment (1996) (Report ES/ER/TM-187 prepared by the Oak Ridge National Laboratory for the U.S. Department of Energy).

[27] *See* Attachment B at 18.

[28] Travis et al., Cancer Risk Management, 21 ENVIRON. SCI. TECHNOLOGY 415, Table 1 (1987)(05083-05088).

[29] *Id.* at 418 (05086).

[30] Ecology, Washington State Water Quality Standards: Human health criteria and implementation tools – Overview of key decisions in rule amendment ("Ecology, Overview")(Pub. No. 14-10-058)(January 2015) at 18 (00001-00073 at 00024).

[31] Calabrese, Edward J. "Origin of the Linearity No Threshold (LNT) Dose-Response Concept." ARCHIVES OF TOXICOLOGY at 7-8 (2013)(01097-01109 at 01103-01104).

[32] Graham, John D. "The Legacy of One in a Million" RISK IN PERSPECTIVE (1993)(01110-01111).

reflect an essential zero risk of cancer at exposures considered in the resulting criteria.[33] As initially conceived, the risk levels were proposed in a range of one in one hundred million to one in a million—10^{-8} to 10^{-6}.[34]

The FDA through the 1970s and 1980s sought to establish amounts of carcinogenic compounds using an appropriate risk that when present as residue in human food would be consistent with "a zero tolerance (no residue)" policy.[35] To achieve this goal FDA made an early proposal based on the one in one-hundred-million risk level.[36] In its final rule, however, the FDA determined that the proposal was too conservative and offered no additional benefit to public health. As a result, the FDA determined that a one in one million risk was "essentially zero."[37]

It is important for EPA to consider that the trajectory of FDA regulations was to deem a 10^{-8} risk level as too conservative "after considering that and listening to both the industry and to the scientists in FDA, the final regulation as the sensitivity of the methods and the level chosen by FDA ever since then was reduced to 1 in a million."[38] FDA has explained that the 10^{-6} risk means no carcinogenic risk at all, that while there is a mathematical possibility, it is not a real risk in the actual practical world.[39]

EPA engaged in a similar public discussion as the FDA in the 1970s and 1980s.[40] EPA recognized that absolute criteria for carcinogens could not be established given uncertainties

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[33] Hutt, Peter B. "A Brief History of Risk Assessment," FDA ORAL HISTORY (November 2000)(01112-01132).

[34] FDA, Compounds used in Food-Producing Animals, 38 Fed. Reg. 19226-19230 at 19226 (July 19, 1973)(01133-01137 at 01133).

[35] *Id.*

[36] *Id*. at 19227 (01134).

[37] *Id.* at 19227 (01134). *See also* 37 Fed. Reg. 15747 (Aug. 4, 1972) (FDA adopts the Mantel-Bryan equation and its probit dose-response model as the tool used for quantitative risk assessment. Through Mantel-Bryan, one in 100,000,000 (10^{-8}) becomes a guide for determining safe doses of carcinogenic substances). FDA, Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals, 42 Fed. Reg. 10412 (Feb 22, 1977) (Following public response, industry critique, regulator reevaluation and economic considerations the one in 100,000,000 (10^{-8}) safe dose level is increased to a more lenient one in 1,000,000 (10^{-6})). FDA, Criteria and Procedure for Evaluating Assays for Carcinogenic Residues 44 Fed. Reg. 17070 (Mar. 20, 1979) (The Mantel-Bryan Equation is again adjusted; one in 1,000,000 is maintained). FDA, D&C Green No. 5, 47 Fed. Reg. 24278 (June 4, 1982) (Color additive D&C Green No. 6 permanently listed as acceptable for human consumption by FDA). FDA, Sponsored Compounds in Food-Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues, 50 Fed. Reg. 45530, 44541 (Oct. 31, 1985) (Responding to the Delaney clause, the FDA argues that one in a million risk level represents a truly insignificant degree of risk but that the agency cannot confidently assert a one in one-hundred thousand risk level would adequately protect the general public). FDA, Cosmetics; Proposed Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products, 50 Fed. Reg. 51551 (Dec. 18, 1985) (FDA claims one in a million risk level represents a "*de minimis*" level of risk)(01138-01280).

[38] Hutt, "A Brief History of Risk Assessment," FDA ORAL HISTORY, at 17 (November 2000)(01112-01132 at 01130).

[39] *Id.*

[40] EPA, Health Risk and Economic Impact Assessments of Suspected Carcinogens: Interim Procedures & Guidelines 41 Fed. Reg. 21402 (May 25, 1976) (EPA proposes "a balancing of risks and benefits as the basis for final regulatory action" regarding carcinogenic pesticides). EPA, Water Quality Criteria Documents; Availability, 45 Fed. Reg. 79323 (Nov. 28, 1980) (The EPA presents a range of acceptable risk levels in regard to Superfund

including variances of sensitivities and exposure levels.[41] Instead, EPA presented a range of concentrations associated with risk levels of 10^{-5}, 10^{-6}, and 10^{-7}.[42] EPA's objective in deriving these water quality criteria was to estimate concentrations "which do not represent a significant risk to the public."[43]

The EPA risk policy discussed above was affirmed in *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995). The same risk policy as applied under CERCLA was affirmed in *State of Ohio v. EPA,* 997 F.2d 1520, 1533 (D.C. Cir. 1993). Plaintiffs contended that EPA cannot allow a lower, one in ten thousand, risk level for the protection of populations near a Superfund site. The court rejected this contention:

> The States next challenge EPA's use of a cancer risk range between 10^{-6} and 10^{-4} in the NCP, arguing that an exposure level greater than 10^{-6} is never appropriate. A 10^{-4} risk subjects the surrounding population to an increased lifetime cancer risk of 1 in 10,000. A 10^{-6} risk subjects the surrounding population to an increased lifetime cancer risk of 1 in 1,000,000. When EPA develops objectives for a remedial action at a site, it selects a remediation goal that "establish[es] acceptable exposure levels that are protective of human health." 40 C.F.R. § 300.430(e)(2)(i). EPA attempts to use health-based ARARs to set the goal, but if ARARs are nonexistent or unsuitable for use, EPA establishes the goal based on criteria in the NCP. 55 Fed. Reg. 8712 (1990). "For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-6} and 10^{-4}...." 40 C.F.R. § 300.430(e)(2)(i)(A)(2). The NCP expresses a preference for remedial actions that achieve a level of 10^{-6} however, the ultimate decision depends on a balancing of nine criteria, including cost. *Id.;* 55 Fed. Reg. 8718 (1990).
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> The States contend that by permitting cost to play a role in determining the level of exposure, the cancer risk range fails to meet the requirement in § 9621 that remedial actions be "protective of human health." 42 U.S.C. § 9621(b)(1); *see also* 42 U.S.C. § 9621(d)(1). The States' argument necessarily depends, though, on the notion that an exposure level greater than 10^{-6} is not protective of human

(CERCLA) cleanup). EPA, National Emission Standards for Hazardous Air Pollutants: Regulations of Radionuclides, 49 Fed. Reg. 43906-43911 (Oct. 31, 1984) (EPA prescribes different levels of protection for those who have carrying levels of exposure; distinguishes between individual risk and population risk). EPA, Regulations of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41104 (Oct. 19, 1988). (EPA proposes using one in a million as a definitive acceptable risk level in an effort to supersede the Delaney clause). EPA, Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristics Revisions, 55 Fed. Reg. 11798 (Mar. 29, 1990) (EPA opts to use a one in one-hundred-thousand carcinogenic risk level for hazardous waste cleanup). EPA, Guidelines for Exposure Assessment, 57 Fed. Reg. 22888-22938 (May 29, 1992) (Discussion of individual and general population risks). EPA, Final Water Quality Guidelines for the Great Lakes System, 60 Fed. Reg. 15366-01 (March 23, 1995) (EPA approves a one in one-hundred-thousand risk level for the general population of the Great Lakes region because the most exposed populations would still be protected at a one in ten-thousand level, which is deemed adequate)(01281-01742).

[41] EPA, Notice of Water Quality Criteria Documents, 45 Fed. Reg. 79318, 79347 (Nov. 28, 1980).

[42] *Id.* at 79348.

[43] *Id.* at 79348.

> health. CERCLA requires the selection of remedial actions "that are protective of human health," not as protective as conceivably possible. A "risk range of 10^{-4} to 10^{-6} represents EPA's opinion on what are generally acceptable levels." 55 Fed. Reg. 8716 (1990). Although cost cannot be used to justify the selection of a remedy that is not protective of human health and the environment, it can be considered in selecting from options that are adequately protective.
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> The States also argue that the actual risk range selected is not adequately protective. EPA concluded, though, that all levels of exposure within the risk range are protective of human health. *Id.* EPA has used 10^{-4} as an upper bound for establishing risk levels in the past, *see* 53 Fed. Reg. 51,394, 51,426 (1988), and "[m]any ARARs, which Congress specifically intended be used as cleanup standards at Superfund sites, are set at risk levels less stringent than 10^{-6}," 55 Fed. Reg. 8717 (1990). The States offer no evidence challenging EPA's position that 10^{-4} represents a safe level of exposure, and in any event, we give EPA's findings on this point significant deference. *See New York v. EPA,* 852 F.2d 574, 580 (D.C.Cir.1988), *cert. denied,* 489 U.S. 1065, 109 S.Ct. 1338, 103 L.Ed.2d 809 (1989).
>
> The States also argue that EPA failed to justify the use of a range, instead of a single point. But EPA explained its decision to use a range. While "[t]he use of 10^{-6} expresses EPA's preference for remedial actions that result in risks at the more protective end of the risk range," 55 Fed. Reg. 8718 (1990), the Agency is also required to consider other factors in selecting an appropriate remedy. "Factors related to exposure, uncertainty and technical limitations may justify modifications of initial cleanup levels that are based on the 10^{-6} risk level." *Id.* A flexible approach to developing remedial goals is justified by the multiple statutory mandates of CERCLA, so long as EPA meets the statutory requirement of protectiveness.

State of Ohio v. EPA, 997 F.2d at 1533.

EPA's policy on acceptable risk is based on an extended scientific evaluation and has withstood legal challenges.[44] The risk policy for human health water quality criteria was resolved in the NTR. The NTR and subsequent EPA guidance documents have consistently articulated a policy to accept human health water quality criteria protecting the general population at a risk level of 10^{-6} or 10^{-5} as long as higher exposed populations are protected to at least a level of 10^{-4}.[45] EPA left it to each state to make its own risk management decision: "Adoption of a 10^{-6} or 10^{-5} risk level, both of which States and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes."[46]

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[44] *See* Attachment A at 13-27.

[45] NTR at 60855 (00779); *see also* EPA, 2000 Human Health Methodology at 1-12 (00104).

[46] EPA, 2000 Human Health Methodology at 2-6 (00112); *see also* Attachment A at 13-14.

A long line of EPA decisions have affirmed the existing risk policy in human health criteria approvals for states on the Great Lakes[47], the California Toxic Rule, 40 C.F.R. § 131.38, and the state of Oregon human health criteria, and, recently, the approval of the Idaho human health criteria using a median tribal FCR and a 10^{-5} risk factor.[48] The 2011 Technical Support Document for the Oregon criteria unequivocally states:

> EPA has identified a risk level range of 1 x 10^{-6} (1:1,000,000) to 1 x 10^{-5} (1:100,000) to be an acceptable risk management goal for the general population….
>
> EPA's 2000 Methodology states that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} risk policy.[49]

EPA elaborated on this policy with respect to more highly exposed people, saying:

> EPA understands that highly exposed populations may be widely distributed geographically throughout a given State or Tribal area. EPA recommends that priority be given to identifying and adequately protecting the most highly exposed population. Thus, if the State or Tribe determines that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, and by the national … criteria in particular, EPA recommends that the State or Tribe adopt more stringent criteria using alternative exposure assumptions….
>
> EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen.
>
> …changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are relative, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level.

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[47] EPA, Final Water Quality Guidelines for the Great Lakes System, 60 Fed. Reg. 15366 (March 23, 1995)(01775-01907).

[48] EPA, Technical Support Document: EPA Approval of the State of Idaho's New/Revised Human Health Water Quality Criteria for Toxics and other Water Quality Standards Provisions Submitted on December 13, 2016 (April 4, 2019)(07962-08008).

[49] EPA, Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria and Associated Implementation Tools Submitted July 12 and 21, 2011, at 27 (October 17, 2011)(01908-02010 at 01934).

> Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6}, those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level).

Attachment A, 17-18.

What should be clear is that if EPA relied on the only scientifically valid consumption rate for the general population, 43 g/day, and criteria based on a risk factor of 10^{-5}, the resulting standards would be protective of all consumers. This is illustrated in the Arcadis analysis in tables 8a and 8b.[50] Across all populations, the resulting criteria would be consistent with EPA guidance. EPA has no legal basis to revise the risk factor for the Washington water quality standards, while continuing to use a 175 g/day FCR. Washington used the FCR in the context of its broader risk management approach—all components are inter-related. EPA had no legal basis to override the state. If the Washington HHWQC are going to be revised, only the state can do it.

Comment No. 3: EPA violates its own methodology by relying on the 175 g/day FCR for its proposed rule.

EPA's use of the 175 g/day value is not consistent with its own methodology for developing FCRs used for deriving human health criteria. Specifically, EPA is relying on fish consumption survey data reported in 1994,[51] but collected years earlier. EPA has not applied statistical corrections to those data that are designed to mitigate problems with the analysis of short-term recall surveys. EPA now considers the use of the National Cancer Institute (NCI) method, or at least an approximation of the NCI method, to be the basis for science based FCRs relative to the approach used by EPA prior to 2015[52].

EPA has no legal basis to impose its proposed HHWQC on the State of Washington. If it did have a legal basis, EPA would have an obligation to revisit the derivation of the FCR in order to have a defensible rule. In particular, EPA would have to apply the statistical methods described by NCI for developing appropriate distributional parameters derived from short-term food consumption recall survey data. Human health criteria are developed to protect people from lifetime exposure to chemicals in surface water. Over the last decade or two, scientists have come to realize that FCRs observed during short-term dietary surveys are not representative of a person's lifetime FCR. Variations over time in the consumption habits of individuals can be substantial, particularly for episodically consumed foods such as fish. Because human health criteria are derived based on a lifetime of exposure, developing long-term average FCRs from short-term dietary survey data is critical. Researchers at NCI developed a statistical methodology to estimate FCRs from repeated short-term dietary surveys. The NCI method provides distinct

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[50] Attachment A at Tables 8a and 8b.

[51] EPA, Restoring Protective Human Health Criteria in Washington, Proposed Rule, 87 Fed. Reg. 19046-19063 at 19055, n. 81 (April 1, 2022).

[52] Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations, (NHANES 2003-2010), Final Report, April 2014, EPA-820-R-14-002, at Section 4, 21-46 (08009-08118 at 08038-08063).

advantages over previously proposed methods by accounting for days without consumption, distinguishing within-person variability from between-person variation, allowing for the correlation between the probability of consuming a food and the consumption per day amount, and relating covariate information to usual intake[53]. EPA, in its 2015 update of national recommended human health criteria and the Idaho Department of Environmental Quality (IDEQ) have used the NCI method to develop estimates of fish consumption[2,54]; USEPA, IDEQ, and Florida Department of Environmental Protection (FDEP) have employed FCRs (i.e., consumption rates assumed to represent long-term consumption behavior rather than consumption rates from short-term surveys that may result in biased estimates of consumption) to derive HHC[55,56,57].

Despite EPA's acknowledgment that the use of the NCI method is appropriate when analyzing fish consumption survey data for purposes of establishing an FCR, discussion of the NCI method and its use is completely absent in the proposal. Because the NCI methodology is designed to correct what would otherwise be high-biased estimates of upper percentiles, the corrected FCR should be lower, perhaps much lower, than the currently used value of 175 g/day. Reliance on the 175 g/day FCR outside the broader context for the state risk management decisions is contrary to the best available science and EPA's own guidance.

It is clear that the 175 g/day fish consumption rate used by EPA to derive the proposed human health criteria is not supported by technical information and is not necessary to protect the residents of Washington. EPA, if it is going to disregard the state risk management decisions, must use a fish consumption rate of 43 g/day as the only available and verified consumption rate of the general population at the 90th percentile of consumers surveyed under the NCI methodology for a consumption study. EPA has no other data on general population consumption rates in Washington.[58]

The fish consumption rate used by EPA in the proposed rule exceeds the fish consumption rate used by any state to derive human health criteria, with the exception of the Oregon human health criteria adopted in 2012.[59] EPA guidance recommends for exposure to carcinogens that states use a fish consumption rate that protects the 90th percentile consumption of the general population while ensuring that subsistence fishers are protected at their average

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[53] Tooze JA, et al. 2006. A new statistical method for estimating the usual intake of episodically consumed foods with application to their distribution. *J Am Diet Assoc* 106:1575–1587 (08119-08131).

[54] Attachment A at Tables 8a and 8b.

[55] USEPA. June 2015a. *Human Health Ambient Water Quality Criteria: 2015 Update*. EPA 820-F-15-001. Office of Water (08132-08134).

[56] EPA, Technical Support Document: EPA Approval of the State of Idaho's New/Revised Human Health Water Quality Criteria for Toxics and other Water Quality Standards Provisions Submitted on December 13, 2016 (April 4, 2019)(07962-08008).

[57] Florida Department of Environmental Protection (FDEP). June 2016. *Technical Support Document: Derivation of Human Health-Based Criteria and Risk Impact Statement*. Division of Environmental Assessment and Restoration (08135-08392).

[58] Ecology, Fish Consumption Rates: Technical Support Document, Version 2.0 at 95 (05514).

[59] Ecology, Fish Consumption Rates & Risk Levels for Carcinogens Used in Human Health Criteria Calculations, (November 5, 2013)(00259-00267).

intake rate. EPA guidance recommends a default fish intake rate of 22 grams a day to protect the general population.[60] The same guidance recommends that state criteria use an average intake rate of 142.4 grams a day for subsistence fishers. "EPA believes that the assumption of 142.4 grams/day is within the average consumption estimates for subsistence fishers based on studies reviewed."[61]

The rationale for this guidance is to ensure that human health criteria are protective within a broad range of consumption rates in a state from the general population at the 90th to the 99th percentile rates of consumption. EPA guidance describes the use of the general population consumption of 22 grams a day at the 90th percentile as a baseline to ensure protection of the 99th percentile of the general population and average consumption rate for more exposed populations including subsistence fishers.[62] EPA confirmed this policy in a conference call with state regulators on April 17, 2013. EPA was asked during that conference call how EPA defines high exposure or high risk population for determining fish consumption rates. Beth Doyle, on behalf of EPA, responded that "EPA used the 99th percentile of the general population, as representing what they figured approximated the median consumption rate for subsistence fishers."[63] The fish consumption rate of 175 g/day by Ecology is over three times the 90th percentile consumption rate established by EPA guidance for the general population. In response to these comments, EPA should acknowledge that 175 g/day is based on the 50th to 90th percentiles of tribal consumption rates. Oregon developed the 175 grams a day fish consumption rate for its criteria using the same consumption studies relied on by EPA in the Federal Register Notice and concluded that the value reflects the 95th percentile consumption rate in the Columbia River Inter-Tribal Fish Commission study and the 90th percentile consumption rates documented for Puget Sound Tribes.

> Consequently, the recommended rate [175 g/day] reflects consumption of salmon, and lamprey relative to rates documented in the CRITFC study (to protect at least 95% of fish consumers in Oregon), as well as marine fish and shellfish relative to the rates documented in the Puget Sound studies (to protect at least 90% of fish consumers in Oregon).[64]

The following table from the Technical Support Document summarizes the consumption rates from Tribal studies. The 175 grams per day fish consumption rate used by EPA exceeds the median (50th percentile) for all Tribes and the 90th percentile for all Tribes with the exception of the Tulalips, 206 g/day, and the Suquamish, 489 g/day. The Suquamish consumption rate shown in this table is heavily influenced by high consumption rates reported by a few individuals. In other studies, such as the Tulalip study, similar high rates were excluded from the analysis as

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[60] Ecology, Overview at 15 (00021).

[61] EPA, 2000 Human Health Methodology at 4-27 (00186).

[62] EPA, Fish Consumption and Environmental Justice at 28. ("EPA's default value of 142.4 grams/day for subsistence fishers reflects the 99th percentile value of 142.41 grams/day for freshwater and estuarine ingestion by adults.")(00311).

[63] D. Essig, Email to S. Kirsch (April 5, 2013)(00453-00454).

[64] Oregon DEQ, Human Health Criteria Issue Paper: Toxics Rulemaking at 9 (May 24, 2011)(00476-0559 at 00484).

"outliers."[65] Oregon DEQ recognized that "[w]ith no adjustments made for the high consumption rates, it was noted that the reported means may be highly influenced by the consumption of just a few individuals."[66]

Table 37. Summary of Fish Consumption Rates, All Finfish and Shellfish

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

See Polissar et al., 2012, Table E-1.

EPA should acknowledge that the percentiles for tribal consumption rates in this table are overstated. Ecology commissioned a report from the consultants who conducted the Tulalip, Squaxin and Suquamish studies. In a report dated October 3, 2013, the data was analyzed for a hypothetical combination of the Puget Sound Tribes.[67] This analysis calculated the median Tribal consumption rate to be 127.2 g/day for all fish.[68]

EPA should also acknowledge that the 175 g/day FCR was originally derived from the Columbia River Inter-Tribal Fish Commission (CRITFC) fish consumption rate survey (CRITFC 1994) using survey methods that have been shown to not represent the true, long-term fish consumption rate as now defined by EPA and referred to as the usual fish consumption rate (UFCR) by EPA. The State of Washington has reviewed and summarized a range of fish consumption rates developed using both the older survey methods and the newer National Cancer Institute (NCI) methodology used by USEPA and others to derive UFCRs representative of long-term fish consumption. The NCI method is currently believed to be the state-of-the-art approach for conducting dietary intake surveys, including consumption of fish. Idaho considered these survey results in developing its new and revised state HHWQC. These estimates show that the fish consumption rate of 175 g/day used in the proposed HHWQC is based on an outdated

[65] Oregon DEQ, Human Health Focus Group Report Oregon Fish and Shellfish Consumption Rate Project at 10-12 (June 2008)(00560-00631 at 00575-00577).

[66] *Id.* at 12 (00577).

[67] Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes (October 31, 2013)(00632-00657).

[68] *Id.,* Table A at 2 (00633).

survey methodology, overstates the long-term fish consumption rate of the general population and tribal populations (as shown below), and is no longer appropriate to use to derive HHWQC.[69]

Method	Population	50%	Mean	75%	90%	95%	99%
Food Frequency Questionnaire	Nez Perce[1]	70.5	123	---	270	437	796
NCI	Nez Perce[1]	49.5	75.0	---	173	232	---
Food Frequency Questionnaire	Shoshone Bannock[1]	74.6	158	---	392	603	1058
NCI	Shoshone Bannock[1]	14.9	34.9	---	94.5	141	---
Standard	General Population[2]	37.9	56	78.8	128	168	---
NCI	General Population[2]	12.7	18.8	24.8	43.3	56.6	--=

[1] Polissar et al. (2016).

[2] National Survey: NHANES 2003–2006, Adult Respondents, values as reported in Ecology (2013)

EPA has also failed to assess the ratio of its FCR that represents fish, namely salmon, that are not impacted by water quality in state waters. Ecology addressed this in its risk management decision to use a RSC of 1.0. If EPA is going to disregard that risk management decision, the FCR used in the federal standards must reflect the consumption of fish that are likely to be impacted by water quality conditions within the state of Washington. The CWA and EPA regulations require HHWQC to protect exposures that may result from pollutants in state waters. EPA guidance accordingly does not require human health criteria to regulate pollutant levels in marine fish that do not accumulate pollutants in waters of the United States within the jurisdiction of a state. The default value of 22 grams a day in EPA guidance thus reflects freshwater/estuarine fish and shellfish only.[70] The range of consumption rates in the 2000 EPA guidance similarly do not include marine fish.[71]

Salmon, as a marine species, should accordingly be excluded from the consumption rate used to derive criteria for Washington. The data on fish tissue samples from salmon in Puget Sound indicates that the predominant fraction of PCBs detected is accumulated while the fish are in the ocean-phase of their life cycle.[72] Salmon, which accumulate contaminants in marine waters beyond the jurisdiction of the state, will not be materially impacted by these HHWQC.[73]

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[69] Attachment A at 5.

[70] EPA, 2000 Human Health Methodology at 4-25 (EPA default fish consumption rates represent the ingestion of "freshwater and estuarine fish")(00184).

[71] *Id.*; *see also* Ecology, Decision Factors in Development of Human Health Criteria (November 6, 2013)("Current federal guidelines do not use salmon in the fish consumption rate because most do not reside for their full life in water regulated by the Clean Water Act")(00726-00727 at 00726).

[72] *See* National Council for Air and Stream Improvement (NCASI), Comments on Publication No. 11-09-050, Fish Consumption Rates Technical Support Document, Appendix A, page 11 (January 11, 2012)(00728-00740 at 00738), *see also* NCASI, Comments on Proposed Human Health Criteria and Implementation Tools Rule Proposal, Attachment A at 2 (March 4, 2015)(00741-00767 at 00744).

[73] *Id.*

Even for the small percentage of salmon that are resident for longer periods of time more stringent water quality standards are not likely to result in significant reductions in the body burden of contaminants.[74]

Excluding salmon from the fish consumption rate lowers the median consumption rate documented for Puget Sound Tribes to 80.4 g/day—less than half of the FCR used by EPA for the proposed criteria.[75] Even if consumption rates are apportioned for that portion of the salmon that are found to accumulate pollutants and are resident in Puget Sound for a longer period in their life cycle, the median tribal consumption rate for all seafood and the portion of anadromous fish intake was estimated by Ecology consultants to be 108 grams per day.[76]

Comment No. 4: EPA has failed to provide any basis in established science to require that a more stringent risk policy be applied in Washington.

EPA is proposing a significantly more stringent risk policy for application to the state of Washington. On the face of the proposed rule the risk policy would be to "target" tribal fish consumption rates as though they are the consumption rate for the general population, and apply a risk level factor that is associated with general population exposures. The result is the use of 175 g/day for fish consumption in calculating human health water quality criteria. EPA has not explained the basis for this consumption rate. Within various analyses of tribal consumption studies this rate may reflect the 95th percentile of tribal consumption rates, an average tribal consumption rate, or a consumption rate that has been endorsed by one or more tribal leaders or organizations representing tribal interests. EPA couples this approach with a risk management decision that all tribal consumption rates—the highest documented individual consumption rates—must be protected to 10^{-6}.

Under the EPA proposed rule, compared to the current state risk policy, the general population consumption rate, results in criteria that will be protective to a level more stringent than 10^{-7}. The 100th percentile of tribal consumption will be protected to 10^{-5}. Ecology concluded that the mean consumption rate for the general population in Washington is 18.8 g/day including all fish.[77] The effective rate for deriving human health water quality criteria is substantially less than this value, as it includes both fish that are store bought and anadromous fish that do not spend sufficient time in Washington waters to bio accumulate toxics. As such, EPA would effectively require that water quality standards applicable to Washington protect the general population at a risk level of 10^{-8}, and median tribal consumption rates at a risk level of 10^{-6}.

Criteria based on existing EPA guidance would be fully protective of tribal consumption without this dramatic change in risk policy. If EPA used, for example, 22 g/day as the consumption rate for the general population in Washington, at a risk level of 10^{-6}, the resulting

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[74] Hope, Bruce K., Acquisition of Polychlorinated Biphenyls (PCBs) by Pacific Chinook Salmon: An Exploration of Various Exposure Scenarios, 8 INTEGRATED ENVIRONMENTAL ASSESSMENT AND MANAGEMENT 553, 561 (January 2012)(05073-05082 at 05081).

[75] Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes at 2 (00633).

[76] *Id.*

[77] Ecology, Fish Consumption Rates: Technical Support Document Version 2.0 at 40-44 (05459-05463).

criteria would be protective to a consumption rate of 175 g/day at a 10^{-5} risk level and for a consumption rate of 1,750 g/day at a risk of 10^{-4}. The Washington Office of Financial Management estimates that there are 104,000 American Indian and Alaska natives in Washington.[78] If EPA followed established guidance and science and applied a 10^{-6} risk level to the general population the resulting exposures at risk levels of 10^{-5} and 10^{-4} would not predict a single excess cancer risk for this population—a result that is more stringent than EPA guidance which calls for no excess cancer risk at the median consumption rate for high consuming populations at 10^{-4}.

ARCADIS, Summary of Health Risk Assessment Decisions in Environmental Regulations (May 2022), Attachment A, explains in detail why tribal consumers would have essentially a zero increased risk of cancer if EPA complied with its own guidance in setting criteria based on the general population consumption rate. The risk of cancer from all causes far outweighs the possible risk of cancer from exposure to chemicals in the environment. *Id.* at 2. To add some meaning to these risks, the excess cancer risk that may occur as a result of exposure to a carcinogen in the environment in Washington on an annual basis is 0.54% while the lifetime risk of cancer based on a risk level of 10^{-4} used to set water quality criteria is 0.00014%. *Id.* at 8-9. A 10^{-4} risk level is clearly an acceptable and protective upper bound risk level to use in deriving water quality criteria as there is no real increase in the overall risk of incurring cancer. This is especially true when comparing an **annual** risk to a risk level based on a **lifetime** exposure every day for 70 years. In theory only, a 10^{-4} risk level would predict one excess cancer in Washington. *Id*. at 2. This is only theoretical as risk managers across EPA and other federal programs have long considered this level of risk insignificant and, in fact, the absence of any real risk. *Id.* at 21. It is inexplicable why EPA is proposing to ignore and, in some sense, misrepresent the best available science and policy in risk management.

Overestimating risks in the interest of precaution must consider the unintended consequences of such choices. *Id.* at 5. First and foremost, the rule as proposed is unachievable even with cost-prohibitive control technology, which could lead to facility closures and job losses in Washington communities. Additionally, as ARCADIS explains, available pollution control technologies to attempt compliance with the rule, even while unable to provide full compliance, carry "a cost to reducing the levels of chemicals in the environment to meet more-stringent limits, a cost that may be measured in dollars, energy usage, or the risk of injury to workers to meet lower standards." *Id.* An estimate of those costs in terms of additional water quality treatment and energy consumption is provided in HDR, Treatment Technology Review and Assessment for Association of Washington Business, Association of Washington Cities and Washington State Association of Counties (May 24, 2022)—Attachment C. HDR evaluated the cost of compliance with the EPA proposed human health water quality criteria for arsenic, benzo(a)pyrene, mercury, and PCBs. *Id.* at 1. The HDR report looked at advanced treatment systems including reverse osmosis and membrane filtration and estimated the range of unit costs for improving a 0.5 Million Gallon a Day (mgd) facility at $31 to $168 per gallon per day. *Id.* at 3. The range of unit costs for improving a 25 mgd facility to advanced treatment is $18 to $74 per gallon per day of treatment capacity. *Id.* at 3.

If these costs are applied to just the 73 major NPDES facilities identified by EPA in its economic impact analysis, the total net present value (as of 2022) would be in the range of $5.5

[78] *Id.* at 18 (05437).

billion and $11.7 billion. This does not include the 333 minor permits identified by EPA or the thousands of facilities and additional municipalities that are subject to NPDES stormwater permits. HDR also points to substantial collateral impacts above the cost of construction and operation of advance treatment including higher energy consumption, increased greenhouse gas emissions and increased solids production. *Id.* at 61.

HDR has pointed out several impacts from advance treatment needed to meet the EPA proposed criteria including:

> • Land area for additional system components (which for constrained facility sites may necessitate land acquisition and encroachment into neighboring properties with associated issues and challenges, etc.).
>
> • Increased energy use and atmospheric emissions of greenhouse gases and criteria air contaminants associated with power generation to meet new pumping requirements across the membrane filter systems (UF and RO) and GAC.
>
> • Increased chemical demand associated with membrane filters (UF and RO).
>
> • Increased chemical demand associated with AOP
>
> • Energy and atmospheric emissions associated with granulated charcoal regeneration.
>
> • RO brine reject disposal. The brine recovery systems are energy intensive and increase atmospheric emissions as a consequence of the electrical power generation required for removing water content from brine reject.
>
> • Increase in sludge generation from transitioning from the baseline to the advanced treatment alternatives. There will be additional sludge captured with the chemical addition to the primaries and membrane filters (UF and RO). Additionally, the GAC units will capture more solids.

Id.

HDR projects the advanced treatment options energy demand ranges from 2.0 to 2.8 times greater than the baseline evaluated in its study. This large increase in energy demand is attributed to the energy required to pass water through the membrane barriers and the granular activated carbon. This increase aligns with findings from both research, including EPA research that evaluated various tiers of nutrient levels with the results also suggesting increases 2+ times with the most stringent requiring advanced treatment. HDR forecasts additional energy required to handle the constituents removed as either regenerating/disposing of the GAC or handling the RO brine reject water. *Id.*, at 62, Table 4-5.

EPA has failed to provide any meaningful basis for a risk policy that would be the equivalent of 10^{-8} to 10^{-6}. The best EPA can muster after several years of refusing to engage publicly on this issue is the frustrating *non sequitur* that some tribes have treaty rights to fish, and therefore have a right to safe and healthy fisheries, and therefore the tribal consumption rates must be protected to a risk level of 10^{-6}.

EPA has simply failed to provide a rationale for changing accepted risk management policies. Any obligation of the United States under tribal treaties is the same obligation EPA has to all residents in the state of Washington—the obligation to establish criteria that are protective of beneficial uses including the beneficial uses attributed to high fish consuming populations, which encompass tribal consumers.

With the exception of the state of Washington, EPA has never revoked or disavowed the risk management guidance that evolved prior to and since the adoption of the NTR in 1992. In June 2015 EPA published final updated ambient water quality criteria for the protection of public health in accordance with section 304(a)(1) of the CWA.[79] The risk-based criteria were updated based on the application of a 10^{-6} risk level to a general population consumption rate. EPA did not suggest that its risk management decision placed high consuming populations at risk and certainly did not consider whether there was any scientific basis for protecting those populations at a risk of 10^{-6}. The criteria are in fact based on the same understanding of the range of acceptable risk levels used in developing the NTR and the 2000 Human Health Criteria Guidance.[80] EPA proclaimed, based on this approach, that its recommended criteria "are scientifically derived numeric values that EPA determines will generally protect aquatic life or human health from adverse effects of pollutants in ambient water."[81]

There is no basis for the proposed rule's departure from EPA's consistent approach that high consuming populations are adequately protected at a risk level of 10^{-4}. And by adequately protected, EPA has meant that the exposures at the levels recommended under national guidance afford an insignificant and essentially zero additional risk of cancer. EPA has no basis for differentiating its obligations to an entire population including subpopulations of more highly exposed members based on the existence of tribal treaty rights in Washington. EPA and reviewing courts have consistently said that high consuming populations are protected within the existing framework for risk. EPA has offered no scientific or legal basis for the assertion that tribal fish consumers in Washington are uniquely at risk and require some additional level of protection.

Comment No. 5: The proposed rule does not comply with requirements of the Clean Water Act and the Administrative Procedures Act to provide a basis for the proposed rule and adequate public notice and participation in the rulemaking.

From the inception of rulemaking in early 2013 by Ecology through publication of EPA's proposed rules in 2015 and 2022, EPA has aggressively pursued its *policy preferences* on two key factors—fish consumption rates and acceptable risk levels—and failed to engage in any discussion on the merits or basis for its preferred policies. The background information provided

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[79] EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health, 80 Fed. Reg. 36986 (June 29, 2015)(04807-04810).

[80] EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update, EPA-820-F-14-003 at 2 (May 2014)(01772-01774 at 01773).

[81] EPA, Final Updated Ambient Water Quality Criteria, 90 Fed. Reg. at 36987 (04808).

in the proposed rule Federal Register notice again pursues these EPA *policy preferences* and, in several cases, misstates the cited references and basis for the proposed rule.

EPA made clear that it had a viewpoint on fish consumption and acceptable risk levels that was not changeable in a meeting with the regulated community in Washington on April 9, 2013. That meeting took place in the offices of EPA Region 10 in Seattle, Washington and was attended by EPA Regional Administrator Dennis McLerran and Daniel Opalski, the manager of the Region 10 Office of Water and Watersheds, representatives of Northwest Pulp & Paper, the Association of Washington Business, the Association of Washington Cities, the City of Everett, Weyerhaeuser, and Inland Empire Paper Company. Mr. McLerran commenced the meeting by stating that the criteria in Washington should be based on a 175 g/day FCR and risk factor 10^{-6}. Mr. McLerran explained that this was so because "everyone should be protected to the same level."[82] Mr. McLerran further stated that there had to be regional, meaning EPA regional, consistency on the toxic criteria. Mr. McLerran further stated that he was unwilling to discuss these factors with the regulated community.

EPA has been equally opaque in its dealings with the state of Washington. Ecology presented the risk level policy issue to EPA Region 10 on numerous occasions over the past decade. The origins and basis for the one in one million risk policy were the subjects of several emails to EPA regional staff in January and February 2013.[83] We believe that EPA staff attended the February 8, 2013, and March 28, 2013 Ecology Policy Forum meetings where the current risk policy in Washington and EPA guidance on risk policy were discussed.[84] EPA staff never indicated in response to these emails or at the meetings that there has been any change in EPA policy—or any circumstances that require toxic criteria in Washington to vary from national guidance.

Ecology specifically raised the risk policy issue to EPA national and regional staff at a meeting on March 20, 2013. The regional staff included Lisa Macchio, Mary Lou Soscia, Matthew Szelag, Lon Kissinger and Angela Chung.[85] The following questions and answers were recorded regarding EPA guidance on risk policy:

> Question: Does EPA agree that [the Washington] risk level applies to [the] general population?
>
> Angela Chung: EPA can't answer that now.
>
> Question: Would EPA disapprove a standard based on 10^{-6} for general population as long as 10^{-4} is max for highly exposed?

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[82] D. McLerran, Pers. Communication to NWPPA Members (April 9, 2013).

[83] C. Niemi, Email to L. Kissinger (January 2, 2013)(03933-03934).

[84] *See* Attendance Lists for Meetings on June 24, 2013, November 6, 2013, and July 2014 (03935-03943).

[85] C. Niemi, Handwritten Notes (March 20, 2013)("Dennis [EPA Region 10 Administrator] thinks the OR outcome was the right outcome, regionally wants to explore that position.")(00455-00458).

Angela Chung: EPA can't answer that now.[86]

Ecology raised this issue with EPA staff again in emails and meetings in October and November 2013.[87] At these meetings between agency staff, the risk policy was listed as a topic for discussion. Ecology also presented its range of policy options at a public meeting on November 6, 2013.[88] EPA staff were present for the meeting but made no comment on national guidance for setting risk policy and there is no record of any comments from EPA regarding the policy options presented at this meeting. In meeting after meeting EPA staff remained silent on this issue. This included two public meetings held in 2013 and 2014, at seven delegate table meetings in 2012, 2013 and 2014, and at five Policy Forum meetings in 2013.

The issue was most pointedly raised in a meeting with EPA regional staff on March 11, 2014. After months of silence, Mr. McLerran apparently stated "175 grams a day at 10^{-6} is a baseline for environmental justice."[89] Mr. McLerran reportedly represented that this assertion was based on EPA guidance. In a follow-up email, Ecology requested that Region 10 verify the existence of that guidance. Ecology specifically asked:

> I have a copy of the document: "EPA Policy on Environmental Justice for Tribes and Indigenous Peoples." It is a pre-decisional working draft dated November 14, 2012.
>
> Is that the document Dennis referred to?
>
> …
>
> As we discussed, tribal members, and anyone eating high amounts of fish, are at higher risk. They are at a risk exactly proportionate to the consumption rate and will be at the same ratio (proportion) regardless of where the rule lands. Interpreting this section of the policy to mean that they can't be at a higher risk would frustrate the entire system the HHC equations are based on and make it impossible to comply. **Is there a statement somewhere that one in a million risk rate is the baseline to establish environment justice?**[90]

Mr. Opalski responded to this email and confirmed that there is no such statement (much less a rule or guidance). In an email dated March 11, 2014, he conceded: "Regarding the environmental justice concern, you are right that there isn't anything that will/does call out particular risk levels."[91]

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[86] *Id.*

[87] M. Gildersleeve, Email to A. Chung and M. Szelag (October 1, 2013)(03944).

[88] Ecology, Preliminary Draft – HHC Tools Summary, Water Quality Standards Rule Making, Human Health Criteria, Summary, (November 6, 2013)(03945).

[89] K. Susewind, Email to D. Opalski (March 11, 2014)(00459-00461).

[90] *Id.* (emphasis added).

[91] D. Opalski, Email to K. Susewind (March 11, 2014)(03946).

EPA Region 10 provided an additional comment on the Washington proposal in a letter dated July 1, 2014. This letter was in response to two letters from the late Washington State Senator Doug Ericksen. Sen. Ericksen, in his first letter on April 3, 2014, asked the EPA Regional Administrator, "I specifically would like to know what your agency considers to be an appropriate cancer risk level for the state of Washington."[92] Three weeks later Mr. McLerran responded with a letter that was not responsive to this question.[93] Sen. Ericksen sent a second letter to Mr. McLerran on May 28, 2014, pointing out that "I asked a specific question relating to a very important issue that will affect Washington's economy and public health, but you did not provide me with a specific answer."[94] Sen. Ericksen requested an answer to his question and rephrased it as follows:

(1) Have you or your staff indicated to the Washington Department of Ecology that there is a threshold cancer risk level that must be proposed for the state's criteria to receive approval?
(2) Have you or your staff indicated to Ecology that a cancer risk level of 10^{-6} is required or that it is a level you want the state to propose?
(3) Have you or your staff provided any specific directives to Ecology outlining what you will accept for a cancer risk level for Washington?[95]

Mr. McLerran, in a letter dated July 1, 2014, responded that certain "groups could be provided less protection than they have now" if Washington uses a one in one hundred thousand risk policy.[96] There is no merit to this contention where the state adopted criteria that are no less stringent than the current NTR criteria.

By the summer of 2014 it was clear that EPA was struggling to find some post-hoc rationalization for its insistence that the State of Washington accede to EPA's demands. In some instances EPA staff would abandon any pretense of what is required under the CWA and simply assert its policy preferences are appropriate because "Dennis is concerned" or "Dennis feels."[97] At other times EPA would assert grounds for its demands that later disappeared. In March and July 2014, EPA claimed that its preferred fish consumption rate and risk level was required as a matter of environmental justice. This argument is notably absent from both the EPA comment letter on the Ecology proposed rule and the Federal Register explanation for the basis of the EPA proposed rule in 2015 and now 2022.[98]

On March 23, 2015, EPA submitted a formal comment letter on the Ecology proposed rule. The letter was signed by Mr. Opalski, who participated in many of the meetings and telephone conversations and emails discussed above. EPA's letter asserted an entirely new basis

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[92] D. Ericksen, Letter to D. McLerran (April 3, 2014)(03947-03948).

[93] D. McLerran, Letter to D. Ericksen (April 24, 2014)(03949).

[94] D. Ericksen, Letter to D. McLerran (May 28, 2014)(03950-03951).

[95] *Id.*

[96] D. McLerran Letter to D. Ericksen (July 1, 2014)(03952-03953).

[97] Attendance Lists for Meetings on June 24, 2013, November 6, 2013, and July 2014 (03935-03943); C. Niemi, Handwritten Notes (00455-00458); and A. Chung, Pers. Communication, NWPPA Annual Meeting (June 6, 2013).

[98] D. Opalski, Letter to C. Niemi re EPA's Comments on Proposed Revisions to Washington's Human Health Criteria and New and Revised Implementation Provisions (March 23, 2015)(07230-07249).

for EPA's demands, stating that a one in one million risk level applied to tribal consumption rates is a "compromise position" of Washington tribes.[99] This is a statement that is not supported by any of the tribal letters that EPA has included in the rulemaking docket or the comments from tribes and tribal organizations on the Ecology draft rule. NWPPA submitted a Freedom of Information Act request to EPA for any documents that reflect the claim in the EPA comment letter. Matthew Szelag and Andre Szalay, EPA Region 10 staff, initially responded in a telephone conference that there were no public records to support the statement by EPA. EPA nonetheless produced twenty-six pages of heavily redacted emails and publicly available documents, not one of which includes a communication from or on behalf of any tribe stating that a one in one million risk level is a "compromise position of the tribes."[100] At most some tribal representatives have requested a 10^{-6} risk level but there is no evidence in the documentation provided by EPA of any scientific research or data to support what will be a significant change in the risk policy applied in Washington. Nor is there a sufficient basis under the CWA for EPA to depart from long-standing CWA policies, procedures, and requirements to mandate its preferred position on a state as it develops its criteria.

The March 23, 2015, comment letter is also noteworthy as being the first time EPA asserted that tribal treaty rights require the application of a particular risk level to tribal consumption rates. EPA had never before cited this rationale in prior meetings with the regulated community or in communications or meetings EPA had with Ecology staff. Having asserted this claim, however, EPA has consistently refused to explain how a treaty right to take fish dictates any particular risk management decision. This question was specifically posed to EPA by Ecology on July 15, 2015:

> Does EPA have an OGC [Office of General Counsel] or other legal opinion or rationale on how risk level and treaty tribal rights are connected, and why 10-6 is looked upon by EPA as fulfilling the rights, and 10-5 is not? Could you send me a copy of the opinion/rationale document?[101]

This becomes one of the central questions in the EPA rule. What are the legal and scientific connections between a tribal treaty and the use of a particular risk level as a factor in the equation that derives water quality criteria. Consistent with its now long-standing refusal to provide a legal, scientific and policy basis for its demands or engage in any meaningful public process, the EPA general counsel in an internal email directed EPA Region 10 to respond to Ecology by referring Ecology back to EPA's March 23, 2015 comment letter and EPA's February 2, 2015 decision to disapprove in part human health water criteria developed by the State of Maine.[102] It is not surprising that Ecology's subsequent July 2015 draft responses to

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[99] *Id*.

[100] M. Szelag, Email to J. Edgell (July 14, 2015)(06440-06442); K. Brown, Email to B. Duncan (June 5, 2015)(06466-06467); M. Szelag, Email to P. Ford (March 17, 2015)(06464-6465), EPA FOIA Response, EPA-R10-2015-008998 (August 2015).

[101] *Id.,* M. Szelag, Email (06442).

[102] *Id.*, M. Szelag, Email (06440).

comments on the proposed Washington State rule concluded that there is no legal basis for requiring criteria based on tribal consumption rates using a 10^{-6} risk level.[103]

EPA has never disavowed this effort to coerce the State of Washington into adopting standards based on a 175 g/day FCR and 10^{-6} risk factor for carcinogens in either the EPA response to comments for the 2016 EPA rule or in the federal register basis for the current proposed rule. Washington ultimately gave in to EPA on this demand with the exception of the criterion for PCBs. As to PCBs, EPA's proposed rule exemplifies its continued failure to provide a sound scientific rationale for its demands regarding risk policy and the fish consumption rate. The actions of EPA violate the CWA and the APA and preclude EPA from issuing a final rule based on the Federal Register notice. EPA has placed on its regulatory agenda a revision to 40 CFR Part 131 to explicitly protect tribal reserved rights.[104] EPA appears to acknowledge that it must go through rulemaking to effect any change in the current regulations and guidance for the development of human health criteria based on its interpretation of tribal treaty rights. If so, it must also do that with respect to human health standards it is imposing on the state of Washington.

Comment No. 6: The proposed rule is contrary to the established criteria for environmental justice.

EPA should acknowledge that its proposed rule is inconsistent with current EPA guidance on environmental justice. This undoubtedly explains why EPA abandoned environmental justice as the basis for its demands on the state of Washington that it adopt EPA's preferred risk policy. In 2013 and 2014 Dennis McLerran made the unsupported statement that "everyone deserves to be protected to the same level" and that "10^{-6} is a baseline for environmental justice."[105] Neither has support in the CWA or EPA guidance or policies. It is notable that there is virtually no mention of environmental justice in the EPA March 23, 2015, comment letter on Washington's proposed rule and in the Federal Register notice for EPA's own proposed rule. This is not surprising since EPA guidance on environmental justice, including consideration of tribal consumption rates, in fact supports the rule proposed by Washington in January 2015.

In May 2015 EPA published formal guidance on considering environmental justice in agency actions, including rulemaking.[106] The guidance document does not reference and therefore implicitly endorses EPA's long-standing policy on the acceptable range of risk levels. The following discussion from the guidance document exemplifies how EPA will determine whether there is a disproportionate impact from EPA action:

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[103] Ecology, Draft Responses to Comments on Proposed State Rule (July 2015)(04758).

[104] EPA, Revising the Federal Water Quality Standards to Protect Tribal Reserved Rights, accessed May 5, 2022.

[105] D. McLerran, Pers. Communication to NWPPA Members (April 9, 2013); *see also* K. Susewind, Email (00459-00461).

[106] EPA, Guidance on Considering Environmental Justice During the Development of Regulatory Actions (May 2015)(available at http://www3.epa.gov/environmentaljustice/resources/policy)(05991-06046).

> It is important to note that the role of the analyst is to assess and present differences in anticipated impacts across population groups of concern to the decision-maker and the public. The determination of whether there is a potential disproportionate impact that may merit Agency action is ultimately a policy judgment informed by analysis, and is the responsibility of the decision-maker. These analyses will depend on the availability of the scientific and technical data. As noted in the *Draft Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (U.S. EPA 2013), examples of the type of information that may be useful to provide to decision-makers for considering whether or not effects are disproportionate include: the severity and nature of health consequences; the magnitude of the estimated differences in impacts between population groups; **mean or median exposures or risks to relevant population groups**; distributions of exposures or risk to relevant population groups; characterization of the uncertainty; and a discussion of factors that may make population groups more vulnerable.[107]

Thus, the EPA 2015 environmental justice guidance focuses on the mean or median consumption or exposure rate of a more highly exposed subpopulation, not the maximum consumption or exposure rate of a subpopulation.

EPA has consistently defended this range as protective of the entire population under the principles of environmental justice. This was addressed in the response to comments for the 1995 Final Water Quality Guidelines for the Great Lakes System where EPA approved the use of a one in one hundred thousand risk level:

> Commentators argued that a 15 gram per day assumption in the methodology would not adequately protect populations that consume greater than this amount (e.g. low-income minority anglers and Native Americans). And that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (February 16, 1994, 59 Fed. Reg. 7629). **EPA believes that the human health criteria methodology, including the fish consumption rate, will provide adequate health protection for the public, including more highly exposed sub-populations.** In carrying out our regulatory actions under a variety of statutory authorities, including the CWA, EPA has generally viewed an upper bound incremental cancer risk in the range of 10^{-4} to 10^{-6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a risk level of 10^{-5}. Therefore, if fish are contaminated at the level permitted by the criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected to 10^{-4} risk level.[108]

In promulgating the California Toxics Rule in 2000 EPA specifically rejected several comments that the 10^{-6} to 10^{-4} risk policy offended notions of environmental justice.

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[107] *Id.* at 6-7 (emphasis added)(06002-06003).

[108] EPA, Final Water Quality Guidelines for the Great Lakes System, 60 Fed. Reg. 15366-15425 at 15 (emphasis added)(01775-01907 at 01789).

> EPA believes that this rule is consistent with the terms of the Executive Order (E.O.) on Environmental Justice. EPA rejects the notion that the rule is, in any respect, discriminatory against persons or populations because of their race, color, or national origin. The final rule establishes criteria that are designed to ensure protection of the public, including highly exposed populations. While some groups and individuals, including some low income and minority persons and populations, may face a greater risk of adverse health effects than the general population due to their particular fish consumption patterns, EPA believes that these groups will nonetheless receive a level of public health protection within the range that EPA has long considered to be appropriate in its environmental programs (e.g., 10^{-4} to 10^{-6} incremental cancer risk). **Obviously, as long as there is variability in fish consumption patterns among various segments of the population, it would be impossible for EPA to ensure that all groups would face identical risk from consuming fish. Therefore, EPA has sought to ensure that, after attainment of water quality criteria in ambient waters, no group is subject to increased cancer risks greater than the risk range that the EPA has long considered protective**. EPA disagrees that individuals who consume up to a pound of fish per day would face a 10^{-3} cancer risk. Given that the basis of the criteria are a 6.5 gm/day assumption at a 10^{-6} risk level, individuals who consume a pound of fish per day would be protected within the established acceptable range of 10^{-4} to 10^{-6}, consistent throughout current EPA program office guidance and regulatory actions.[109]

EPA should acknowledge in response to these comments that the agency engaged in extensive consultations and considerations of tribal concerns and treaty interests in developing the 2015 guidance. Trust responsibilities and treaty rights were specifically addressed at a meeting of the EPA National Environmental Justice Advisory Council in December 2001 in Seattle, Washington.[110] Treaty rights are also discussed in a 2002 EPA report on fish consumption and environmental justice.[111] The 2002 document had been part of the EPA "EJ" tool kit documents including the "Plan EJ 2014."[112]

There is no question that the 2015 guidance on environmental justice fully reflects the consideration of tribal consumption rates and concerns about the EPA trust and treaty obligations. The current Administration is keenly focused on environmental justice. Nonetheless, the 2015 guidance remains in effect and is currently being implemented in the current EPA environmental justice efforts. EPA should explain in response to these comments how it is possible for its existing guidance on risk levels to be consistent with environmental justice but not consistent with a newly invented interpretation of tribal treaty responsibilities.

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[109] EPA, California Toxics Rule Response to Comments Report, CTR-002-005a (Dec. 1999) (emphasis added)(02311-03812).

[110] EPA, Meeting Summary of the Executive Council of the National Environmental Justice Advisory Council December 3, 4, and 6, 2001 (06107-6157).

[111] EPA, Fish Consumption and Environmental Justice at 8 ("[t]he tribes have fought too hard for too long to let the salmon and their treaty rights to harvest salmon to go extinct")(00291).

[112] EPA, Plan EJ 2014 Legal Tools (December 2011)(03813-03932).

Comment No. 7: The EPA improperly relies on alleged suppressed fish consumption rates to justify rule.

EPA improperly bases its proposed criteria on the concept of suppressed fish consumption rates for northwest tribal members. 87 Fed Reg.at 19049 (April 1, 2022) It is not possible to comment meaningfully on this basis for the rule as EPA does not cite to a single study, document or statistic of any kind to support its contention other than consultation with Washington tribes and Columbia River basin tribes. Reliance on meetings that are closed to the public and on propositions for which there is no documentation or scientific analysis is a facial violation of CWA and APA requirements to provide a scientific basis for proposed standards and an opportunity for public participation.

The only regulatory authority cited in this section of the Federal Register notice is a cross-reference to section III.B.c *in the same notice* that includes a representation that EPA "generally" recommends "selecting a FCR that reflects consumption that is not suppressed by fish availability or concerns about the safety of available fish." 87 Fed. Reg. at 19049. EPA has conceded that this posting was done improperly and previously assured state regulators that the document would be withdrawn.[113] EPA has also conceded that it is not sure how suppression should be factored into criteria.[114]

EPA's rationale and basis is unclear for its recommendation to "generally" consider suppressed consumption rates when there is no guidance on how EPA and the states are supposed to factor this into developing water quality criteria.[115] EPA has long advised states to use data to develop criteria (with a preference for local or regional data over national data).[116] EPA is now asserting that it is permissible for it to consider unknown impacts on consumption rates for which there is no data.

The Federal Register notice does not reference any evidence to support a contention that fish consumption in Washington is suppressed due to "concerns about the safety of available fish." There is likewise a lack of any information in the proposed rule docket posted by EPA to support such a contention. EPA should acknowledge the results of a recent fish consumption survey in Idaho on this issue that found only 3% of the population indicated that they limited fish consumption due to health concerns about pollution or contamination.[117]

It is also inappropriate to employ an alleged lack of availability of fish as a factor in setting human health criteria. Human health criteria do not impact fish availability. Imposing

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[113] S. Braley, Email to M. McCoy, C. Niemi and D. Essig (January 9, 2014)(06692); S. Braley, Email to D. Essig and C. Niemi (July 28, 2014)(06693).

[114] D. Essig, Email to B. Burnell (September 30, 2014)(06691).

[115] EPA, Comments on Washington Department of Ecology's Proposed Human Health Criteria and Implementation Tools Rule (March 23, 2015)(07233-07249).

[116] EPA, 2000 Human Health Methodology at 2-2 (00108).

[117] Idaho Department of Environmental Quality, Considerations in Deciding Which Fish to Include in Idaho's Fish Consumption Rate: Policy Summary at 7 (August 2015)(04792-04802 at 04800).

EPA policy preferences on the state of Washington will in no way enhance fish runs or increase the availability of fish.

Even if it was appropriate to factor availability of fish in consideration of consumption rates, EPA has failed to cite to any evidence that there is a lack of availability of fish that would drive suppression. There is no documentation for example that tribal members lack access to fish. On the contrary, the tribal consumption studies document that at most two individual tribal members eat as much as 1600 g/day of fish.[118] This does not suggest a lack of available fish.

It appears, moreover, that tribal consumption fish rates have been growing and are not suppressed. In 1992, the Columbia River basin tribes claimed a fish consumption rate of 150 g/day.[119] By 2012, the Columbia River Inter-Tribal Fish Commission was claiming that the 95th percentile of tribal members were consuming 175 g/day.[120] In 2015 the Northwest Indian Fisheries Commission Columbia River Inter-Tribal Commission claimed that there are contemporary consumption rates of between 500 and 918 g/day.

EPA itself has increased the fish consumption rate from 6.5 g/day in the NTR to 22 g/day in criteria included in the 2015 update to the Section 304 human health criteria. This trend is consistent with national data showing an increase in consumption of fish over time. The U.S. Department of Agriculture has reported that the per capita consumption of fish grew from 12.4 pounds to nearly 16 pounds from 1980 to 2009.[121] This indicates that consumption rates used in setting criteria are adjusting with increasing consumption rates. This is illustrated in the following figure from the Idaho negotiated rulemaking process:[122]

[118] EPA, Comments on Washington Department of Ecology's Proposed Human Health Criteria and Implementation Tools Rule (07233-07249); *see also* Polissar and Hippe, Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes (00632-00657).

[119] *Dioxin/Organochlorine Ctr. v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995)("In addition, the EPA argues that even assuming consumption of 150 grams of fully contaminated fish, as claimed by DOC, the risk level would still be only 23 in a million.").

[120] EPA, Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria and Associated Implementation Tools Submitted July 12 and 21, 2011 at 27 (October 17, 2011)(01908-02010).

[121] U.S. Census Bureau, Statistical Abstract of the United States: 2012, Sec. 3, Table 217: Per Capita Consumption of Major Food Commodities (August 2011)(06986).

[122] Idaho Department of Environmental Quality, Considerations in Deciding Which Fish to Include in Idaho's Fish Consumption Rate: Policy Summary at 7 (August 2015)(04792-04802 at 04800).

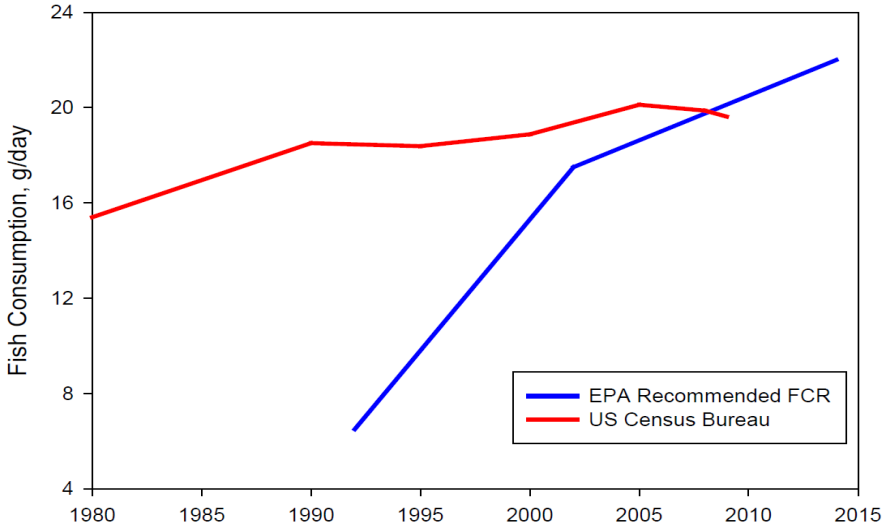

Figure 4. Per capita consumption of fish in the United States and EPA-recommended fish consumption rate (FCR), 1980–2014.

In short, there is no valid basis for EPA to impose its policy preferences on the State of Washington based on speculation unsupported by any evidence.

Comment No. 8: Tribal treaty rights do not provide a legal basis for EPA's proposed rule.

As in 2016, EPA asserts in the 2022 Proposed Rule that 1850s treaties reserving to Indian tribes the "right of taking fish" require that Washington's human health criteria (1) utilize the Indian tribal population as the "target general population" for the purposes of deriving the criteria, (2) adopt a cancer risk level of 10^{-6} to be applied to that newly defined "target general population," and (3) use a fish consumption rate that reflects unsuppressed fish consumption. The 2016 Final Rule relied heavily on what EPA characterized as a "treaty-reserved subsistence fishing right" that has no basis in law (contrary to EPA's assertions in the following citation). *See, e.g.,* 81 Fed. Reg. at 85423 (§ III.B.b) ("[r]elevant case law, including Supreme Court precedents, unequivocally confirms that the treaty-reserved right to take fish includes the right to take fish for subsistence purposes"). The 2022 Proposed Rule similarly references a tribal "legal right to harvest and consume fish and shellfish at subsistence levels." 87 Fed. Reg. at 19055 (§ V.B.c). *See also* 87 Fed. Reg. at 19054 n. 64 ("As described in EPA's 2016 final Washington WQS rule, 81 FR 85422-26, numerous tribes in Washington have treaty-reserved rights to fish for their subsistence on waters throughout the State.").[123] In fact, the federal courts have never interpreted the treaty reserved fishing right as a right to take and consume fish at a subsistence

[123] The 2016 Final Rule used the term "subsistence" nearly sixty times in describing the tribal treaty right to take fish and contained a lengthy discussion of case law that purported to support EPA's invented "treaty-reserved subsistence fishing right." *See* EPA, Revision of Certain Federal Water Quality Criteria Applicable to Washington, 81 Fed. Reg. (November 28, 2016) 85417-85437 at 85421-27. Although EPA's 2020 Proposed Rule omits much of this language but references those pages of the 2016 Final Rule as support for its interpretation of the tribal treaty right to take fish. *See* 87 Fed. Reg. at 19050 n. 34, 19054 n. 64, 19055 n. 78.

rate. The treaties only reserve to the Indian tribes the right to a fair share of the available fish. There is no legal support for EPA's attempt to use the treaty fishing right as a rationale for imposing its preferred human health criteria on the State of Washington.

The treaties only reserve to the Indian tribes the right to a fair share of available fish.

Reserved treaty rights are not unlimited in scope. The right is shared with other citizens and is similar to a cotenancy. *Anderson v. Evans*, 314 F.3d 1006 (9th Cir. 2002). And tribal fishers may be subject to federal and state regulation, so long as that regulation is non-discriminatory and for conservation purposes. *Puyallup Tribe v. Dep't of Game of Washington*, 391 U.S. 392, 398 (1968); *United States v. Oregon*, 657 F.2d 1009, 1016-17 (1981). Although treaties are to be interpreted liberally in favor of the Indians, it has long been the law that Indian treaties "cannot be re-written or expanded beyond their clear terms to remedy a claimed injustice or to achieve the asserted understanding of the parties." *Choctaw Nation of Indians v. United States*, 318 U.S. 423, 432 (1943); *See also Gros Ventre Tribe v. United States*, 469 F.3d 801, 813 (9th Cir. 2006) ("Whatever duty exists at law today must be expressly set forth in statutes or treaties.").

The treaties at issue were negotiated by territorial Governor Isaac Stevens in 1854 and 1855 with several northwest Indian tribes, for the principal purpose of extinguishing Indian claims to land in what is now Washington State. *Washington v. Wash. State Commercial Passenger Fishing Vessel Ass'n* (*"Fishing Vessel"*), 443 U.S. 658, 661-62 (1979). A critical component of the Stevens Treaties was the reserved "right of taking fish, at all usual and accustomed grounds and stations. . . in common with all citizens of the Territory." Federal courts began to recognize and interpret this treaty right as early as 1905. *See United States v. Winans,* 198 U.S. 371 (1905). The Supreme Court also held in the early 1900s that the treaties guaranteed to tribes' access to all of their usual and accustomed fishing grounds, including those off-reservation. *See Seufert Bros. Co. v. United States*, 249 U.S. 194 (1919); *Winans*, 198 U.S. 371 (1905). Interpretation of the treaty right to take fish accelerated with a suit brought in 1970 by fourteen tribes and the federal government against the state of Washington, resulting in the "Boldt decision," which was ultimately upheld by the U.S. Supreme Court in *Fishing Vessel*.

In *Fishing Vessel*, the Supreme Court held that "[b]oth sides have a right, secured by treaty, to take a fair share of the *available* fish." *Fishing Vessel*, 443 U.S. at 684-85 (emphasis supplied). The right is more than merely a right to compete with nontreaty fishermen, but rather reserves for the tribes "the right to take a share of each run of fish that passes through tribal fishing areas." *Id.* at 679. In determining what constitutes a fair share of fish, the Court viewed a tribal share of 50% of the fish as a ceiling, which could be reduced if a lesser quantity was sufficient to meet the tribes' "moderate living" needs. *Id*. at 685-89.

The underpinning of much of EPA's position with regard to cancer risk level, target population, and FCR is its assertion that the treaties reserve to tribes a right to take the amount of fish reflecting an unsuppressed, subsistence level of consumption. But in *Fishing Vessel*, the Supreme Court specifically considered and rejected the tribes' argument that the Stevens treaties "had reserved a pre-existing right to as many fish as their commercial and subsistence needs dictated." *Fishing Vessel*, 443 U.S. at 670, 679, 684-687. Other courts have consistently held that the treaty right to take fish does not include a right to take an amount of fish at the subsistence level existing when the treaties were signed. *See United States v. Adair*, 723 F.2d 1394 (9th Cir.

1983) (confirming to the Klamath Tribe an amount of water necessary to support its reservation hunting and fishing rights as currently exercised to maintain the livelihood of Tribe members, "not as these rights once were exercised by the Tribe in 1864"); *Nez Pearce Tribe v. Idaho Power Co*., 847 F. Supp. 791, 808-10 (D. Idaho 1994) (holding that "Indian tribes do not have an absolute right to the preservation of the fish runs in their original 1855 condition, free from all environmental damage caused by the migration of increasing numbers of settlers and the resulting development of the land"). The Ninth Circuit has also confirmed that the treaty right to take fish does not entitle tribes to a particular minimum allocation of fish. *United States. v. Washington*, 759 F.2d 1353, 1358-59 (9th Cir. 1985). There is simply no basis in law for EPA's assertion that the treaties require that Washington's human health criteria be based on a subsistence level of fish consumption.[124]

The treaties do not include an implied environmental right nor guarantee a particular quality of fish habitat.

EPA appears to continue in the 2022 Proposed Rule to read the treaty right to a share of available fish as containing an implied guarantee of a certain quality of fish habitat. *See* 87 Fed. Reg. at 19054, 19061; 81 Fed. Reg. at 85423 n. 39 (asserting that the treaty right to a share of available fish contains an implied guarantee or "subsidiary right" to a certain quality of fish habitat or environment). However, rather than finding any such broad environmental servitude, courts have held that at most the treaties impose on the state a duty not to take affirmative actions that will harm fish runs.

The issue of whether the treaty right to take fish includes an implied "environmental" right has been addressed in two lines of cases. In Phase II of *United States v. Washington*, the Ninth Circuit overturned a district court decision and held that in *Fishing Vessel* the Supreme Court "did not adopt a comprehensive environmental servitude." *United States v. Washington*, 694 F.2d 1374, 1381 (1982). That decision was later vacated on procedural grounds. *United States. v. Washington*, 759 F.2d 1353 (9th Cir. 1985) (en banc). However, the Ninth Circuit "did not overrule its decision or reverse the analysis of the legal issues and its reasoning." *Nez Pearce Tribe v. Idaho Power Co*., 847 F. Supp. at 808.

In subsequent litigation, the Western District of Washington held on cross motions for summary judgment that the treaty right to take fish imposes a duty on the State to refrain from building or operating culverts that hinder fish passage and thus decrease the number of fish available for tribal harvest. *United States v. Washington*, No. CV 70-9213, 2007 WL 2437166 (2007). After a bench trial the Court issued a permanent injunction directing the state to correct the barrier culverts. *United States v. Washington*, No. CV 70-9213, 2013 WL 1334391 (2013).

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[124] As the Idaho Department of Environmental Quality noted in its responses to EPA's comments on Idaho's proposed human health water quality criteria and in its subsequently submitted criteria, there is also no legal support for EPA's position that tribal fishing rights mandate that tribes be treated as the general population. Idaho Department of Environmental Quality, Water Quality: Docket No. 58-0102-1201 Proposed Rule Rulemaking and Public Comment Summary, at 21 (07312-07348); Idaho Human Health Criteria Update Justification and Compliance with Clean Water Act (December 2016) at 11 (08393-08429 at 08403). EPA has promulgated state-wide criteria to protect *all* Washington citizens, including tribal members. According to the 2015 census, Washington's Native American and Alaska Natives populations combined constitute just 1.9% of Washington's population. *See* http://www.census.gov/quickfacts/table/PST045216/53,00. The Indian population in Washington is an obvious subpopulation of the entire state and should be treated as such for purposes of HHQWC.

The district court emphasized that the state's duty not to block fish passage "is not a broad 'environmental servitude' or the imposition of an affirmative duty to take all possible steps to protect fish runs. . . but rather a narrow directive to refrain from impeding fish runs in one specific manner." *United States v. Washington*, 2007 WL 2437166 at *10; *United States v. Washington*, 2013 WL 1334391 at *24 ("it is a narrow and specific treaty-based duty that attaches when the State elects to block rather than bridge a salmon-bearing stream with a roadbed"). The Ninth Circuit Court of Appeals' affirmance of the district court decision was similarly narrowly based on the lower court's factual findings that the state had acted affirmatively to build and maintain barrier culverts under its roads, that the consequence of these affirmative actions had been to diminish the supply of fish, and that if the culverts were replaced or modified to allow free passage of fish, several hundred thousand additional mature salmon would be produced every year. *United States v. Washington*, 853 F.3d 946, 966 (9th Cir. 2017), *aff'd by an equally divided court*, ____ U.S. _____, 138 S. Ct. 1832, 201 L.Ed.2d 200 (2018).[125] *See also United States v. Washington*, 864 F.3d 1017, 1020 (9th Cir. 2017), *denial of rehearing and rehearing en banc* (Ninth Circuit did not hold that the Stevens treaties' promise of a moderate living "is valid against all human-caused diminutions, or even against all State-caused diminutions;" rather "we hold only that the State violated the Treaties when it acted affirmatively to build roads across salmon bearing streams, with culverts that allowed passage of water but not passage of salmon").

Most importantly, even if the treaties did contain some implied right to habitat protection, any such right is fully satisfied by the human health criteria adopted by Washington and approved by EPA in 2020. There is no basis for EPA's position in the 2022 Proposed Rule that setting water quality standards that treat the tribal population as the target general population, establishing a cancer risk level of 10^{-6}, and utilizing an unsuppressed fish consumption rate is required by the CWA or any other law. Nor is there evidence that EPA's past approach to water quality standards—using the general population as the target population and allowing states to choose a cancer risk level of either 10^{-5} or 10^{-6} so long as high consuming subpopulations are protected to 10^{-4}—either has caused or will cause damage to the fisheries. The situation here is thus unlike the culverts case, where the court found clear evidence that the barrier culverts were diminishing fish quantity and thus adversely affecting the treaty fishing right. Finally, Washington's fish populations are already protected by Washington's EPA-approved aquatic life criteria. *See* WAC 173-201A-200, 210, 240.

> <u>EPA's 2019 decision to approve Washington's adopted human health criteria appropriately rejected the tribal treaty right interpretation put forth by EPA in 2016 and in the 2022 Proposed Rule.</u>

The expansive interpretation of tribal treaty rights put forth in the 2022 Proposed Rule, and in EPA's 2016 Final Rule, was rejected by EPA just three years ago in the technical support

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[125] Although EPA suggested in its 2016 Final Rule that the Ninth Circuit's decision in the culverts case supports the concept of an affirmative treaty right to a certain water quality, EPA's position is directly contrary to that taken by the Department of Justice at oral argument before the 9th Circuit. The DOJ attorney represented to the Court that

> As we see this right, it's a purely negative one. It says to the State you can't take action which blocks fish passage. It's not a positive right that says the State is responsible for restoring habitat or restoring the fish. The District Court did not put it in those terms at all. This is only about actions of the State that have a direct effect on the fish runs by blocking a certain amount of habitat.

Transcript of oral argument in *U.S. v. Washington* at 16 (October 16, 2015)(08430-08450 at 08445).

document issued with its May 2019 decision to approve of the Washington-submitted human health criteria.[126] EPA noted that the agency's interpretation of the state's designated uses to also mean or include subsistence fishing, and identifying tribal populations as the target general population, "*had not been promulgated in any nationally applicable rule or articulated in any national recommended guidance or the 2000 Methodology* . . . . [EPA's interpretation] departed from longstanding EPA policy and the Agency's recommendations for setting HHC, including the 2000 Methodology." *Id.* at 24 (emphasis added). EPA explained that the 2000 Methodology spoke directly to the greater consumption of fish by Indian tribes, and that it had been EPA's longstanding view that a state could consider tribes with treaty fishing rights to be a highly exposed population, rather than a target general population, and that such consideration gave due effect to such fishing rights. *Id.* at 25. EPA further stated that Washington's election to be more protective of high consumers than necessary by selecting a FCR of 175 g/day and setting a cancer risk level of 10^{-5} for PCBs gave due effect to the tribal treaty rights and was consistent with the 2000 Methodology. *Id.* As EPA stated:

> While the reserved rights in these tribal treaties may be considered by the State and the EPA when setting and reviewing criteria, they do not expand the EPA's authority under the CWA. Likewise, these treaties do not limit or prohibit the EPA from taking an otherwise lawful action under the CWA.[127]

The 2022 Proposed Rule contains no reference to the Technical Support Document's discussion of tribal treaty rights. As noted above, EPA did not issue any new technical support document with the 2022 Proposed Rule. EPA does not refute the agency's statements in the 2019 Technical Support Document that EPA's 2016 treaty rights interpretation—now resurrected in the newly proposed rule—has never been promulgated in any other rule, articulated in any guidance, or in the 2000 Methodology.

Comment No. 9: Just as with federal trust responsibilities to the tribes, compliance with the Clean Water Act is sufficient to meet tribal treaty rights.

EPA's position in the 2022 Proposed Rule is contrary to the position taken in briefing before the federal district court for the Western District of Washington, in which EPA successfully asserted that its compliance with the CWA and its regulations satisfied any federal trust responsibility owed to the Spokane Indian Tribe. *Sierra Club v. McLerran*, Case No. 2:11-cv-01759-BJR Docket No. 91 at 40-43 (January 29, 2014). EPA explained that the scope of its trust responsibility is not defined by common law fiduciary duties or those imposed on a private trustee, but rather must be based on specific statutes and regulations. *Id*. at 41-42 (citing *United States v. Jicarilla Apache Nation*, 131 S. Ct. 2313, 2323, 2325 (2011)). As EPA asserted:

> There is a "distinctive obligation of trust incumbent upon the Government in its dealings with [Indian tribes]." *Gros Ventre Tribe v. United States*, 469 F.3d 801,

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[126] EPA, Technical Support Document: The EPA's Reversal of the November 15, 2016, Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria Submitted on August 1, 2016 and decision to Approve Washington Criteria (May 10, 2019) at 23-26 (08451-08481 at 08473-08476).

[127] *Id.* at 25 (08475).

> 810 (9th Cir. 2006) (quoting *United States v. Mitchell*, 463 U.S. 206, 225 (1983)). However, "[w]ithout an unambiguous provision by Congress that clearly outlines a federal trust responsibility, courts must appreciate that whatever fiduciary obligation otherwise exists, it is a limited one only." *Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1476, 1482 (D.C. Cir. 1995). While that general trust relationship allows the federal government to consider and act in the tribes' interests in taking discretionary actions, *it does not impose a duty on the federal government to take action beyond complying with generally applicable statutes and regulations*. *Jicarilla,* 131 S. Ct. at 2325. Accordingly, in the absence of a specific duty that has been placed on the government with respect to the Tribe, the United States' general trust responsibility "is discharged by the agency's compliance with general regulations and statutes not specifically aimed at protecting Indian tribes." *Morongo Band of Mission Indians v. F.A.A.*, 161 F.3d 569, 574 (9th Cir. 1998); *Okanogan Highlands Alliance v. Williams*, 236 F.3d 468, 479 (9th Cir. 2000) (Bureau of Land Management's approval of gold mine satisfied trust obligations by the agency's compliance with NEPA); *Gros Ventre*, 469 F.3d at 814.[128]

Judge Rothstein ruled in favor of EPA on the trust responsibility issue, agreeing that EPA had discharged its trust duty by complying with the CWA. *Sierra Club v. McLerran*, Case No. 2:11-cv-01759-BJR Docket No. 120 at 23 (March 16, 2015).

Just as in *Sierra Club v. McLerran*, any responsibility owed by EPA to Indian tribes based upon the treaty fishing right at issue here is discharged by EPA's compliance with the CWA, the aim of which is to protect the water quality for the entire population. The Stevens treaties do not impose any specific duty on EPA to adopt a particular cancer risk or fish consumption rate for the benefit of the tribes. *See Shoshone-Bannock Tribes v. Reno,* 56 F.3d 1476 (D.C. Cir. 1995)(existence of treaty-created right to hunt did not impose duty on the federal government to litigate tribal water rights claims); *Vigil v. Andrus*, 667 F.2d 931, 934 (10th Cir. 1982) (treaty obligation to support and educate Indians did not expressly impose a duty on government to provide free lunches to all Indians); *Ctr. for Biological Diversity v. U.S. Bureau of Land Mgt.*, 2015 WL 794327 *2 (D. Nevada February 24, 2015) (treaty with Goshute and Shoshone Indians did not impose an "enhanced" statutory duty on federal government beyond what [environmental statutes] already require; "the federal government's compliance with the [environmental statutes] satisfies its general trust obligations to Indian tribes"). As EPA itself argued before Judge Rothstein, EPA's responsibility to the tribes is discharged by complying with the CWA. And compliance with the CWA means basing Washington's human health criteria on sound scientific rationale.

Comment No. 10: EPA's use of a tribal treaty rights theory to support extraordinarily stringent and unachievable HHWQC raises serious constitutional problems.

The proposed rule relies in part on EPA's assertion that the CWA gives it authority to interpret federal treaties with Indian tribes, and then use its interpretations as grounds for

[128] *Sierra Club v. McLerran*, Case No. 2:11-cv-01759-BJR Docket No. 91 at 42 (January 29, 2014)(04811-04860 at 04852).

concluding that it is necessary for EPA to adopt more-stringent water quality criteria than the CWA would otherwise require. In this case, EPA asserts that its interpretations of treaty rights allow it to bootstrap to extraordinarily stringent HHWQC—so stringent that they are unachievable for the regulated community. The possible ramification is that EPA could interpret federal treaties to require state water quality standards that could severely restrict or effectively prohibit large swaths of economic activity in a state, as EPA has proposed here. The CWA should not, and cannot, properly be interpreted to give EPA such sweeping authority, particularly when there is no clear statutory direction to that effect, as well as no indication of limiting principles from Congress as to how that authority would be applied.

Comment No. 11: EPA has no authority to interpret tribal treaties.

EPA does not have authority to overrule, based on its interpretation of treaty rights, state determinations about what particular uses the state's water quality standards must protect and to what degree. Those are decisions that the CWA accords to the states in, inter alia, sections 101 and 303 of the CWA. The possible ramification is that EPA could interpret federal treaties to require state water quality standards that would severely restrict or effectively prohibit large swaths of economic activity in a state, as EPA has proposed here. The CWA should not, and cannot, properly be interpreted to give EPA such sweeping authority without a clear statutory direction to that effect, and without clear Congressional direction as to how that authority is to be applied.

EPA's interpretation of the CWA, a statute which it administers, may under certain circumstances be entitled to deference pursuant to *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778 (1984). EPA interpretation of Indian treaties is not entitled, however, to any deference. *See Maine v. Johnson*, 498 F.3d 37, 45 (1st Cir. 2007). A precondition to deference under *Chevron* is a congressional delegation of administrative authority. *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 649-50 (1990). EPA has not been delegated the authority to interpret Indian treaties. *Maine*, 498 F.3d at 45. To the contrary, the federal courts have sole jurisdiction over questions of treaty-guaranteed rights. *See* 28 U.S.C. § 1362; *Confederated Salish and Kootenai Tribes of Flathead Reservation, Montana v. Flathead Irr. & Power Project*, 16 F. Supp. 1292, 1295 (D. Mont. 1985).[129]

[129] To the extent that EPA may be continuing to rely upon the interpretation of the Stevens treaties contained in a January 30, 2015, letter from Hilary Tompkins, of the Department of Interior Office of the Solicitor, to Avi Garbow, EPA General Counsel, written in connection with EPA's disapproval of Maine's WQS, that interpretation is similarly not entitled to deference. *Cherokee Nation of Okla. v. Norton*, 389 F.3d 1074, 1078-79 (10th Cir. 2004) (Department of Interior's position based solely on its analysis of Indian treaties and agreements was not afforded any deference "because Congress did not give [the Department] the discretion to administer those treaties and agreements"). *See* 87 Fed. Reg. at 19054 n. 34, 64, 84; 81 Fed. Reg. at 85423 n. 39.

Comment No. 12: EPA's focus on treaty rights is part of a national effort to compel states to adopt EPA's preferred human health criteria, without an adequate basis.

An examination of EPA communications and actions between 2013 and 2015 regarding Washington's human health criteria illustrates that the agency's "discovery" of the existence of tribal treaty rights came *after* it adopted the position that the tribes must be considered the target general population and that that high consuming population must be protected to a 10^{-6} risk level. The documents indicate that EPA Region 10 decided that it wanted the cancer risk level for Washington to be 10^{-6}, and then apparently sought a theory upon which to base that position. And it adopted the treaty rights theory as part of a national EPA effort to use Indian treaty rights as a means of forcing states to adopt EPA's preferred human health criteria.

In a December 11, 2012 telephone call between EPA staff and Idaho Tribes, EPA was specifically asked whether EPA would require "subsistence fishers to be protected to the same extent as the general population."[130] Christine Psyk, Associate Director for Region 10, responded that "**EPA would not because that requirement does not appear in EPA regulations or guidance.**"[131]

As detailed in Comment No. 5 above, in 2013 Ecology had numerous meetings and communications with EPA national and regional staff as it worked to develop Washington's new human health water quality criteria and attendant risk policy. Throughout that year and into 2014, EPA remained silent as to whether there had been any change in EPA policy regarding cancer risk levels. *See supra* 3-4. Nor did EPA communicate any concern regarding the protection of Indian treaty fishing rights.

The issue was most pointedly raised in a meeting with EPA regional staff on March 11, 2014, when after months of silence Mr. McLerran declared that "175 grams a day at 10^{-6} is a baseline for environmental justice."[132] Mr. Opalski admitted immediately after the meeting that there is no such statement in EPA guidance to support this proposition.[133] EPA thus articulated for the first time in March 2014 a position that the cancer risk level must be 10^{-6}, gave as its rationale considerations of environmental justice, and then simultaneously admitted that environmental justice policy does not in fact dictate any particular risk level. EPA apparently was seeking a rationale for its new position on risk policy, but had not found it in environmental justice considerations. EPA at this point still had made no mention of tribal treaty rights in any of its communications with Ecology.

On April 8, 2014, Mr. McLerran wrote to Maia Bellon and informed Ecology that if it did not adopt a final rule by the end of 2014 EPA would move on its own to amend the NTR human

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[130] D. Ostermann, Letter to EPA at 2 (January 9, 2013)(02308-02310 at 02309).

[131] *Id.* (emphasis added).

[132] C. Niemi, Handwritten Notes ("Dennis [EPA Region 10 Administrator] thinks the OR outcome was the right outcome, regionally wants to explore that position.")(00455-00458).

[133] D. Opalski, Email to K. Susewind (March 11, 2014)(03946).

health criteria for Washington.[134] With regard to cancer risk level, Mr. McLerran stated that "another element of a final rule is choosing a cancer risk level that provides risk protection for all Washington citizens, including communities that eat higher amounts of fish." Again, no mention was made of changes to EPA's national guidance, nor any reference to tribal treaty rights.

On April 24, 2014, in response to an April 3, 2014, letter from Sen. Doug Ericksen requesting an articulation of what EPA considered to be an appropriate cancer risk level for Washington, Mr. McLerran did not answer the question, but did make vague references to the health protection of all citizens of Washington, including high fish consumers.[135] Mr. McLerran made no reference to environmental justice, Indian tribes, treaties, or fishing rights. On June 19, 2014, EPA Region 10 staff confirmed again that there is no stand-alone environmental justice analysis in developing water quality standards.[136]

In a July 1, 2014 response to a second letter from Senator Ericksen, Mr. McLerran stated that he had in fact "recommended that Ecology retain their current state-wide cancer risk level of 10^{-6}," and listed three reasons for EPA's position.[137] Despite the fact that Region 10 had conceded on March 11, 2014[138] and June 19, 2014[139] that there is no separate environmental justice basis for applying a specific risk level to tribal consumption rates, Mr. McLerran resurrected the environmental justice rationale, stating that the use of a cancer risk level other than 10^{-6} would raise "environmental justice concerns, which are a significant consideration in the EPA review of the State's overall submittal." For the first time, after months of communication with Ecology regarding the development of new HHWQC, Mr. McLerran also referenced treaty fishing rights as potential support for EPA's newly-announced position that Ecology must utilize a cancer risk level of 10^{-6}.

EPA's next formal communication to Ecology regarding its development of human health criteria for Washington came in a December 18, 2014 letter from Mr. McLerran to Ms. Bellon, informing her that EPA had initiated internal federal rulemaking to amend the NTR for Washington's human health criteria.[140] Mr. McLerran reiterated EPA's inaccurate characterization of Washington's approach as a change in the state's cancer risk protection level, and asserted that EPA's rulemaking process would include policy and legal considerations including "an assessment of downstream waters protection, environmental justice, federal trust responsibility, and tribal treaty rights and how those issues should inform the EPA's analysis of the protectiveness of the water quality criteria." Mr. McLerran seemed to be adopting an "all of the above" rationale for EPA's predetermined opinion that Washington must use a 10^{-6} cancer risk level, resurrecting environmental justice, making reference to tribal treaty rights, and for the

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[134] D. McLerran, Letter to M. Bellon (April 8, 2014)(04738-04739).

[135] D. Ericksen, Letter to D. McLerran (May 28, 2014)(03950-03951).

[136] A. Chung, Email (June 19, 2014)(02231-02232). It was apparent by the summer of 2014 that EPA would insist on a 10^{-6} regardless of its own policies and all available data. *See* D. Essig, Email to C. Neimi (June 24, 2014)(EPA refuses to fund or cooperate with consumption surveys in Idaho because tribal consumptions need to be protected to 10^{-6} risk level)(06689-06690).

[137] D. McLerran, Letter to M. Bellon (December 18, 2014)(04790-04791).

[138] D. Opalski, Email to K. Susewind (March 11, 2014)(03946).

[139] A. Chung, Email (June 19, 2014)(02231-02232).

[140] D. McLerran, Letter to M. Bellon (December 18, 2014)(04790-04791).

first time also pointing to EPA's federal trust responsibility (presumably to Indian tribes) as support for its position.

Notably, Mr. McLerran's letter came just weeks after a December 1, 2014, memorandum issued by Gina McCarthy announcing a new EPA policy regarding tribal treaty rights[141]:

> While treaties do not expand the EPA's authority, the EPA must ensure its actions do not conflict with tribal treaty rights. In addition, EPA programs should be implemented to enhance protection of tribal treaty rights and treaty-covered resources when we have discretion to do so. To help guide the agency's decisions when treaty rights should be considered, the Office of General Counsel and the American Indian Environmental Office will develop an analytical framework, with input and consultation from other EPA offices and tribal governments.[142]

On February 2, 2015, two months after Ms. McCarthy's memorandum, EPA disapproved in part water quality standards adopted by the state of Maine. [143] Although many of EPA's conclusions regarding Maine's water quality standards are specific to Maine's unique Indian Settlement Acts, EPA based much of its decision on the lengthy analysis of Indian treaty fishing rights contained in the January 30, 2015 Maine Tribal Fishing Rights Letter. For the first time, EPA set out in detail its theory that tribal fishing rights mandate that tribes be considered the target subject population for the purposes of development of human health criteria, and that the fishing rights require protection of that target population to a certain level of cancer risk. Never before in its history had EPA disapproved a state's water quality standards based on the existence of Indian treaty rights.

In its March 23, 2015, comments EPA applied this same new treaty right rationale to support its position on Washington's human health criteria. Unlike any past communications regarding proposed human health criteria for Washington, EPA's cover letter to Ecology contained six separate references to "tribal members with treaty-protected fishing rights" and set forth EPA's position that Washington's adoption of a cancer risk level of 10^{-5} would not adequately protect such tribal members.[144] In the comments EPA announced that treaty reserved rights to take fish mandated that the tribal population be treated as the target general population rather than as a high-consuming subpopulation, as in the past.[145] For the first time, EPA asserted that "[a] 10^{-6} cancer risk level is necessary to ensure that the target population of tribal fish consumers exercising their treaty-reserved rights, including those whose consumption is not

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[141] G. McCarthy, Memorandum Commemorating the 30th Anniversary of the EPA's Indian Policy (December 1, 2014)(05396-05397).

[142] *Id.*

[143] H. Spalding, Letter to P. Aho (February 2, 2015)(07305-07310) and Attachment A, Analysis Supporting EPA's February 2, 2015, Decision to Approve, Disapprove, and Make No Decision on, Various Maine Water Quality Standards, Including Those Applied to Waters of Indian Lands in Maine (07254-07304).

[144] EPA, Comments on Washington Department of Ecology's Proposed Human Health Criteria and Implementation Tools Rule (07233-07249).

[145] *Id.* at 2-3 (07234-07235).

suppressed, are adequately protected."[146] EPA made no reference in its cover letter or comments to environmental justice or trust responsibility—by this point EPA had apparently rejected those prior rationale in favor of reliance solely on tribal treaty rights. And as with the March 2015 comments on Washington's proposed rule, EPA's own proposed rule does not point to environmental justice as support for its rule.[147]

As the above shows, EPA did not even publicly mention tribal treaty rights before its July 2014 letter to Senator Ericksen and did not communicate the treaty rights rationale directly to Ecology until December 2014, after nearly three years of meetings and communications regarding Washington's adoption of new human health criteria. After experimenting throughout 2014 with reliance on environmental justice and trust responsibility as rationale for its insistence on a 10^{-6} risk level, it is only in March 2015, shortly after EPA's December 2014 announcement of a new national policy on treaty rights, that EPA fully articulated and adopted its new position that tribal treaty fishing rights mandate certain human health criteria. This basis lacks a sound scientific or legal rationale.

EPA's reliance on treaty rights is not limited to Maine and the Pacific Northwest. EPA's February 2015 disapproval of Maine's water quality standards and its March 2015 comments on Washington's proposed criteria were followed by May 2015 comments on the State of Idaho's proposed revisions to its water quality standards, in which EPA once again articulated its position that treaty fishing rights mandate that states select fish consumption rates reflecting unsuppressed fish consumption.[148] EPA articulated the treaty rights rationale in its November 6, 2015 further comments on Idaho's proposed rule.[149]

EPA's national effort to use treaty rights as support for its preferred state water quality standards is further evidenced by the February 19, 2016, guidance for consulting with Indian tribes regarding treaty rights.[150] This guidance references EPA review of state water quality standards and appears aimed at providing support for EPA's new nationwide interpretation of treaty fishing rights as mandating particular state water quality standards:

> Treaties also may contain necessarily implied rights. For example, an explicit treaty right to fish in a specific area may include an implied right to sufficient water quantity or water quality to ensure that fishing is possible. Similarly, an explicit treaty right to hunt, fish or gather may include an implied right to a

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[146] *Id.* at 5. As in its own proposed rule, EPA "explained" its departure from the 2000 Guidance by stating that the Guidance did not consider how CWA decisions should account for treaty fishing rights (07237).

[147] EPA's proposed rule does contain one reference to Executive Order 12898 regarding federal actions to address environmental justice in minority populations, but environmental justice concerns are not described as the basis for EPA's proposed Washington HHC. EPA Proposed Rule, 87 Fed. Reg. at 19060-19061.

[148] EPA, Letter to Idaho DEQ (May 29, 2015)(04746-04753).

[149] EPA, Comments on Idaho's Revised Human Health Toxic Criteria (November 6, 2015)(04759-04789).

[150] EPA, EPA Policy on Consultation and Coordination with Indian Tribes: Guidance for Discussing Tribal Treaty Rights (February 19, 2016)(08482-08485).

certain level of environmental quality to maintain the activity or a guarantee of access to the activity site.[151]

EPA's broader approach of mandating a particular state's water quality standards is also illustrated by its consideration of a new Baseline Water Quality Standards Proposed Rule, which would establish national "baseline" federal WQS for Indian reservations not currently covered by EPA-approved water quality standards.[152] By setting EPA-preferred WQS for reservations, and then acting to "[protect] reservation water quality from upstream discharges flowing into reservation waters from other jurisdictions" questions have been raised about EPA authority to set state water quality standards without using the process for development set forth in the CWA.

Comments by the National Association of Clean Water Agencies regarding EPA's response to Washington's proposed human health criteria rule provide a cogent summary of EPA's current actions:

> [T]he language in the CWA and the implementing regulations was not intended to give EPA authority to disapprove standards because the state's science and policy decisions are not identical to [EPA's] preference, policies and guidance. . . In the case of Washington's proposed rule, which in fact was consistent with the range of values and approaches included in existing federal guidance, EPA appears to ignore the flexibility afforded to states in its own guidance by insisting that the state's program conform to EPA's preferred approach. These tactics are inconsistent with the CWA's cooperative federalism foundation and history that provides the states the responsibility for developing and approving water quality standards. . . . The structure established by the CWA—where EPA provides criteria recommendations and guidance and the states develop water quality standards based on that information as well as state policy and risk decisions (where a range of acceptable CWA options exist)—must be preserved to ensure that federal preference and the criteria recommendations do not become de facto regulations.[153]

Comment No. 13: Executive orders and EPA policies regarding consultation and coordination with tribes do not support EPA's proposed rule.

EPA refers to its consultation with Indian tribes as justification for the selection of an unsuppressed fish consumption rate of 175 g/day and a cancer risk level of 10^{-6}.[154] In fact, EPA

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[151] *Id.* at 3 (08484).

[152] EPA, Consultation Plan for Considering a Baseline Water Quality Standards Proposed Rule (August 2015)(05066-05072).

[153] K. Kirk, Letter to D. McLerran re EPA Efforts to Influence Washington Rulemaking at 2-3 (May 13, 2015)(04743-04745 at 04744-04745).

[154] EPA 2022 Proposed Rule, 87 Fed. Reg. at 19049 (§ II.B.c) ("[S]electing a FCR that reflects unsuppressed fish consumption could be necessary where tribal treaty or other reserved fishing rights apply. In such circumstances, if sufficient data regarding unsuppressed fish consumption levels are unavailable or inconclusive, states should consult with tribes when deciding which fish consumption data should be used in selecting an FCR"); *Id.* at 19050 (§II.C)

admits that it had insufficient evidence of unsuppressed fish consumption rate for the tribes, and lacking such data, simply adopted both the fish consumption rate and the cancer risk level that the tribes asked for.[155] EPA thus relies on its obligation to consult and coordinate with Indian tribes—and the tribes' preferences as to the fish consumption rate and cancer risk—rather than complying with the CWA and promulgating human health criteria based on sound scientific rationale. EPA is required to consult and coordinate with Indian tribes. However, that requirement does not allow EPA to circumvent the requirements of the CWA.

EPA's obligation to consult with Indian tribes regarding tribal treaty rights is not new. It dates back to at least 1994, with a memorandum issued by President Clinton.[156] *See* EPA Policy for the Administration of Environmental Programs on Indian Reservations" Memorandum on Government-to-Government Relations with Native American Tribal Governments, 59 Fed. Reg. 22,951 (Apr. 29, 1994) ("1994 Presidential Memorandum"). This Presidential Memorandum was followed by Executive Order 13084 "Consultation and Coordination with Indian Tribal Governments," 63 Fed. Reg. 27655 (May 14, 1998) (references tribal treaty rights in introduction and §§ 2, 5), which was replaced two years later with Executive Order 13175 "Consultation and Coordination with Indian Tribal Governments," 65 Fed. Reg. 67349 (Nov. 6, 2000) (references tribal treaty rights in §§ 2(a), 2(b), 3(a), 5(d)).

("[E]PA proposed HHC based on a FCR of 175 g/day and CRL of 10^{-6} to reflect consideration of tribal treaty-reserved rights, as informed by consultation with the tribes and fish consumption surveys of tribal members"); *Id*. at 19050 ("The 2016 final rule was informed by . . . consultation with a number of federally recognized tribes"); *Id.* at 19055 n. 78 ("In 2016, tribes in Washington State generally viewed 175 g/day *as a compromise minimum consumption rate* so long as it is coupled with a CRL of $10^{-6.}$") (emphasis added); *Id.* at 19060 ("The tribes have repeatedly asked EPA to reinstate the 2016 federal HHC for Washington, which EPA is proposing to do in this rule"); *Id.* at 19061 ("FCR of 175 g/day is a "compromise rate"). EPA similarly relied on tribal consultation as a justification for its decision-making in the 2016 proposed and final rules. *See* 80 Fed. Reg. at 55066 (§ II.B.c) ("If sufficient data regarding unsuppressed fish consumption levels are unavailable, consultation with tribes is important in deciding which fish consumption data should be used"); 80 Fed. Reg. at 55067 (§ IV.C.a) (FCR "reflects input received during consultation with tribes;" "EPA considered the input received during consultation with tribes when selecting which fish consumption data would be used to estimate a FCR for calculating human health criteria. . . ")); 80 Fed. Reg. at 55068 (§ IV.C.b) ("EPA considers 10^{-6} to be sufficiently protective, and the tribes have supported this during consultation") 80 Fed. Reg. at 55074 (§ VI.F) ("At . . . meetings, the tribes consistently emphasized that the human health criteria should be derived using at least a minimum FCR value of 175 g/day, [and] a cancer risk level of 10^{-6}. . . ."). *See also* EPA, Comments on Washington Department of Ecology's Proposed Human Health Criteria and Implementation Tools Rule (07233-07249) at 5 ("[T]he EPA supports the state's decision to derive the human health criteria using a FCR of 175 g/day so long as the state also retains a cancer risk level of 10^{-6}, *which the tribes have generally viewed as a compromise minimum value in tribal consultation*") (emphasis added) (07237 at 07233). *See* EPA 2016 Final Rule, 81 Fed. Reg. at 85426 (§ III.B.e) ("Consultation with tribes is important to ensure that all data and information relevant to this [FCR suppression data] issue are considered"); 81 Fed. Reg. at 85426 (§ III.C.a) ("The Washington tribes have generally agreed that 175 g/day is acceptable for deriving protective criteria at this time. . . ."); *Id.* at 85427 (§ III.C.b) ("Throughout tribal consultation, the tribes generally supported 175 g/day as an acceptable FCR . . . when accompanied by other protective input parameters. . ."); *Id.* at 85435 (§ V.F) ("At these meetings, the tribes consistently emphasized that the human health criteria should be derived using at least a minimum FCR value of 175 g/day, [and] a cancer risk level of 10^{-6}. . . .").

[155] *Id.*

[156] The Bureau of Indian Affairs first promulgated internal guidelines for consultation with Indian tribes in 1972, which were broadened in 1977. *Lower Brule Sioux Tribe v. Deer*, 911 F. Supp. 395, 398-99 (D.S.D. 1995). In 1984, EPA issued its own policy establishing coordination and cooperation with tribes as to their environmental interests on reservation lands. EPA, Policy for the Administration of Environmental Programs on Indian Reservations (November 8, 1984) (06436-06439).

In 2009 President Obama issued a Presidential Memorandum on Tribal Consultation, 74 Fed. Reg. 57881 (Nov. 5, 2009) ("2009 Presidential Memorandum") directing all executive departments and agencies to develop a detailed plan of actions each agency would take to implement Exec. Order No. 13175. In compliance with the 2009 Presidential Memorandum, EPA issued its EPA Policy on Consultation and Coordination with Indian Tribes ("EPA Consultation Policy") on May 4, 2011. As with the executive orders and the presidential memoranda, this policy specifically references tribal treaties. EPA Consultation Policy at 3. EPA in February 2016 also issued an EPA Policy on Consultation and Coordination with Indian Tribes: Guidance for Discussing Tribal Treaty Rights ("EPA Treaty Rights Consultation Policy").

In 2021 President Biden issued a Presidential Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships, 86 Fed. Reg. 7491 (Jan. 26, 2021) ("2021 Presidential Memorandum"), reaffirming the policy announced in the 2009 Presidential Memorandum. Like the 2009 memorandum, the 2021 Presidential Memorandum directed executive departments and agencies to develop a plan of actions each agency would take to implement Exec. Order No. 13175. EPA issued such a plan in April 2021.

By their terms, the tribal consultation executive orders and presidential memoranda are intended only to improve the internal management of the executive branch, and do not "create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law by a party against the United States, its agencies, or any person." 1994 Presidential Memorandum; Exec. Order No. 13084 § 7; Exec. Order No. 13175 § 10; 2009 Presidential Memorandum; 2021 Presidential Memorandum. They are "intended primarily as a political tool for implementing the President's personal Indian affairs policy. . . ." *Lower Brule Sioux Tribe v. Deer,* 911 F. Supp. 395, 401 (D. S. D. 1995). They do not have the force of law and do not establish legal standards. *Hoopa Valley Tribe v. Christie,* 812 F.2d 1097, 1103 (9th Cir. 1986) (holding that 1994 Presidential Memorandum does not create any enforceable duty to consult with tribes).

Moreover, compliance with the executive orders and the Memorandum are specifically limited to those actions consistent with existing law. "[A]gencies shall adhere, *to the extent permitted by law*, to the following criteria when formulating and implementing policies that have tribal implications. . . ." Exec. Order No. 13175 § 3 (emphasis added); "Executive departments and agencies shall carry out the provisions of this memorandum *to the extent permitted by law and consistent with their statutory and regulatory authorities* and their enforcement mechanisms." 2009 Presidential Memorandum (emphasis added); "This memorandum shall be implemented consistent with applicable law. . . ." 2021 Presidential Memorandum. Presidential executive orders cannot impose legal requirements on the executive branch that are inconsistent with a statute—such as the CWA—duly enacted by Congress. *United States v. R.I. Dep't of Corr.*, 81 F. Supp. 3d 182, 188 (D.R.I. 2015) (*citing Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1332-34 (D.C. Cir. 1996)); *Utah Ass'n of Cntys. v. Bush,* 316 F. Supp. 2d 1172, 1184 (D. Utah 2004).

Appropriately, EPA's own consultation policy is entirely procedural, outlining how and when consultation is to occur, and the roles and responsibilities of those involved in the consultation process. EPA Consultation Policy. The policy in no way *requires* that the agency

adopt the tribes' position. *Id.*[157] Thus, to the extent that EPA's internal policies impose a duty on EPA to consult with tribes while promulgating water quality standards, that consultation does not require that EPA adopt whatever fish consumption rate or cancer risk level the tribes insist upon during that consultation. *Hoopa Valley Tribe v. Christie*, 812 F.2d at 1103 (finding that BIA consultation guidelines were not binding, but even if they were, there was no violation of APA where tribe was consulted even though tribe's advice was not accepted); *Lower Brule Sioux Tribe v. Deer*, 911 F. Supp. at 401 (holding that although BIA guidelines require meaningful tribal consultation "that is not to say the BIA must obey those who are consulted or that the BIA must accept their advice"). Consultation is not the same as obeying those who are consulted. *Hoopa Valley Tribe*, 812 F.2d at 1103.

Executive orders, presidential memoranda and EPA policies simply do not allow tribes to dictate the appropriate cancer risk level and fish consumption rate. Under the CWA EPA must base water quality standards on sound scientific rationale. EPA does not have authority to impose its policy preference on Washington HHWQC based on tribal input when the current standards clearly meet the requirements of the CWA. And if a policy decision is to be made to voluntarily follow tribal preferences, it is for the State to decide, not EPA.

Comment No. 14: Compliance with downstream water quality standards is not a basis for the proposed rule.

EPA has improperly relied on the purported need to protect downstream water quality standards as a basis for its demands that the state of Washington use a high tribal consumption rate and 10^{-6} risk policy. This was declared by Mr. McLerran in his meeting with Mr. Opalski and the regulated community in April 2013.[158] It was echoed by EPA staff at meetings with state officials.[159] It was repeated in a July 1, 2014 letter from Mr. McLerran wherein he states he "supports regional consistency among Region 10 states" to protect downstream waters under 40 C.F.R. § 131.10(b).[160] EPA repeats these post-hoc rationalizations in the Federal Register notice. 87 Fed. Reg. at 19055 ("a FCR of 175 g/day helps ensure that Washington's criteria will provide for the attainment and maintenance of Oregon's downstream WQS."

EPA should acknowledge that 40 C.F.R. § 131.10(b) does not require upstream states to adopt the same water quality standards as downstream states. EPA issued a Frequently Asked Questions document in June 2014 that allows the state to comply with this provision in EPA regulations by adopting a narrative provision in its water quality standards that discharges from the state will not cause or contribute to a violation of applicable downstream state water quality

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[157] EPA, EPA Policy on Consultation and Coordination with Indian Tribes: Guidance for Discussing Tribal Treaty Rights at 1 (08482). EPA's consultation policy specific to tribal treaty rights similarly states that the policy "does not create any new legal obligations for EPA or expand the authorities granted by EPA's underlying statutes, nor does it alter or diminish any existing EPA treaty responsibilities."

[158] D. McLerran, Pers. Communication (April 9, 2013).

[159] C. Niemi, Handwritten Notes (00455-00458); and A. Chung, Pers. Communication, NWPPA Annual Meeting (June 6, 2013).

[160] D. McLerran, Letter to M. Bellon (December 18, 2014)(04790-04791).

standards.[161] The EPA approved water quality standards for Washington satisfy the requirements of 40 C.F.R. § 131.10(b) by expressly providing that all "Upstream actions must be conducted in manners that meet downstream water quality criteria." WAC 173-201A-260(3)(b).

EPA should also acknowledge that Ecology has in fact taken into account the Oregon human health criteria when recently issuing NPDES permits on the Columbia River.[162] As of today, these are the only NPDES permits on the Columbia River, both issued by Ecology, that have actually applied the Oregon human health water quality criteria. To our knowledge, Oregon has yet to address its human health criteria in a NPDES permit decision. Ecology has also applied its regulation to protect downstream water quality standards in the Total Maximum Daily Load plan for dissolved oxygen on the Spokane River.[163] Ecology has made the same consideration of the downstream Spokane Tribe of Indians criteria in developing a PCB TMDL on the Spokane River.[164] The actions of Ecology, consistent with the state water quality standards, demonstrate that there is no basis for EPA's demand that the same toxic criteria apply in both Oregon and Washington.

EPA and federal courts have recognized that upstream states are not required to have the same water quality standards as downstream states. EPA, for example, denied a petition for rulemaking by the Ozark Chapter of the Sierra Club to establish the same criteria for states on the Mississippi and Missouri Rivers.[165] EPA made clear that upstream states are not required to adopt criteria that are the same as downstream states:

> The federal regulations state, "In designating uses of a water body and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters." 40 C.F.R. §131.10(b). **The regulations do not compel states to adopt the same criteria and uses, nor do they suggest that this is the only way a state can meet these requirements. The water quality program is structured to provide states with flexibility to determine the best way to meet their obligations under § 131.10(b).**

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[161] EPA, Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions, EPA-820-F-14-001 at 6 (June 2014) ("Adoption of narrative criteria or numeric criteria (or both) that are protective of downstream waters are viable options under 40 C.F.R. 131.10(b).")(03954-03965 at 03959).

[162] Ecology, Draft Response to Downstream Waters Comments (July 2015)(addressing a NPDES permit issued in Longview)(04949-04954); *see* Ecology, Fact Sheet for NPDES Permit WA0000124 Weyerhaeuser Longview at 60 (06987-07133 at 07046); Ecology, Fact Sheet for NPDES Permit WA0000256, Georgia Pacific Consumer Products (Camas), LLC, at 35 and 60, Table 25 (March 10, 2015)(07134-07229 at 07168, 07193).

[163] EPA, Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions (03954-03965).

[164] Ecology, Spokane River PCB Source Assessment 2003-2007 (April 2011)(Ecology Pub. No, 11-03-013)(06808-06963).

[165] EPA, Decision on Petition to Publish Water Quality Standards for the Mississippi and Missouri Rivers within Arkansas, Illinois, Iowa, Kansas, Kentucky, Missouri, Nebraska and Tennessee (June 25, 2004)(available at http://www2.epa.gov/sites/production/files/2015-02/documents/sierra-club-petition-response.pdf)(06754-06807).

(Emphasis added.)[166]

In the response to the Mississippi and Missouri River petition, EPA pointed out that there is no violation of 40 C.F.R. §131.10(b) simply because upstream states rely on different risk management decisions:

> As discussed in the "Statutory and Regulatory Background" section, EPA publishes section 304(a) criteria based on a 10^{-6} risk level for carcinogens; states may select a specific risk level based on their own risk management decisions. EPA believes that adoption of criteria within a risk level of 10^{-6} (one in a million incremental risk for cancer) or 10^{-5} (one in one hundred thousand incremental risk for cancer) represents an acceptable range of risk management discretion for states and tribes. Within the petition states, each state adopts criteria to protect human health based on risk management decisions. Iowa, Arkansas, Tennessee, and Nebraska have adopted PCB criteria based on a 10^{-5} risk level; Illinois, Kentucky and Missouri have adopted PCB criteria based on a 10^{-6} risk level; and Kansas chose to adopt a PCB criterion to protect human health at a 10^{-7} risk level.[167]

EPA Region 10 has advised Washington and Idaho to consider EPA decisions on other state water quality standards in the state risk management decisions.[168] EPA should do the same with respect to its proposed rule. Based on the long-standing precedent, the CWA does not require the risk policy decisions in Washington to match those in Oregon. EPA is obligated to comply with the federally approved risk policy in Washington that is well within the range of risk policies that are protective of public health. "Consistency" with the Oregon criteria is not a requirement of the CWA and is not required under 40 C.F.R. §131.10(b). As such it is not a sufficient or appropriate post-hoc rationalization for EPA to compel implementation of its preferred human health criteria in Washington.

EPA revised in 2015 its water quality standards regulations applicable to states. 80 Federal Register 51019. (August 21, 2015). EPA did not require state and authorized tribes to adopt identical standards as those of downstream states. Instead, the agency maintained the requirement that states and tribes "consider relevant provisions in section 131.10, including downstream protection…." 80 Federal Register at 51026.

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[166] *Id.* at 4 (06759).

[167] *Id.* at 18 (*citing* EPA, 2000 Methodology for Human Health Criteria) (06773). *See also* EPA, Response to Comments for Water Quality Standards; Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico, EPA-HQ-OW-2012-0095 at 4-5 (2012)(EPA approval of human health criteria for New Jersey that are less stringent that downstream water quality standards)(01072-01085 at 01075-01076).

[168] L. Macchio, Letter to D. Essig (January 20, 2015)(01086-01088).

Comment No. 15: The Relative Source Contribution value used by EPA is arbitrary and capricious.

EPA has relied in the 2022 Proposed Rule on the same Relative Source Contribution (RSC) values developed for its 2016 rule. 87 Fed. Reg. 19055. The RSC is a factor in the derivation of criteria representing the portion of exposure to a contaminant that is attributable to sources regulated by the CWA.[169] It is arbitrary and capricious for EPA to use a RSC factor of less than 1.0 in deriving the proposed criteria where it is simultaneously using a FCR that includes all fish whether or not that fish is purchased from a store or is a marine fish that does not accumulate pollutants in waters regulated by the state's water quality standards. By using a fish consumption rate that reflects the 90th to 95th percentile of tribal consumption rates that includes all fish, there is no other source of water intake or fish consumption that should be accounted for in a RSC of less than 1.0.

EPA 2014 guidance clearly states that human health considerations in deriving water quality criteria are based on the risk only from exposure to fish and drinking water:

> 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. **Thus the criteria are based on an assessment of risks related to the surface water exposure route only**.[170]

This guidance is the same as EPA set forth in the 2000 Human Health Methodology: "[Ambient Water Quality Criteria] for the protection of human health are designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and consumption of fish obtained from surface waters."[171]

EPA Region 10 has endorsed the use of an RSC of 1.0 where a state is including all salmon in its criteria development methodology. The state of Oregon applied a RSC of 1.0 in the human health criteria approved by EPA in 2012. The rationale for this risk management decision included a discussion that it is a preferred means to account for salmon consumption compared

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[169] Ecology, Overview at 21 (00027).

[170] EPA, Water Quality Standards Handbook, Chapter 3, Section 3.1.3 (2014)(available at http://www2.epa.gov/wqs-tech/water-quality-standards-handbook)(emphasis added)(06158-06215).

[171] EPA, 2000 Human Health Methodology at 1-11 (00103). *See* D. Essig, Email to C. Niemi (September 6, 2012)(06685-06688).

to a lower or fractional RSC.[172] EPA Region 10 has urged Northwest states to consider EPA action on water quality standards for other states.[173] EPA Region 10 has further endorsed the Oregon approach as "the right outcome."[174]

This endorsement is also set forth in a letter dated September 5, 2014, from EPA to the state of Idaho.[175] EPA submitted this letter to Idaho on the question of whether the state should include or partially include salmon in its consumption rate for developing human health criteria. The letter sets forth alternatives to inclusion of salmon by reducing the RSC. EPA states that an "acceptable approach to reducing the RSC is to fully include salmon consumption in the consumption rate."[176] EPA also approved the Spokane Tribe of Indians human health criteria using a RSC of 1.0 where the tribe used a historical rate of consumption.[177]

EPA should acknowledge that there is significant difference between risk assessment in other programs such as the Safe Drinking Water Act (SDWA) and Superfund Cleanup Program.[178] The SDWA uses a RSC of 20% and 80% of exposure but does so in terms of goals, not water quality criteria.[179] The SDWA is using this range of RSC for establishing Maximum Contaminant Level Goals that are not by definition regulatory limits.[180] This is in contrast to criteria in approved water quality standards that must be enforced through TMDLs and end of the pipe limits in NPDES permits.

In this instance EPA should follow its own handbook for developing water quality criteria and address risk in the proposed standards only in terms of surface water exposure through drinking water and fish consumption. Where EPA is including all fish in its proposed consumption rate, there is no basis for using a RSC value of less than 1.0.

Comment No. 16: The Arsenic criteria proposed by EPA are not based on substantial evidence and are arbitrary and capricious.

The arsenic criteria proposed by EPA for Washington are arbitrary and capricious and lack a substantial scientific basis. The proposed criteria are derived using the same methodology employed by EPA in adopting the 1992 NTR even though the agency has long understood and

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[172] Oregon DEQ, Human Health Criteria Issue Paper Toxics Rulemaking at 9 (00484). Oregon used RSC values recommended by EPA for 15 of 17 chemicals and a RSC value of 1.0 for all other non-carcinogens.

[173] L. Macchio, Letter to D. Essig (January 20, 2015)(01086-01088).

[174] C. Niemi, Handwritten Notes. ("Dennis thinks the Oregon outcome is the right outcome.")(00455-0458).

[175] L. Macchio, Letter to D. Essig (September 5, 2014)(04242-04244).

[176] *Id.* at 2 (04243).

[177] EPA, Letter approving Spokane Tribe of Indians 2010 Revision to Their Surface Water Quality Standards (December 19, 2013)(01020-01071).

[178] Ecology, Overview at 22 (00028).

[179] *Id.*

[180] *Id.; See also* Ecology, Draft Comments from Washington and Idaho on EPA 2013 Human Health Ambient Water Quality Criteria and Fish Consumption Rates FAQ (April 17, 2013)(04245-04256).

acknowledged that its approach for arsenic was not valid or appropriate in developing human health water quality standards.

On June 29, 2015, EPA published its final updates to the section 304 human health criteria.[181] The updated criteria did not include new criteria for arsenic. EPA stated in the announcement of the proposed updates in 2014, the agency did not have the ability to update the arsenic criteria due to "outstanding technical issues."[182] In responding to these comments EPA should explain the technical issues that specifically precluded an update to the section 304 criteria in June and how those issues were resolved by April 1, 2022, when EPA published the current draft rule.

EPA has publicly acknowledged that the NTR methodology for its arsenic criteria is invalid. This is indicated in the final NTR where EPA places an asterisk next to its arsenic criteria noting that it only applies to "inorganic arsenic."[183] EPA describes in its response to comments that this action reflects that only inorganic arsenic is toxic to humans.[184]

In 1997 EPA approved arsenic criteria from Alaska based on the SDWA MCL and withdrew application of the NTR criteria to the state.[185] In that action EPA stated that "a number of issues and uncertainties arose concerning the health effects of arsenic" since the adoption of the NTR.[186] EPA deemed these issues sufficiently significant to require a careful evaluation of the risks of arsenic exposure. A large area of uncertainty in the regulation of arsenic is the form of arsenic present in marine fish. EPA reported in 1997 that the form of such arsenic is typically organic and thus not relevant to establishing human health criteria.[187] The report recommends that EPA use the SDWA MCL for arsenic as the ambient water quality criteria until EPA updates its risk assessment for arsenic.[188]

In 2002 EPA adopted toxic criteria for the state of California but did not include criteria for arsenic.[189] EPA explained that this action was necessary due to the ongoing "issues and uncertainties" and contemplated revision to the SDWA MCL based on a report from the National Research Council (NRC). The NRC recommended to EPA that the MCL be reduced from 50 µg/L to 10 µg/L. EPA stated that after "promulgating a revised MCL for drinking water, the Agency plans to revise the CWA 304(a) human health criteria for arsenic in order to harmonize the two standards."[190] EPA should explain in response to these comments why it has failed to

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[181] EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health at 36987 (04808).

[182] EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update (01772-01774).

[183] *See* n. 18. NTR, 56 Fed. Reg at 60868 (00792).

[184] *Id.*

[185] EPA, Withdrawal from Federal Regulations of Applicability to Alaska of Arsenic Human Health Criteria, 62 Fed. Reg. 27707 (May 21, 1997)(04803-04806).

[186] *Id.* at 27708 (04804).

[187] EPA, Arsenic and Fish Consumption at 2-5 (December 3, 1997)(05043-5062 at 05046-05049).

[188] *Id.* at 1 (05045).

[189] EPA, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California, 65 Fed. Reg. 31682 (May 18, 2000)(00861-00898).

[190] *Id.* at 31696 (00875).

harmonize its proposed arsenic criteria for Washington consistent with its representation that it would do so in 2002.

Nationally, about half of the states have obtained EPA approval for arsenic human health criteria based on the SDWA MCL.[191]

Comment No. 17: The PCB criteria proposed by EPA are not based on substantial evidence and are arbitrary and capricious.

In response to these comments EPA should explain how it has resolved technical issues associated with deriving human health water quality criteria for polychlorinated biphenyls (PCBs) and how EPA reconciles the technical difficulties that it has acknowledged in revising PCB standards under the Toxics Substance Control Act (TSCA). EPA should also explain how it justifies such stringent water quality criteria for PCBs when it authorizes ongoing PCB generation and release to the environment under its TSCA rules and through tribal and federal hatchery operations in the state of Washington.

On June 29, 2015, EPA issued a final update to its CWA section 304(a) criteria for the protection of public health. PCBs were among the chemicals that EPA did not update due to "outstanding technical issues."[192] The scope of these technical issues is described in statements by EPA justifying its failure to revise the TSCA PCB regulations. Dennis McLerran, in a letter addressed to the Spokane River Regional Toxics Task Force through Ecology, wrote:

> Revising current regulations to reduce inadvertently generated PCBs presents both policy and scientific challenges. Before proposing more stringent regulations on the inadvertent generation of PCBs in pigments, the EPA would seek to further understand the complexities and contributions of not only pigments, but also other congeners that be present [in receiving water]….
>
> …The aggregation of PCB congeners may in some instances be problematic for risk assessment because the toxicity of different PCB congeners varies and a fixed water quality concentration for total PCBs may not adequately represent the variable toxicity of the various congeners actually present in a particular water body. While the EPA is not proposing to undertake a comprehensive analysis of the remaining PCB congeners, we are examining the characterization of PCBs in water bodies. As stated above, characterizing all of the PCBs in the EPA recommended water quality criteria for PCBs (i.e., expressed as total PCBs) is one topic we are discussing.[193]

If EPA does not have the ability for the reasons set forth in the above letter to revise PCB regulations under TSCA, it certainly does not have the ability to revise the PCB criterion adopted

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[191] Ecology, Overview at 44 (00050).

[192] EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update at 2 (01773).

[193] D. McLerran, Letter to A. Borgias (February 24, 2015)(04239-04241).

by Washington and previously approved by EPA. EPA affirmed as recently as August 3, 2015, that revising PCB regulations "presents both policy and scientific challenges."[194]

As of today, EPA has apparently concluded this work but has refused to share the information publicly. In a letter dated November 15, 2021, the acting regional administrator for EPA Region 10 announced that some portion of the work has been completed and that final report would be issued within the "next six months."[195] Despite requests for this information, EPA refuses to release the results of this work that by the agency's own representation will be used to inform the development of water quality standards.

EPA should withdraw the proposed PCB criterion as the uncertainties described above have not been addressed or resolved in the Federal Register notice. It is entirely arbitrary and capricious for the agency to conclude on several occasions that it does not have a substantial basis for revising PCB water quality criteria and then propose revised criteria for Washington that will be potentially devastating to Washington industries, local governments and continued hatchery operations. EPA failed to respond to previous comments on this issue and it is not addressed in the current rule making.

EPA also needs to explain in particular how it justifies the ongoing release of PCBs into the environment through its TSCA regulations in the context of the proposed PCB criteria. The TSCA regulations allow PCB concentrations up to 50 ppm in manufactured products. 40 C.F.R. §§ 761.3 and 761.20. This amounts to the equivalent of 50 billion pg/L allowed under TSCA compared to the EPA proposed PCB water quality criteria for Washington at 7 pg/L. EPA needs to explain how it is now "necessary" to impose water quality criteria that are seven orders of magnitude more stringent than the PCB concentrations it has found not to threaten human health or the environment under TSCA, 40 C.F.R. § 761.20.[196]

EPA needs to address this issue because even if the technology existed to consistently treat effluent down to 7 ppq. which the HDR study demonstrates does not exist, it still would be all but impossible to meet its proposed criteria due to the ongoing release of PCBs that EPA authorizes under a standard it deems adequately protective of human health under TSCA. A recent study in Washington documented the ubiquitous presence of low PCB levels in manufactured products including paints, used motor oil, road striping, dust suppressants, antifreeze, hydro-seed materials, packaging, toothpaste, hand soap, laundry soap and shampoo.[197]

For many dischargers in Washington, the EPA allowed PCB concentrations under TSCA are a significant portion of the PCBs in their effluent. For pulp and paper mills using recycled materials, PCBs in effluent can be the result of inadvertent byproducts from pigments in inks and dyes. [198] The same is true for wastewater treatment plants. In a 2015 report, Spokane County reported that PCB-11, a PCB congener associated with EPA allowed PCB concentrations, "was

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[194] L. Mann, Email to M. Macintyre at 2 (August 3, 2015)(05063-5065 at 05064).

[195] M. Pirzadeh, Letter to Doug Krapas (November 15, 2021)(08486-08487).

[196] NTR at 60868 (00792).

[197] City of Spokane, PCBs in Municipal Products (Rev.), Table B-1 (July 21, 2015)(06694-06738 at 06737-06738).

[198] D. Krapas, Slide Show "Dealing with PCBs in the Spokane River" at 3 (October 2, 2012)(06443-06463 at 06445).

measured at relatively high concentrations…in both the influent and effluent."[199] PCB-11 was the "single most abundant congener in the effluent.[200] The same study evaluated PCB concentrations from three neighborhoods predominantly developed before 1970, from 1970 to 1985 and after 1985. The study found the highest PCB concentrations from the two most recently developed neighborhoods and concluded that there is "little correlation between the year of construction and the source of PCB contamination."[201]

It is also apparent that tribal and federal fish hatcheries discharge a significant percentage of the annual PCB loading to Washington waters. EPA authorizes the operation of these hatcheries and the contamination of fish released by these hatcheries under the authority of a general NPDES permit.[202] Ecology has identified hatcheries as a significant source of PCB loading to waters of the state. Ecology has estimated that as much as ten percent of annual PCB loading to Puget Sound is attributable to returning salmon.[203]. In 2011, Ecology calculated that returning salmon contribute up to 0.3 kg/yr based on PCB residues per whole-body fish ranging from 7 µg for pink salmon to 336 µg for Chinook salmon.[204]

Ecology has also acknowledged, in addition to the PCB loading from returning salmon, that PCB contaminated hatchery fish play a significant role in section 303(d) listings for PCBs.[205] Ecology concluded that hatchery fish "may contribute to impairment and, in some cases, may cause the bulk of impairment."[206] *Id.*, at 30.

The 2006 Ecology report on hatchery fish included an analysis of skin-on fillets of pre-release rainbow trout from 11 hatcheries with PCBs concentrations ranging from <2.3 to 67 ng/g (wet weight) with an average of 13.0 ng/g (wet weight) PCBs.[207] Assuming that the fillet concentrations reflect whole-body concentrations, these concentrations corresponded to <103 to 9700 ng total PCBs per fish (using hatchery-specific average fish weights, which ranged from 83 to 678g). Other researchers have found between 39 and 59 ng/g total PCBs in whole-body juvenile Chinook salmon from six west coast hatcheries.[208] The authors concluded, "contaminated salmon may be a significant source of toxicants in the environment and in the

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[199] Brown and Caldwell, 2015 Annual Toxics Management Report Spokane County Regional Water Reclamation Facility NPDES Permit WA-0093317 at 2-18 (2015)(04861-04948 at 04896).

[200] *Id.*

[201] *Id.* at 2-27 (04905).

[202] EPA, Preliminary Draft NPDES Permit for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country, Permit No. WAG-130000 (August 2015)(06216-06319).

[203] Ecology, Control of Toxic Chemicals in Puget Sound: Assessment of Selected Toxic Chemicals in Puget Sound 2007-2011 at 93 (2011)(Ecology Pub. 11-03-055)(04297-04593 at 04391).

[204] *Id.*

[205] Ecology, Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries (April, 2006)(Ecology Pub. No. 06-03-017)(04681-04732).

[206] *Id.* at 30 (04714).

[207] Ecology, Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries (April, 2006)(Ecology Pub. No. 06-03-017)(04681-04732).

[208] L. Johnson *et al*, Contaminant Exposure in Outmigrant Juvenile Salmon from Pacific Northwest Estuaries of the United States, 124 ENVIRON. MONIT. ASSESS. 167-194 (2007)(04955-04982).

food chain."[209] A study of British Columbia hatcheries found on average 25.5 and 48.5 ng/g (wet weight) PCBs in Chinook smolts from two hatcheries and 34.9 ng/g (wet weight) in Coho smolts from a third (BC) hatchery.[210] An analysis of pre-release juvenile Chinook from eight hatcheries feeding on the Columbia River found whole body concentrations of PCBs ranging from 6.9 to 61 ng/g (wet weight), corresponding to 22 to 323 ng per fish (individual hatchery-specific average weights from 3.2 to 6.2 g).[211] An analysis of pre-release juvenile Chinook salmon from the Soos Creek hatchery on Puget Sound over a three year period found total PCB concentrations ranging from 10 to 50 ng/g (wet weight), corresponding to 90 to 125 ng PCB per fish (fish weight ranged from 2.5-9.4 g).[212] NOAA Fisheries has also documented the significant PCB concentrations in hatchery fish feed and in hatchery origin fish.[213]

Tribal and federal hatcheries are undoubtedly an increasing source of PCB loading to Washington waters. In 2010, the combined hatchery release in Washington was 229.5 million fish including 117.4 million Chinook salmon.[214] In 2015, the Northwest Indian Fisheries Commission reported that tribal hatcheries alone released 40 million salmon and steelhead.[215] EPA apparently believes that this level of PCB loading to Washington waters is consistent with applicable water quality standards and will not cause any degradation to existing beneficial uses. EPA has not sought to regulate these discharges or require any additional monitoring or best management practices in the preliminary draft general hatchery permit in Washington that will authorize tribal hatcheries to continue to release PCBs to the environment.[216]

EPA should withdraw the proposed rule and not take further action on the proposed PCB criteria until the outstanding technical issues are resolved and in light of the on-going PCB loading attributable to EPA authorization of PCB concentrations in manufactured products and in hatchery fish. EPA has concluded through TSCA and its hatchery permits that these levels of PCBs do not pose a threat to human health or the environment. It is arbitrary and capricious for EPA to then turn around and impose more draconian PCB water quality standards as necessary to protect human health.

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[209] *Id.*

[210] Kelly et al., Persistent Organic Pollutants in Aquafeed and Pacific Salmon Smolts from Hatcheries in British Columbia, Canada, 285 AQUACULTURE 224-233 (2008)(08488-08497).

[211] Johnson et al., Contaminant Concentrations in Juvenile Fall Chinook Salmon from Columbia River Hatcheries, 72 N. AMERIC. J. AQUACULTURE73-92 (2010)(08498-08517).

[212] Meador et al., Bioaccumulation of Polychlorinated Biphenyls in Juvenile Chinook Salmon (Oncorhynchus Tshawytscha) Outmigrating through a Contaminated Urban Estuary: Dynamics and Application, 19 ECOTOXICOLOGY141-152 (2010)(08518-08530).

[213] NOAA Fisheries, Draft Environmental Impact Statement on Two Joint Tribal Resource Management Plans for Puget Sound Salmon and Steelhead Hatchery Programs, Appendix K: Chemicals Used in Hatchery Operations (2014)(04257-04273).

[214] The Role of Hatcheries in North American Wild Salmon Production, The Great Salmon Run: Competition Between Wild and Farmed Salmon, Table IV-1 at 44 (06739-06752 at 06740).

[215] Northwest Indian Fisheries Commission, Tribal Natural Resources Management, A Report from the Treaty Tribes in Western Washington at 4 (2015)(06530-06545 at 06533).

[216] EPA, Preliminary Draft NPDES Permit for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country (06216-06319).

Comment No. 18: The proposed methylmercury criterion is arbitrary and capricious and not supported by substantial evidence.

EPA should defer action on a methylmercury criterion (MeHg) for the state of Washington. EPA is proposing to adopt a fish tissue concentration criterion of 0.033 mg/kg (wet weight). This value is derived from the outdated basis for the EPA 2001 recommended criteria for methylmercury.[217] EPA has acknowledged unresolved technical issues and delayed action on updating this value in the 2015 recommended updated human health water quality criteria.[218] EPA should acknowledge technical problems with the 2001 recommendation and defer any action on adopting this criterion as applicable to Washington.

Washington already has in place criteria for mercury based on human health protection that are more stringent than the NTR criteria. [219] The NTR criteria are 0.14 µg/L (organisms and water) and 0.15 µg/L (organisms only), 40 C.F.R. § 131.36(b), compared to the Washington chronic freshwater criterion of 0.012 µg/L, WAC 173-201A-240, Table 240(3). There is no justification for EPA to impose a flawed criterion on the state of Washington when there is already in place a human health based criterion that is fully protective of human health.

Ecology has previously identified to EPA the numerous technical difficulties it will have in implementing the EPA tissue based criterion.[220] These include unresolved technical issues regarding:

- Mixing zones
- Variances
- Field sampling recommendations
- Assessing non-attainment of fish tissue criteria
- Developing TMDLs for water bodies impaired by mercury
- Incorporating methylmercury limits into NPDES permits.[221]

Ecology has explained to EPA that the EPA guidance on implementing the flawed 2001 criterion does not address these outstanding issues.[222] EPA has not responded to these concerns or explained in the Federal Register notice how the state and regulated community in Washington can feasibly implement the proposed methylmercury criteria. EPA should accordingly withdraw the proposed MeHg criterion and take no further action on establishing a MeHg criterion for Washington until the recognized technical issues with outdated and flawed 2001 criterion are resolved.

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[217] Ecology, Overview at 50 (00056).

[218] EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health (04807-04810) and EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update (01772-01774).

[219] Ecology, Overview at 49 (00055).

[220] Ecology, Overview at 50 (00056).

[221] Ecology, Overview (00001-00073).

[222] *Id.*

Additionally, even if the 2001 national criterion was still valid, EPA's proposed MeHg fish tissue criterion of 0.033 mg/kg (wet weight) is not. It is overly conservative and unattainable in Washington (and the rest of the United States) as the levels of mercury in fish are consistently higher than the proposed criterion.

EPA derived the proposed criterion following the methodology used to develop the national criterion but changed two key variables in the exposure assumptions: (1) the body weight from 70 kg to 80 kg; and (2) the fish consumption rate of 17.5 g/day to 175 g/day. As discussed in our previous comments, EPA's fish consumption rate of 175 g/day is not defensible and results in overly stringent criteria not only for MeHg, but for PCBs and other pollutants. EPA offers no information or evidence that the nationally-recommended MeHg fish tissue criterion of 0.3 mg/kg would ***not be*** protective of residents in Washington, even tribal groups with relatively high fish consumption rates, assuming the issues previously discussed can be and are resolved. This is not surprising as there is no support in the technical literature that human health would be adversely affected if residents consumed fish having an average MeHg concentration of 0.3 mg/kg. There likewise can be no scientific evidence supporting the assumption that consuming fish—even at moderate to high ingestion rates—with tissue concentrations exceeding 0.033 mg/kg causes, or is likely to cause, adverse health effects.

There also is controversy surrounding the reference dose for MeHg (0.1 µg/kg/day) used in deriving the national and Washington criterion. The National Academy of Science selected this value based on a Faroes Island study. [223] Island residents consumed both fish and pilot whales, and subtle effects were observed in some children. In addition to mercury, the pilot whales contained elevated levels of chlorinated, recalcitrant pollutants. These confounders were not appropriately considered in establishing the mercury reference dose. The most comprehensive study on potential health effects of mercury in children is the Seychelles Island study.[224] In that study, women of childbearing age consumed fish having mercury levels higher than most fish species in the United States and there was no evidence of developmental or neurological adverse effects in the children studied from birth to age five.

Significantly, the proposed MeHg fish tissue criterion is well below observed concentrations of mercury in several fish species collected in Washington waters as documented in various studies.[225] For example, the median concentration of mercury in 97 fish samples collected and analyzed in 2004 and 2005 was 0.154 mg/kg (wet weight), five times the proposed MeHg criterion. A study conducted by USGS in Franklin D. Roosevelt Lake and the upper Columbia River basin reported the mean and minimum mercury concentrations in walleye, smallmouth bass, and rainbow trout, all of which were four to five times higher than EPA's

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[223] National Academy of Science, Toxicological effects of methylmercury. Committee on the Toxicological Effects of Methylmercury, Board on Environmental Studies and Toxicology, National Research Council. National Academy Press (2000)(07570-07934).

[224] Davidson, et al., Effects of Prenatal and Postnatal Methylmercury Exposure from Fish Consumption on Neurodevelopment: Outcomes at 66 months of Age in the Seychelles Child Development Study. 280 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 701–707 (1998)(07349-07355).

[225] Ecology, Washington State Toxics Monitoring Program: Contaminants in Fish Tissue from Freshwater Environments in 2004 and 2005 (2007)(Publication No. 07-03-024)(available at www.ecy.wa.gov/biblio/0703024.html)(07356-07390).

proposed criterion.[226] The walleye mean and minimum fillet concentration was 0.33 mg/kg and 0.11 mg/kg, respectively; the smallmouth bass mean and minimum fillet concentration was 0.28 mg/kg and 0.17 mg/kg, respectively; and the rainbow trout mean and minimum fillet concentration was 0.20 mg/kg and 0.16 mg/kg, respectively. From a national perspective, for predator (game fish) species for all states combined, the median mercury concentration was 0.285 mg/kg. The 5th percentile concentration was 0.059 mg/kg.[227] Based on these data, adoption of the proposed criterion would lead to widespread and pervasive water quality impairment in Washington streams, rivers, and lakes. The economic impact would be staggering, while the human health benefit would likely be none.

Indeed, the proposal could result in adverse health impacts if people reduce their consumption of fish because of this criterion. The health benefits of eating fish are well-documented relative to the potential risks of contaminants in the fish.

> For major health outcomes among adults, based on both the strength of the evidence and the potential magnitudes of effect, the benefits of fish intake exceed the potential risks. For women of childbearing age, the benefits of modest fish intake, excepting a few selected species, also outweigh risks. [228]

Before proposing an unattainable human health fish tissue criterion, EPA should carefully evaluate the voluminous information regarding the health benefits of consuming fish. The proposed overly-conservative MeHg criterion value of 0.033 mg/kg is misleading to the public and implies that the potential risks of mercury in fish (even at such a low level) outweigh any health benefits. The health benefits are predictable and supported by numerous studies, whereas the adverse effects assumed by EPA are highly speculative and largely theoretical.

Finally, EPA also fails to discuss or consider the protective effect selenium has on potential mercury health effects although many toxicologists have advocated that traditional risk assessments of mercury in fish without concomitant information on tissue selenium levels is scientifically flawed and misleading.[229] Recent reports have explained the mechanisms of this protective effect.[230] When the molar ratio of selenium to mercury in fish tissue exceeds 1.0 in

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[226] United States Geological Survey, Concentrations of Mercury and Other Trace Elements in Walleye, Smallmouth Bass, and Rainbow Trout in Franklin D. Roosevelt Lake and the Upper Columbia River, Washington, 1994 USGS Open-File Report 95-195 (1995)(available at http://pubs.er.usgs.gov/publication/ofr95195)(07391-07429); *See also* Munn and Short, Spatial Heterogeneity of Mercury Bioaccumulation by Walleye in Lake Roosevelt and the Upper Columbia River, Washington. 126 *TRANSACTIONS OF THE AMERICAN FISHERIES SOCIETY* 477–487 (1997)(07935-07946).

[227] EPA, Report on the Environment: The National Study of Chemical Residues in Lake Fish Tissue (2009)(EPA-823-R-09-006)(07430-07433).

[228] Mozaffarian and Rimm, Fish Intake, Contaminants, and Human Health: Evaluating the Risks and the Benefits, 296 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1885 at 1885 (2006)(07434-07449 at 07434).

[229] Zhang, et al., New Insights into Traditional Health Risk Assessments of Mercury Exposure: Implications for Selenium, 48 ENVIRONMENTAL SCIENCE & TECHNOLOGY 1206 (2014)(07947-07953).

[230] Ralston and Raymond, Dietary Selenium's Protective Effects Against Methylmercury Toxicity, 278 TOXICOLOGY 112 (2010)(07954-07959).

freshwater and marine fish, a protective effect can be assumed.[231] EPA should evaluate the selenium/mercury molar ratios in fish from Washington waters and use this information to assess the need for a human health MeHg fish tissue criterion 10 times more stringent than the nationally recommended MeHg criterion.

Comment No. 19: EPA has improperly used Bioaccumulation Factors rather than Bioconcentration Factors in deriving the proposed criteria.

As part of the process of updating the national human health water quality criteria in 2014, EPA proposed to alter its prior convention of using BCFs to represent bioaccumulation in the criteria derivation equation and instead used modeled BAFs calculated via the EPI Suite software package. In finalizing the human health criteria guidance in 2015, EPA apparently departed from strict reliance on the EPI Suite model and chose to select a value representing bioaccumulation (a BAF or BCF) for each substance using a decision tree published in a 2003 technical document (i.e., Figure 3-1 from EPA-822-R-03-030, December 2003). That decision-tree and information in the chemical-specific criteria support documents suggest that EPA selected BAFs or BCFs for criteria derivation from either measured or predicted BAFs or BCFs from laboratory or field studies.

A considerable body of science exists concerning the accumulation of substances in fish tissue and the choice of a BAF or BCF can have a large influence on the calculated criteria value. Moreover, it is widely recognized that BAFs and BCFs are influenced by several local environmental factors (e.g., food web structure, water temperature, dissolved carbon). Therefore, it is important to understand the basis for EPA's selection of a specific BCF or BAF so that states, the public, and the regulated community may consider the appropriateness of the choice for a particular situation and allow states to modify the national BCF or BAF such that it better represents state-specific conditions.

Unfortunately, the technical documentation issued with EPA's updated 2015 criteria is wholly insufficient to allow technical comment on EPA's selection of BAFs or BCFs, and whether those are appropriate for Washington. This is because EPA has not provided sufficient detail about the origin of the BAF or BCF data upon which the selected value is based nor has EPA provided the specific procedures and choices the agency used to derive the BAF or BCF that was ultimately selected for criteria derivation. This lack of transparency in describing the origin of the BAFs and BCFs violates the APA because it effectively prohibits substantive comment on the technical merits of EPA's choice of a national value and on the appropriateness of that value in specific states or water bodies, such as those EPA is proposing for Washington.

To be transparent, EPA should produce a technical document that clearly identifies the specific procedures used to select each BAF or BCF value and present the data in a manner such that interested and affected parties can reproduce and evaluate EPA's calculations.

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[231] Peterson, et al., How Might Selenium Moderate the Toxic Effects of Mercury in Stream Fish of the Western U.S.?, 43 ENVIRONMENTAL SCIENCE & TECHNOLOGY 3919 (2009)(08531-08537).

The criteria proposal challenges Ecology's 2016 justification for choosing to use BCFs rather than EPA's then recently issued, BAFs. In their TSD (Ecology 2016) Ecology presents more than a dozen pages of history on the development of BCFs and BAFs and the science behind their calculation and use when deriving HHC. Ecology did conclude their extensive review with four brief summary points, but EPA's assertion in the proposed rule that "These justifications are not risk management decisions," 87 Fed. Reg. at 19053, is incorrect and clearly not reflective of the extensive technical justification used by Ecology in making its decision to use BCFs and not BAFs.

In contrast to the Ecology TSD, the proposed rule is completely lacking any scientific justification for reversing the EPA 2019 determination that the use of BCFs as part of the overall HHC derivation in Washington was adequate. Furthermore, EPA has only attempted to compel the use of BAFs since 2015 and even well after that date has approved state water quality standards that have maintained the use of BCFs.

If EPA is actually concerned about human health criteria based on sound scientific principles, it would defer to the scientific and state-specific determination made by the State of Washington to rely on BCFs.

Comment No. 20: The draft EPA rule is arbitrary and capricious for failing to give meaningful consideration to the large potential costs of the proposed HHWQC.

The U.S. Supreme Court has clarified that EPA has broad discretion to weigh costs and benefits in implementing its regulatory statutes, and failing to do so is arbitrary and capricious unless the statutory text precludes it. *See* Michigan v. EPA, 576 U.S. 743 (2015). The CWA does not relieve EPA from this obligation, and the proposed rule fails to provide meaningful estimates of the costs that would result from the rule—and indeed assigns zero costs to the rule—and likewise does not reasonably compare the costs with the benefits likely to occur nor consider reasonable alternatives.

Comment No. 21: EPA's Economic Impact Analysis assessment of the potential impact from proposed Arsenic criteria is illusory and contrary to law.

The economic impact analysis for the proposed arsenic criteria misrepresents the baseline conditions in Washington and the well-accepted and documented understanding of ambient water quality concentrations of arsenic in Washington.[232]

In several instances, EPA has assumed that a facility in Washington has an obligation to take additional actions to comply with the existing NTR arsenic criteria. EPA is well aware that Ecology does not enforce the NTR arsenic criteria. Ecology takes this regulatory approach because the criteria are below natural background conditions and because of the weak scientific basis for the NTR criteria documented above by EPA statements and findings in the Federal

[232] *See* Economic Analysis for the Revision of Certain Federal Water Quality Criteria Applicable to Washington referenced at 87 Fed. Reg. 19058, §VI.

Register.[233] If EPA assumes that an action is required by new arsenic criteria that are based on the same flawed premises as the NTR criteria, those will be new incremental impacts imposed by EPA and not by the current regulation. Ecology has had the same approach to the NTR arsenic criteria since their adoption in 1992. EPA Region 10 has taken the same approach in the NPDES permits it administers in the state of Washington.

There is no support for EPA to assume in the economic impact analysis, twenty-four years later (close to five NPDES permit cycles), that the CWA requires a different approach. EPA should accordingly treat the substantial "baseline" compliance costs in the economic impact analysis as incremental costs under the "policy scenarios" described in the document.

The economic impact analysis incorrectly limits the evaluation of receiving water concentrations of arsenic to those circumstances where there is facility specific receiving water data. In those circumstances, EPA concludes that the applicable arsenic criteria will not be EPA proposed criteria but the ambient arsenic concentrations, and in those instances that the facility will have a "one-time" expense to apply for a variance and a nominal cost to renew that variance every five years. This approach ignores the well-recognized fact that groundwater in Washington ranges from 0.7 to over 1.0 µg/L and that surface water ranges from 0.5 to 1.5 µg/L.[234] EPA should assume that every NPDES permit discharges to a water body where the arsenic criteria are based on natural conditions not the proposed criteria. As such, EPA should acknowledge that any facility discharging to waters of Washington will likely require a variance and fully describe the basis, timing and expense of obtaining a variance.

The economic impact analysis randomly assumes that some facilities will have to install reverse osmosis treatment systems to meet the proposed criteria but that other facilities will only have to apply for a variance. It is not likely that reverse osmosis would be sufficient to meet the proposed EPA arsenic criteria. HDR, in Attachment C, has provided an analysis of treatment system capabilities. Treatment systems for ultra-low arsenic criteria would require additional treatment such as membrane filtration prior to reverse osmosis. Attachment C, 28-29, Table 4-2. EPA should provide a clear explanation as to when a facility will have to use reverse osmosis treatment. In particular, EPA should explain whether installation of reverse osmosis treatment will be required to obtain a variance. If so, the projected incremental costs in the economic impact analysis are vastly understated.

Comment No. 22: EPA's Economic Impact Analysis fails to include any assessment of compliance with proposed PCB criteria.

EPA continues to erroneously exclude the incremental cost of compliance with its proposed PCB criterion from the economic impact analysis. Available data indicates that large portions of state waters would be considered impaired under CWA section 303(d) for failing to meet the proposed PCB criteria. Available data also suggests that essentially every publicly

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[233] Ecology, Overview at 46 (00052). *See also* EPA, Final Updated Ambient Water Quality Criteria for the Protection of Public Health (04807-04810) and EPA, Human Health Ambient Water Quality Criteria: Draft 2014 Update (01772-01774).

[234] *Id.*

owned wastewater treatment plant in Washington would have the potential to cause or contribute to a violation of the PCB criteria and that the facilities will require tertiary membrane filtration treatment to address PCBs. The technology to treat for PCBs in a five Million Gallon a Day (MGD) would be membrane filtration followed by reverse osmosis, with a Net Present Value (2022 dollars) cost of $245 to $600 million as documented in Attachment C—HDR, Treatment Technology Review and Assessment, at 68, Table 4-7. EPA also needs to acknowledge, as documented in the HDR study, that there are no known combinations of treatment trains that will achieve the EPA PCB criterion. *Id*. at 1. As such, the EPA economic impact analysis must consider the impacts of all available tools that will be required to implement the EPA criterion including variance and use attainability analyses.

The economic impact analysis does not address PCBs on the pretext that (1) there is no NPDES permit monitoring results that indicate a potential to cause or contribute to violations on the PCB criteria, (2) the EPA approved test methods to determine PCB in effluent as low as the proposed federal criterion. This "head in the sand" approach to assessing the potential impact from the EPA PCB criterion ignores available data on PCB concentrations is water column data in Washington indicating ambient PCB concentrations below the current PCB criterion of 170 pg/L but above the EPA proposed PCB criterion of 7 pg/L.

EPA is well aware of PCB water column data in Ecology's Environmental Information Management (EIM) database that includes PCB water column data for Puget Sound and the major tributaries to Puget Sound. This data was collected by or for Ecology relatively recently in 2009 and 2010.[235] This report has been reviewed and that data in the report has been included in the EIM database.[236] From this report alone there are well over 12,000 PCB sampling results from Haro Strait, the Strait of Juan de Fuca, the Whidbey Basin, Main Basin, South Sound and Hood Canal.[237] This includes PCB water column data for total congeners collected at each of these sites.[238] All of the total congener data is either unqualified or J qualified. This data should have been identified and listed in the economic impact analysis.

EPA should acknowledge in response to these comments that all of the total PCB water column data from the 2011 Ecology report is above the PCB criteria proposed for Washington but below the NTR criteria. The following chart, based on water column data in the EIM database,[239] shows an average or the total PCBs for each monitoring station at the surface and at depth:

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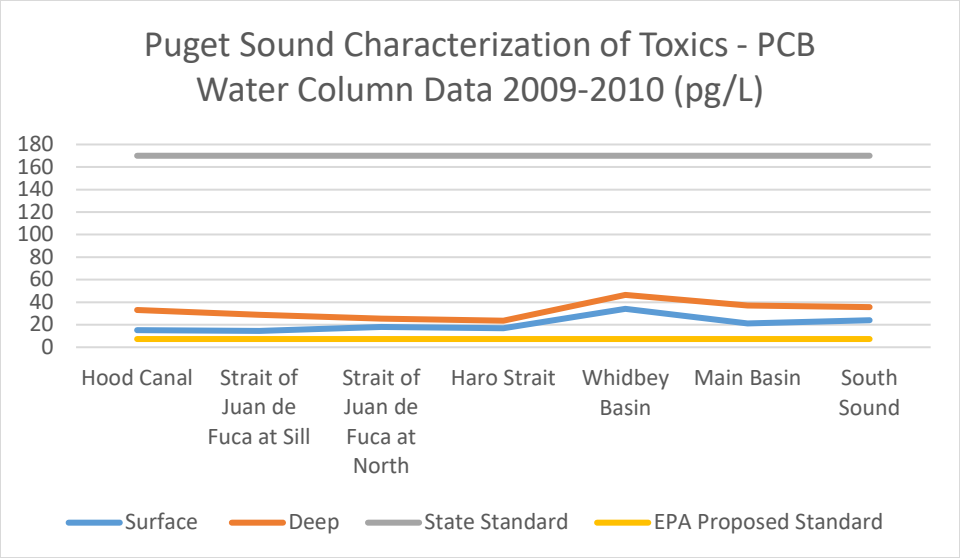
[235] Ecology, Control of Toxic Chemicals in Puget Sound: Characterization of Toxic Chemicals in Puget Sound and Major Tributaries, 2009-10 (January 2011)(available at https://fortress.wa.gov/ecy/publications/documents/1103008.pdf)(05155-05395).

[236] Ecology, Screen-shot of EIM Search Result (December 8, 2015)(available at https://fortress.wa.gov/ecy/eimreporting/Eim/EIMSearchResults.aspx?ResultType=EIMTabs&StudyName=toxic+chemicals+in+puget+sound&StudyNameSearchType=Contains)(06753).

[237] Ecology, Email re download request (07311) and attached EIM Data for Puget Sound (December 8, 2015)(05987). The attached data is limited to water column data for total PCBs.

[238] *Id.*

[239] *Id.*



It is inexplicable why EPA did not consider available data documenting that dischargers are potentially going to cause or contribute to a violation of its proposed PCB criterion. We have previously provided this data to EPA and EPA, with no explanation, has chosen to continue to ignore it in the current rulemaking. EPA made no response to comments for its final rule in 2016 to this data and it is not addressed in the current rulemaking. or the economic impact analysis filed with the 2022 proposed rule.

EPA is arbitrarily relying on discharge monitoring data knowing that such data, if collected, is based on an EPA test method with detection levels that are above its proposed PCB criterion. In doing so EPA ignored data from Ecology on wastewater treatment plants that document levels of PCB concentrations that are well above the proposed PCB criterion. In fact, every wastewater treatment plant sampled by Ecology, with the exception of two facilities with reporting levels of 600 pg/L, were well above the proposed criteria.[240]

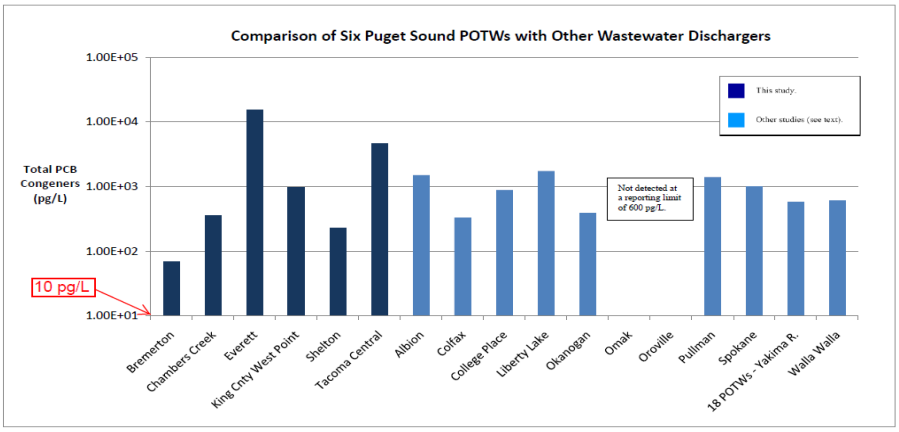


Figure 2. Comparison of Average Total PCB Results among Several POTWs

[240] Ecology, Control of Toxic Chemicals in Puget Sound Summary Technical Report for Phase 3: Loadings from POTW Discharge of Treated Wastewater, Figure 2 (December 2010)(Publication No. 10-10-057)(05746-05986 at 05811).

The failure of EPA to consider this data is inexcusable where EPA has relied on this information to perform a narrative reasonable potential analysis for three municipalities on the Spokane River. In the 20[12] Fact Sheet for the City of Coeur d'Alene wastewater treatment plant NPDES permit EPA makes the following statement regarding the data presented in Figure 2:

> PCBs have been detected in effluent from POTWs discharging to the Spokane River in the State of Washington (i.e., the City of Spokane and Liberty Lake Sewer and Water District) as well as other POTWs in Washington State operated by the Cities of Medical Lake, Okanogan, College Place, Walla, Pullman, Colfax, Albion, Bremerton, Tacoma, and Everett, and King and Pierce counties. Effluent concentrations of total PCBs at these 14 facilities (a total of 34 samples) ranged from 46.6 to 39,785 pg/L with a median concentration of 810 pg/L.[241]

The Spokane River offers a precedent for how EPA will address low PCB concentrations in NPDES permits throughout the state of Washington under its proposed PCB criterion. EPA approved water quality standards for the Spokane Tribe of Indians in 2013 that include a PCB criteria of 1.3 pg/L. In litigation regarding the obligation of EPA to develop a PCB TMDL for the Spokane River EPA has represented in federal court that year-round tertiary membrane filtration treatment is an appropriate best management practice for a wastewater treatment plant.[242]

EPA misrepresents in its rulemaking that there are no potential economic impacts related to PCB since the approved PCB test method is not sufficiently sensitive to result in compliance costs for permittees.[243] This position is entirely at odds with the position taken by EPA that NPDES permits in Idaho and Washington on the Spokane River specifically require monitoring using unapproved test method 1668C.[244] EPA has also insisted that Ecology must use all available data, including data from unapproved test methods to conduct reasonable potential analysis and to derive numeric water quality based effluent limitations. In a NPDES implementation strategy issued by EPA, the agency states:

> Monitoring requirements for PCB congeners using Method 1668C can provide quantitative data about the actual PCB loading from point sources. This represents a significant advantage over numeric WQBELs for total PCBs, which, as explained above, currently must be enforced using the far less sensitive approved analytical methods. Therefore, the EPA is recommending that the permits continue to use a BMP approach to PCB control and require the use of EPA method 1668C for monitoring of final effluents for PCB congeners, instead of

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[241] EPA, City of Coeur d'Alene Revised Fact Sheet NPDES Permit No. ID0022853 at 17 (2013)(07468-07569 at 07484).

[242] *Sierra Club v. EPA*, Case No.2:11-cv-017959-BJR Doc. No. 129-1, EPA, EPA's Plan for Addressing PCBs in the Spokane River (July 14, 2015)(06320-06350).

[243] 80 Fed. Reg. at 19058.

[244] EPA Comment Letter on City of Spokane Draft NPDES Permit, February 28, 2022 (08538-08542).

establishing numeric WQBELs enforced using methods approved under 40 CFR Part 136.

Even if the permitting authority determines that it is appropriate to include numeric WQBELs for PCBs to be enforced using methods approved under 40 CFR 136 in one or more of the subject permits, the EPA nonetheless recommends that the permitting authority include the following BMP requirements and monitoring for PCB congeners using EPA method 1668C in addition to any such numeric WQBELs.[245]

True to these representations, EPA has directed Ecology to reissue a draft permit to the City of Spokane that proposes to set a ten year compliance schedule to either optimize existing treatment or submit an engineering report to install a treatment system that will achieve the state PCB criterion designed on the basis of data collected using an unapproved test method for PCBs.[246] Regardless of whether monitoring using the only approved PCB test will show a violation of the PCB effluent limit, the facility will have to use a more sensitive and unapproved test method for the design and installation of a treatment system. EPA has made clear that the permit should include a reopener clause to adjust the final PCB limit to the EPA proposed criterion when the current rulemaking is complete.[247] Contrary to the representations in the current rulemaking, there will be enormous financial impact on public and private permittees in Washington to comply with the proposed PCB criterion.

EPA is also in the process of developing a PCB TMDL for the Spokane River. EPA Region 10 recently made a broad request for PCB data collected using unapproved test method 1668C by the Spokane River Regional Toxics Task Force for the purposes of its TMDL development.[248]

EPA should also acknowledge that Ecology has codified broad use of unapproved test methods for PCB in its Water Quality Program Permit Writers Manual.[249] Ecology has maintained in litigation challenging this action that it has the discretion to require monitoring using unapproved test methods and that it must use such data for all NPDES purposes except for compliance with a numeric effluent limit. *Northwest Pulp & Paper Ass'n v. Dep't of Ecology*, 500 P.3d 231, 239 (2021). Ecology has gone further in 2022 NPDES permitting on the Spokane River to broadly assert that it must require monitoring using the unapproved method whenever it suspects PCB in the effluent at a permitted facility and must use that data to assess the water quality treatment at the facility.[250] Regardless of whether PCB is detectable at the Spokane River

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[245] EPA, EPA's Plan for Addressing PCBs in the Spokane River, July 14, 2015, at 25-26 (06320-06350 at 06344-06345).

[246] Ecology, City of Spokane Draft NPDES Permit and Draft Fact Sheet, May 2022 (08543-08722).

[247] EPA Comment Letter on City of Spokane Draft NPDES Permit, February 28, 2022 (08538-08542).

[248] G. Johnson, EPA Region email to SRRTTF for PCB data, March 29, 2022 (08723).

[249] Ecology, Water Quality Program Permit Writer's Manual (Publication no, 92-109)(revised July 2018), Chapter 6, Section 4.5: Polychlorinated Biphenyls (PCBs)(08724-08740).

[250] See current NPDES Permits and Fact Sheets for: Kaiser Aluminum Washington, LLC; Inland Empire Paper Company; City of Spokane Riverside Park Water Reclamation Facility and Combined Sewer Overflows (CSOs); Spokane County Regional Water (Division of Utilities); and Liberty Lake Sewer and Water District (08741-09395).

facilities, Ecology has obligated itself and the permittees to ensure that the water quality treatment technology at the facilities must achieve the applicable human health criterion for PCB.

As the information provided above demonstrate, the foundation of EPA's economic impact analysis should be that most state waters will not meet the proposed criteria and that most NPDES wastewater treatment plants will, at a minimum, have to apply tertiary filtration treatment. Attachment C, at ES-3, Table ES-1, provides an incremental cost for such treatment including construction costs and operation and maintenance costs of between $53 and $82 million for a 0.5 MGD plant and net present value unit cost of between $106 and $262 per gallon per day. EPA identified 406 NPDES permits administered by Ecology including 73 "major" permits in its economic impact analysis. If EPA follows the same approach on Puget Sound that it has on the Spokane River, this will amount to a range of compliance costs from nearly $6 billion to over $11 billion just for the "major" permits identified by EPA.[251]

EPA should also address the economic impact of proposed PCB criteria on the continued operations of tribal and federal fish hatcheries. EPA should explain how it intends to regulate hatcheries that discharge to and release salmon in Puget Sound, Hood Canal, Haro Strait, and the Strait of Juan de Fuca. On what basis will EPA allow hatcheries to continue to operate knowing that they are a significant source of PCBs in waters that will be considered impaired for PCBs under the proposed criteria? Specifically, will EPA allow hatcheries to continue to use PCB contaminated feed? Will EPA allow hatcheries to release PCB contaminated fish in waters that are not meeting the water quality criteria? Will EPA allow hatcheries to "seed" tributaries to Puget Sound with fish carcasses that are contaminated with PCBs? Will EPA require monitoring and treatment for water discharges from hatcheries? Will EPA impose PCB management plans on hatcheries to identify sources of PCBs and impose a preference for non-PCB containing equipment and materials including fish feed? EPA is the NPDES permit authority for these facilities and should fully account for the economic impact of its proposed criteria on their continued operations.

The economic impact analysis should also include an assessment of the impact from potential section 303(d) PCB listings based on fish tissue. The economic impact analysis acknowledges that fish tissue data can be a basis for listing under the Ecology Policy 1-11. EPA offers no explanation as to why it failed to consider PCB fish tissue data that is available in the EIM database. This is particularly relevant as Washington is the only state in EPA Region 10 to use fish tissue data as a basis for 303(d) listings. EPA Region 10 has been adamant with Ecology that the state should not revise this policy to remove consideration of fish tissue in 303(d) listings.[252]

EPA should withhold further action on the proposed rule until it has completed an adequate economic impact analysis and provided additional opportunity for public comment on the revised economic impact analysis.

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[251] $75 MM x 73 = $5.5 Billion; $160 MM x 73 = $11.7 Billion.

[252] K. Susewind, Email to D. Opalski (March 17, 2014)(04740-04742).

Comment No. 23: The proposed rule constitutes a significant regulatory action under Executive Order 12866 "Regulatory Planning and Review" and Executive Order 13563 "Improving Regulation and Regulatory Review."

Executive Order 12866 "Regulatory Planning and Review" provides that significant regulatory actions must be submitted for review to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). E.O. 12866 58 Fed. Reg. 51,735 (October 4, 1993). A "significant regulatory action" is any regulatory action that "will likely result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order." E.O. 12866 § 3(f). As EPA notes in its Guidelines for Preparing Economic Analyses (December 17, 2010), any one of the four criteria listed can trigger a proposed regulatory action to be defined as "significant," while those meeting the first criteria are generally defined as "economically significant." EPA Guidelines for Preparing Economic Analyses § 2.1.1. OIRA, not the agency, makes the final determination of which rules are considered to be significant. E.O. 12866 § 6(a)(3)(A).

For each matter identified as a significant regulatory action the issuing agency must provide to OIRA a draft of the proposed regulatory action, along with an explanation of the need for the proposed action and how the action will meet that need, and an assessment of the potential costs and benefits of the action. E.O. 12866 § 6(a)(3)(B). For actions that fall into the § 3(f)(1) category of *economically* significant regulatory actions, issuing agencies must go further and provide OIRA with (i) an assessment, including the underlying analysis, of benefits anticipated from the regulatory action together with, to the extent feasible, a quantification of those benefits; (ii) an assessment, including the underlying analysis, of costs anticipated from the regulatory action together with, to the extent feasible, a quantification of those costs, and (iii) an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. E.O. 12866 § 6(a)(3)(C).

The principles set out in E.O. 12866 were supplemented and reaffirmed in Executive Order 13563 "Improving Regulation and Regulatory Review" E.O. 13563 76 Fed. Reg. 3821 (January 21, 2011). E.O. 13563 emphasizes that in complying with E.O. 12866 agencies must use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible (§ 1(c)), and that regulations should be adopted through a transparent process involving public participation (§ 2). Each agency is to ensure "the objectivity of any

scientific and technological information and processes used to support the agency's regulatory actions." E.O. 13563 § 5.[253]

EPA has determined that its proposed rule is not a "significant regulatory action" under E.O. 12866 and is "therefore, not subject to review under Executive Orders 12866 and 13563." 87 Fed. Reg. 19056 § VII. However, E.O. 12866 contains no requirement that the proposed regulatory action be imposed directly on a regulated entity in order to be considered a significant regulatory action. To the contrary, the entire approach of E.O. 12866 is to assess the totality of the costs and benefits of significant rules on society and the economy as a whole. As EPA well knows, it is proposing water quality standards for the State of Washington that if adopted will be translated by Ecology into enforceable limits in NPDES permits. Rather than actually assessing whether the proposed rule falls within the definition of "significant regulatory action," EPA appears to have simply decided at the outset that it did not want to categorize the proposed rule as a significant regulatory action, presumably in order to avoid the full economic analyses by OIRA required by E.O. 12866.

EPA then goes on to state that its proposed water quality standards "may" serve as a basis for development of NPDES permit limits, that Washington has NPDES permitting authority, and that the state "retains discretion in implementing standards." 87 Fed. Reg. 1960 § VII.D. EPA thus "in the spirit of Executive Order 12866" hired a consultant to evaluate potential costs to NPDES dischargers associated with state implementation of EPA's proposed rule. Again, as EPA knows, if adopted, its proposed human health criteria *will* be written into NPDES permits for the regulated community—there is nothing permissive about a state's obligation under the CWA to write EPA-promulgated water quality standards into NPDES permits administered by that state.

Under any true analysis it is clear that the proposed rule constitutes an economically significant regulatory action requiring economic analyses by OIRA. A cost analysis prepared in 2013 by HDR Engineering estimated the cost of compliance by regulated industries and local governments with the EPA proposed criteria in a range of $5 billion dollars to $11 billion dollars for just the 73 "major" NPDES permits out of 409 NDPES permits administered by Ecology. This does not include the 18 general permits administered by Ecology or federal individual and general NPDES permits administered by EPA in Washington.[254] Compliance costs would be borne not only by local governments and industries, but would also apply to federal, state, Tribal and other private fish hatchery programs in Washington. Ecology has identified returning salmon as contributing up to 10% of the PCB loadings associated with hatcheries.[255] In 2006 Ecology

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[253] Both E.O. 13563 and subsequent E.O. 13579 set forth procedures by which agencies engage in retrospective analyses of existing regulations. E.O. 13563 § 6 (05988-05990); E.O. 13579 76 Fed. Reg. 41,587 (July 11, 2011)(06363-06366). Executive Order 13610 "Identifying and Reducing Regulatory Burdens" sets out additional requirements, including public participation, for regular retrospective review efforts by OIRA. E.O. 13610 77 Fed. Reg. 28469 (May 10, 2012)(06351-06354).

[254] *See* Attachment C. HDR, Treatment Technology Review and Assessment for Association of Washington Business, Association of Washington Cities and Washington State Association of Counties (May 24, 2022).

[255] Ecology, Control of Toxic Chemicals in Puget Sound, Assessment of Selected Toxic Chemicals in the Puget Sound Basin, 2007-11 (04297-04593), and *see* Quality Assurance Project Plan for Phase 3: Characterization of Toxic Chemicals in Puget Sound and Selected Major Tributaries (November 2011)(Publication No. 11-013-055)(06618-06684).

published a report documenting the PCB loadings associated with hatcheries.[256] As illustrated by Ecology's section 401 certification for the Leavenworth Federal Fish Hatchery, this is a statewide problem.[257] EPA's proposed rule could very well have the unintended consequence of shutting down these very fish hatcheries.

The "economic analysis" that EPA had prepared "in the spirit" of E.O. 12866 is no substitute for the full economic analyses required by OIRA.[258] As but one example, E.O. 12866 requires a cost benefit analysis of feasible alternatives to the proposed rule—such as the human health criteria water quality standards adopted by Ecology and approved by EPA—and an explanation of why EPA's proposed rule is preferable to the identified potential alternative. E.O. 12866 § 6(a)(3)(C). The consideration of alternative approaches is in fact one of the key elements of the E.O. 12866 economic analysis. *See* OMB Circular A-4 (September 17, 2003) at 2,7-9.[259] The analysis "should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups." *Id.* at 8. At least one of the alternatives should be a less stringent alternative to the agency's preferred option.[260] The agency must also consider the option of deferring to regulation at the State or local level and assess whether federal regulation is the best solution. *Id*. at 6. Finally, the agency should conduct both a benefit-cost analysis and cost-effectiveness analysis. The "economic analysis" does not examine any alternatives to EPA's proposed rule. It does not include any consideration of the alternative of leaving it to Ecology to develop appropriate human health criteria. Nor does it involve either benefit-cost or cost-effectiveness analyses.

EPA should acknowledge that the proposed rule constitutes an economically significant regulatory action, and forward the proposed rule to OIRA for a full economic analysis as required by E.O. 12866 and 13563.

Comment No. 24: The proposed rule is inconsistent with concepts of federalism under Executive Order 13132.

Executive Order 13132 provides that federal agencies cannot promulgate rules with "federalism implications" unless the agency meets certain prescribed conditions. E.O. 13132, 64 Fed. Reg. 43255 (August 10, 1999). Rules with "federalism implications" have substantial direct effects on states, on the relationship between the national government and the states, or on the

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[256] Ecology, Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries (04681-04732).

[257] Ecology, Final 401 Certification for the Leavenworth National Fish Hatchery, Order No. 7192 (January 7, 2010)(04669).

[258] 87 Fed. Reg. at 19058.

[259] OMB Circular A-4 sets out OMB's guidance to agencies on the development of regulatory analysis required by E.O. 12866 § 6(a)(3)(c)(2013)(04983-05030). *See also* OIRA, Regulatory Impact Analysis: Frequently Asked Questions (FAQs) (February 7, 2011)(05031-05042); OIRA, Regulatory Impact Analysis: A Primer (05139-05154).

[260] *Id.* OIRA, Regulatory Impact Analysis: A Primer at 7 (05145); OIRA, Regulatory Impact Analysis: Frequently Asked Questions (FAQs) at 3 (05033).

distribution of power and responsibilities among the various levels of government. E.O. 13132 § 1(a).

Where a proposed rule has "federalism implications" the agency must adhere to particular criteria. *Id.* § 3. With respect to federal statutes and regulations administered by the states, agencies must grant the states the maximum administrative discretion possible; encourage states to develop their own policies to achieve program objectives and work with appropriate officials in other states; where possible, defer to the states to establish standards; in determining whether to establish uniform national standards, consult with appropriate state and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve state prerogatives and authority; and where national standards are required by federal statutes, consult with appropriate state and local officials in developing those standards. *Id.* § 3 (c), (d). Where the agency action will limit the policymaking discretion of the states it may only be taken where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. *Id.* § 3(b). Where there are significant uncertainties as to whether that national action is authorized or appropriate, agencies must consult with appropriate state and local officials to determine whether federal objectives can be attained by other means. *Id.*

Where the proposed rule has federalism implications and also either preempts state and local law, or imposes substantial direct compliance costs on state and local governments and is not required by statute, E.O. 13132 sets forth specific consultation requirements. *Id*. § 4, 6(b), (c). But even where there is neither preemption nor substantial compliance costs, if the proposed rule has federalism implications EPA must consult to the extent practicable with either elected officials or other representatives of state and local governments. *See* EPA's Action Development Process--Guidance on Executive Order 13132: Federalism (November 2008) at 8. This includes at a minimum consultation with the "Big 10," a list of ten national organizations representing state and local governments.[261] *Id.* Attachment C, at 45-46.

In fact, EPA's internal policy is broader than E.O. 13132: even if a proposed rule does not have federalism implications, "if it has any adverse impact on state and local governments above a minimal level" then EPA must, at a minimum, consult early with appropriate state and local government representatives, and set forth in the preamble to the rule why E.O. 13132 did not apply, any consultation that occurred, the nature of state and local government concerns, and how EPA addressed those concerns or why EPA decided not to implement the changes suggested. *Id.* at 11.

Contrary to EPA's statement in the proposed rule, the rule does have federalism implications and E.O. 13132 does apply. 87 Fed. Reg. 19060 § VII.E. EPA purports to promulgate the rule pursuant to CWA § 303(c)(4)(B), stating that it is making a "determination of necessity" that Washington's existing human health criteria are not protective of the applicable designated uses, and thus that EPA must promulgate new or revised human health

[261] The "Big 10" organizations include the National Governors' Association, National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, International City/County Management Association, National Association of Towns and Townships, County Executives of America, and Environmental Council of States. EPA's Action Development Process – Guidance on Executive Order 13132: Federalism (November 2008) (06047-06106); Attachment C at 45-46.

criteria for Washington. 87 Fed. Reg. 19051 § IV. Yet EPA also acknowledges that Washington's existing human health criteria were promulgated by EPA—not Washington—in the NTR. 87 Fed. Reg. 19050 § III. EPA did so pursuant to a 1992 determination of necessity. NTR, 57 Fed. Reg. 60848, 60856-60860, 60868.

Under the CWA, states are assigned the primary authority for adopting water quality standards, and once adopted, new or revised standards are submitted to EPA for review and approval or disapproval. CWA §§ 303(a), 303(c)(2)(A), 303(c)(3); 40 C.F.R. § 131, 131.5(a). *See PUD No. 1 of Jefferson Cty. v. Wash. Dep't of Ecology,* 511 U.S. 700, 704 (1994); *Pronsolino v. Nastri*, 291 F.3d 1123, 1127 (9th Cir. 2002); *Natural Res. Def. Council, Inc. v. U.S. E.P.A.*, 16 F.3d 1395, 1400 (4th Cir. 1993). EPA could, and under the CWA should, have waited until Ecology promulgated its final rule and submitted that rule to EPA for approval or disapproval pursuant to the CWA. Instead, in December 2014, after Ecology issued its draft rule but before it promulgated its final rule, EPA chose to begin its own rulemaking process. EPA clearly did so because the risk policy adopted in Ecology's draft rule was not EPA's preferred policy. As explained above, EPA ignores the flexibility afforded to states in EPA's own guidance, by insisting that the state's program conform to EPA's preferred approach. EPA's actions are contrary to the cooperative federalism Congress included in the CWA, and the proposed rule would fundamentally alter the state's discretion to make risk management decisions under the CWA.

Because the proposed rule has "federalism implications," E.O. 13132 applies here. EPA's statement that E.O. 13132 does not apply, but that "in the spirit" of E.O. 13132 it is soliciting comments on the proposed rule from state and local officials, is insufficient. *See* 87 Fed. Reg. 19060 § VII.E. EPA's promulgation of the proposed rule is directly contrary to the criteria laid out in E.O. 13132, and the agency has also failed to comply with the Order's consultation provisions. At a minimum, EPA should acknowledge that E.O. 13132 applies to the rule and should comply with the executive order's requirements.

Comment No. 25: The proposed rule fails to consider the increased energy demands required for water quality treatment under Executive Order 13211 "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use."

Pursuant to Executive Order 13211, a "significant energy action" is one that promulgates, or is expected to lead to the promulgation of, a final rule that is a significant regulatory action under E.O. 12866, and likely to have a significant adverse effect on the supply, distribution or use of energy or is designated by the Administrator of OMB/OIRA as a significant energy action. E.O. 13211, 66 Fed. Reg. 28355 (May 22, 2001). For significant energy actions, the federal agency must prepare a Statement of Energy Effects and submit the Statement to OIRA. E.O. 13211 § § 2, 3. The statement, or a summary, must be included in the proposed and final rulemaking notices published by the agency. *Id*. § 3(b). A Statement of Energy Effects is a detailed statement that includes information on any adverse effects on energy supply, distribution, or use, and reasonable alternatives to the action along with the expected effects of such alternatives on energy supply, distribution, or use. *Id.* § 2(b).

EPA's sole reference to E.O. 13211 is, yet again, a conclusory statement with no support: "This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866." 87 Fed. Reg. 19060 § VII.H. As explained in Comment No. 22, the proposed rule is a significant regulatory action under E.O. 12866. Moreover, it will likely have a significant adverse effect on the supply, distribution or use of energy. HDR estimated an increased energy demand of 39.7 MWh/day for membrane filtration treatment.[262] If applied to just the 73 "major" NPDES permits identified by EPA, this is an increase in energy demand that requires review under the Executive Order.

EPA should not take further action on the rule until it has completed this analysis and provided an opportunity for public comment on the analysis.

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[262] *See* Attachment C at 61, Table 4-5.