

NORTHWEST PULP & PAPER ASSOCIATION
COMMENTS ON DRAFT
HUMAN HEALTH WATER QUALITY CRITERIA
FOR THE
STATE OF WASHINGTON
March 23, 2015

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**NORTHWEST PULP & PAPER ASSOCIATION COMMENTS ON
DRAFT HUMAN HEALTH WATER QUALITY CRITERIA
FOR THE STATE OF WASHINGTON**

March 23, 2015

The Northwest Pulp & Paper Association (NWPPA) submits the following comments on the Department of Ecology proposed amendment to WAC 173-201A to adopt human health toxics criteria and to adopt clarifying language and new language related to implementation tools for implementing the state surface water quality standards. NWPPA requests that these comments and the documents referenced in and submitted with these comments be included in the administrative record for the rulemaking.¹

Introduction

NWPPA believes the Department of Ecology's human health proposal is protective of Washington's most sensitive beneficial uses and is *in total* defensible under the federal Clean Water Act. NWPPA in general supports the Department's use of policy discretion to develop these proposed human health water quality criteria (HHC). The proposed criteria for most chemicals addressed in the rulemaking are significantly more stringent than the criteria currently applicable in Washington. The more stringent standards will undoubtedly impact NWPPA facilities as analytical testing methodologies become more sensitive in future permitting decisions.

NWPPA believes that the complete package, taken as a whole, makes logical sense but could be improved in several key areas and we make our comments in the spirit of improving the rule package, making it both workable and defensible. NWPPA's general support is not without concern regarding several highly conservative assumptions that Ecology makes in its risk management decisions. Our concerns also apply to a Washington rule package containing both numeric criteria and comprehensive implementation tools being submitted to the Environmental Protection Agency for final approval. NWPPA believes the implementation tools could be fine-tuned to more fully extend their necessary role in advancing water quality improvement in Washington. These issues are noted below along with our overarching concern that if Ecology were to revise its risk management decisions, it must carefully consider the cost-benefit analysis of the rule and its implementation plan. More importantly, if Ecology reconsiders its risk management decisions, it must provide an explanation for adopting criteria that are more stringent than the current National Toxic Rule criteria and EPA guidance for deriving human health criteria.

¹ NWPPA is providing a CD with the cited documents in these comments with the exception of case law, statutes and regulations. The cited documents on the CD are number stamped with the corresponding number provided within the footnote.

NWPPA commends Ecology for engaging in a thorough and transparent process through public meetings, the policy forum and delegate table process which commenced in 2012. These efforts afforded all those with an interest in this rulemaking an opportunity to understand the requirements of the Clean Water Act, the available technical and scientific data and the basis for policy decisions made in developing the rule. Ecology amplified this process through its willingness to meet with stakeholders, the announcement of the Governor's policy direction in July 2014 and in the release of a preliminary draft rule in September 2014. Ecology has further complied with its obligations by setting forth the rationale for risk management decisions provided in the explanatory material accompanying the draft rule.²

Rulemaking Requirements

Comment No. 1: State Rulemaking Requirements.

The adoption of HHC is subject to the significant legislative rule requirements of the state Administrative Procedures Act (APA). RCW 34.05.328. These include the following³:

- Statement of general goals and objectives. A detailed statement of the general goals and objectives of the statute that the rule implements. RCW 34.05.328 (1)(a).
- Statement of necessity and alternatives analysis. A determination that the rule is necessary to achieve the general goals and specific objectives, an analysis of alternatives to rulemaking, and analysis of the consequences of not adopting the rule. RCW 34.05.328 (1)(b).
- Preliminary and final cost-benefit analysis. A preliminary cost-benefit analysis must be prepared at the time a draft rule is published for public comment. A final cost-benefit analysis must be issued when the rule is adopted. RCW 34.05.328 (1)(c). The cost-benefit analysis must include a determination that 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).
- Least burdensome alternative analysis. A determination, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives identified under RCW 34.05.328 (1)(a). RCW 34.05.328(1)(e).
- Justification for more stringent requirements than federal law. Ecology must determine if the rule is more stringent than federal standards. If so, Ecology must

² Ecology, *Washington State Water Quality Standards: Human Health Criteria and Implementation Tools, Overview of Key Decisions in Rule Amendment*, Publication No. 14-10-058 (January 2015)(00001-73).

³ In addition to these elements, the SLR also requires determinations that the rule does not require actions that violate the requirements of other state or federal laws, RCW 34.05.328 (1)(f), and that the rule does not impose more stringent requirements on private entities than on public entities unless required by federal law. RCW 34.05.328(1)(g).

determine that the difference is justified either by a state statute that explicitly allows the agency to differ from federal standards or by “substantial evidence” that the difference is necessary to achieve the general goals and specific objectives stated under RCW 34.05.328 (1)(a). RCW 34.05.328(1)(h).

- Implementation plan. Prior to adoption, Ecology must provide an implementation plan that describes how the agency intends to implement and enforce the rule including a description of the resources the agency intends to use, how the agency will inform and educate affected persons about the rule, how the agency will promote and assist voluntary compliance, and an evaluation of whether the rule achieves the purpose for which it was adopted. RCW 34.05.328 (3).
- Report to joint administrative rules review committee. After adopting a rule regulating the same subject matter as another provision of federal law, Ecology will be required to submit a report to the legislature identifying the existence of any overlap, duplication, or difference with federal law and making recommendations for any legislation necessary to eliminate or mitigate any adverse effects of such overlap, duplication or difference. RCW 34.05.328 (4).

The APA also requires that the Ecology water quality program identify the sources of information reviewed and relied upon by the agency in preparing a SLR. RCW 34.05.272⁴. The APA further requires that a draft rule package include a small business economic impact statement (SBEIS) that complies with RCW 19.85.040. RCW 34.05.320 (1)(j). RCW 34.05.320. The SBEIS must include an evaluation of compliance impacts on small businesses and provide a determination of whether the rule will have a disproportionate cost impact on small businesses.

A rule can be invalidated under the APA where a court determines that it is arbitrary and capricious. RCW 34.05.570 (2)(c). A rule will not be upheld if it is “willful and unreasoning and taken without regard to the attending facts or circumstances.” *Wash. Indep. Telephone Ass’n v. WUTC*, 149 Wn.2d 17, 65 (2003). Regulatory reform legislation in 1995, in findings appended to RCW 34.05.328, sets forth standards for what constitutes an arbitrary and capricious action. These standards direct courts reviewing administrative rules to “determine whether the agency decision making was rigorous and deliberative; whether the agency reached its result through a process of reason; and whether the agency took a hard look at the rule before its adoption.” Laws 1995 c 403 §1. The 1995 legislative findings include several key principles applicable to Ecology’s rulemaking:

- Rules should assure that policies are clearly understood, fairly applied and uniformly enforced.
- Rules should not impose excessive, unreasonable, or unnecessary obligations.
- Rules should not be used to establish substantial policy decisions; those decisions should be made by the legislature.

⁴ This requirement also applies to the Ecology shorelands and environmental assistance programs.

- Rules should be justified and reasonable based on common sense criteria.

In the case of the proposed human health criteria, a final rule that is consistent with the draft rule will be in compliance with these important rulemaking requirements under state law. There is considerable concern, however, if Ecology reconsiders its risk management decisions. There is no support in the record, for example, to base criteria on a high fish consumption rate and a one in one million risk level or more stringent treatment of the criteria for Arsenic, Methyl Mercury (or a conversion to methyl mercury in tissue) or Polychlorinated Biphenyls (PCBs). Any such reconsideration would require a significant review and modification of the cost-benefit analysis, implementation plan and other requirements for significant legislative rules. Any such reconsideration would also require Ecology to resubmit a notice of rulemaking and allow for public comment on any revised criteria.

Comment No. 2: Federal Requirements for State Water Quality Standards under the Clean Water Act.

In addition to the state APA requirements, Ecology must adhere to requirements of the Clean Water Act and EPA regulations for developing water quality standards. This includes meaningful public participation based on an explanation of the basis for standards. 40 C.F.R. § 131.6(b) and § 131.20(b).

The Clean Water Act assigns to the states the primary authority for adopting water quality standards. CWA § 303(a) requires that states establish water quality standards in compliance with requirements set forth in EPA's implementing regulations. CWA § 303(a), (c); 40 C.F.R. § 131. Specifically, states must adopt water quality criteria that protect all designated uses. 40 C.F.R. § 131.11(a). The criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated uses. *Id.*

Once adopted, new or revised water quality standards are submitted to EPA for review. CWA § 303(c)(2)(A); 40 C.F.R. § 131.5(a). State water quality standards submitted to EPA must include, at a minimum, 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 water quality standards, and water quality criteria sufficient to protect the designated uses. 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.

EPA's role is to then review and either approve or disapprove the state-adopted water quality standards. CWA § 303(c)(3). EPA review must involve a determination of five different factors, including whether the state has adopted water uses which are consistent with the CWA's requirements, and whether the state has adopted criteria that protect the designated water uses. 40 C.F.R. § 131.5(a). If EPA determines that the state's water quality standards are consistent with these five factors, EPA must approve the standards. 40 C.F.R. § 131.5(b). The language of the CWA is clear: If EPA determines that the standards meet the requirements of the Act, the water quality standards "*shall* thereafter be the water quality standard for the applicable waters of

that state.” CWA § 303(c)(3) (emphasis added). Under the Clean Water Act (CWA)⁵, states have primary responsibility for establishing water quality standards.⁶

Risk Management

Comment No. 3: The Fish Consumption Rate used in the proposed HHC exceeds the requirements of the CWA and recommendations in EPA guidance.

NWPPA does not object to the fish consumption rate (FCR) used by Ecology to derive HHC in the specific and limited context of overall risk management decisions made for the rule. The 175 grams per day FCR proposed by Ecology far exceeds the FCR used by any state to derive HHC with the exception of the FCR used by Oregon in its 2012 HHC.⁷ It is important to note that Ecology is taking a conservative approach that exceeds the requirements of the Clean Water Act and EPA guidance. In the event Ecology is required to reconsider its overall risk management decisions or its risk management decisions associated with any specific chemical, Ecology also should reconsider the conservative assumptions used to develop the FCR.

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 intake rate. EPA guidance recommends a default fish intake rate of 17.5 grams a day to protect the general population.⁸ 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.”⁹

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 17.5 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

⁵ 33 U.S.C. § 1313(c)(2)(A) (Section 303).

⁶ EPA, *Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health*, EPA-822-B-00-004, at 1-4 (October 2000)(00074-00258). Water quality standards consist of designated uses of a waterbody and water quality “criteria,” 33 U.S.C. § 1313(c)(2)(A) (also referred to as “ambient water quality criteria”), along with an anti-degradation statement, 40 C.F.R. section 131.6. Criteria, as used in section 1313(c)(2)(A), refer to chemical-specific concentrations, toxicity levels, or narrative statements representing a quality of water that, if not exceeded, support a particular use of a waterbody. 40 C.F.R. § 131.3 (“Definitions”). The term “criteria” is used in a different sense in section 304(a) of the CWA. “[I]n Section 304(a) the term criteria is used to describe the scientific information that EPA develops to be used as guidance by States, authorized Tribes and EPA when establishing water quality standards pursuant to 303(c).”

⁷ Ecology, *Fish Consumption Rates & Risk Levels for Carcinogens Used in Human Health Criteria Calculations*, (November 5, 2013)(00259-00267).

⁸ See n.2, at 15.

⁹ See n.6, at 4-27.

populations including subsistence fishers.¹⁰ 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.”¹¹

The fish consumption rate of 175 grams a day used by Ecology is ten times the 90th percentile consumption rate established by EPA guidance for the general population. Ecology describes the 175 g/day FCR as an “endorsed value” by EPA and several tribes.¹² There are several instances where EPA Region 10 made this clear to Ecology including meetings on March 20, 2013, and on March 11, 2014.¹³ Ecology has heard from Northwest Tribes including the Northwest Indian Fisheries Commission that Washington should use the 175 grams a day consumption rate to set standards.¹⁴ NWPPA has not been able to determine any basis for the use of an endorsed value over national guidance or locally available data to establish a fish consumption rate for use in deriving human health criteria.

More than an endorsed value, however, Ecology should acknowledge that 175 grams a day is based on the average to 90th percentile of tribal consumption rates. Oregon developed the 175 grams a day FCR using the same consumption studies relied on by Ecology in the Fish Consumption Technical Support Document Version 2.0 (January 2013) (TSD) 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).¹⁵

¹⁰ EPA, *Fish Consumption And Environmental Justice, A Report Developed From The National Environmental Justice Advisory Council Meeting of December 3-6, 2001*, at 28 (November 2002)(00268-452). (“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.”)

¹¹ D. Essig, Email to S. Kirsch (April 5, 2013)(00453-454).

¹² See n.2, at 17.

¹³ 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.”)(00455-458); K. Susewind to D. Opalski, Email (March 11, 2014)(00459-461). (175 grams a day at one in one million risk level stated by EPA Region 10 staff to be a “baseline for environmental justice.”); D. McLerran, Personal Communication to NWPPA Members (April 9, 2013)(175 grams a day is a compromise and acceptable number).

¹⁴ F. Wilshusen, Email (March 18, 2014)(00462); M. Grayum, Letter (January 31, 2014)(00463-475).

¹⁵ Oregon DEQ, *Oregon Human Health Criteria Issue Paper Toxics Rulemaking*, at 9 (May 24, 2011)(00476-559).

The following table from the TSD summarizes the consumption rates from Tribal studies. The 175 grams per day FCR proposed by Ecology 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 “outliers.”¹⁶ Oregon DEQ reported 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.”¹⁷

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

Sources: Adapted from Polissar et al., 2012, Table E-1. Data for recreational fishers is from Table 3, Technical Issue Paper: *Recreational Fish Consumption Rates* (Ecology, 2012). General population data are for consumers only, as opposed to per capita. See Chapters 4 and 6.

Ecology affirmed that 175 grams a day is a conservative FCR in a subsequent analysis of this data. In a report dated October 3, 2013, the data was analyzed for a hypothetical combination of the Puget Sound Tribes.¹⁸ This analysis calculated the median Tribal consumption rate to be 127.2 g/day for all seafood.¹⁹

Arcadis also developed a composite distribution of Washington Tribal consumption rates based on the TSD data.²⁰ That distribution calculates the median, 90th and 95th percentiles for Tribal consumption rates to be 55.05, 137.77 and 178.69 grams per day.²¹ Under this analysis, Ecology is proposing criteria based on FCR that exceeds the 90th percentile and is slightly less than the 95th percentile of Tribal consumption rates.

¹⁶ Oregon DEQ, *Human Health Focus Group Report Oregon Fish and Shellfish Consumption Rate Project*, 10-12 (June 2008)(00560-631).

¹⁷ *Id.*, at 12.

¹⁸ N. Polissar and D. Hippe, *Fish Consumption Rates for a Hypothetical Combination of Puget Sound Tribes* (October 31, 2013)(00632-657). In a technical appendix the authors of this study documented that the mean body weight of Puget Sound Tribes in the study was between 79 and 82 kg. See Technical Appendix, at 2 (October 31, 2013).

¹⁹ *Id.*, Table A at 2.

²⁰ Arcadis, *Derivation of Alternative Human Health Risk-Based Ambient Water Quality Criteria Using Probabilistic Methods for the State of Washington*, Attachment A at 6 (February 4, 2014)(00658-723).

²¹ *Id.*

Ecology has taken a highly conservative approach by deriving human health criteria on a FCR that certainly exceeds the median consumption rates of all fish by Tribes and is close to or exceeds the 90th percentile of Tribal consumption rates. By any analysis, Ecology has selected a FCR that is “representative of highly exposed populations.”²²

Comment No. 4: The proposed Fish Consumption Rate is conservative by including all fish and not limiting the rate to fish that are actually exposed to pollutants in waters of the state.

The Clean Water Act and EPA regulations require human health water quality criteria 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 17.5 grams a day in EPA guidance thus reflects freshwater/estuarine fish and shellfish only.²³ The range of consumption rates in the 2000 EPA guidance similarly do not include marine fish.²⁴

Ecology has made a highly conservative risk management decision to include all “fish and shellfish” including all salmon, restaurant, locally caught, imported and other sources of fish.²⁵ Ecology has noted data that some Puget Sound salmon have a higher level of concentrations of specific pollutants over other West Coast salmon.²⁶

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.²⁷ Including all salmon in the fish consumption rate is not likely to benefit public health for contaminants that are accumulated in marine waters beyond the jurisdiction of the state.²⁸

Ecology could have reasonably excluded salmon from the FCR of its HHC. If Ecology excluded anadromous fish from the Tribal consumption rates, the median consumption rate documented for Puget Sound Tribes is 80.4 g/day – less than half of the FCR used by Ecology

²² C. Niemi, Email to K. Susewind (November 20, 2013)(00724-725).

²³ See n.6 at 4-25 (EPA default fish consumption rates represent the ingestion of “freshwater and estuarine fish”).

²⁴ Id., at 4-25; 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.”)(00726-727).

²⁵ See n.2, at 17.

²⁶ See n.2, 15-17.

²⁷ 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) (00728-740), see also NCASI, *Comments on Proposed Human Health Criteria and Implementation Tools Rule Proposal*, Attachment 1 at 2 (March 4, 2015) (00741-767).

²⁸ Id.

for the proposed criteria.²⁹ The Arcadis analysis calculated the “non-salmon” median consumption rate for Washington Tribes at 29.73 g/day.³⁰ Ecology could have reasonably apportioned salmon in consumption studies 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. Ecology did this in the 2013 statistical analysis of the data. That analysis calculated the median consumption rate for all seafood and the portion of anadromous fish intake at 108 grams per day.³¹ The Arcadis analysis calculated a Washington Tribal consumption rate with apportioned salmon with the median rate of consumption under this analysis of 37.78 grams per day and the 95th percentile of 122.63 grams per day.³²

The inclusion of salmon is not required under the Clean Water Act and EPA regulations and should be seen as a very conservative approach by the state. It is a matter that should be carefully reviewed in the event Ecology undertakes a substantial revision to the overall risk management decisions.

Comment No. 5: The current risk policy in the State of Washington is intended to apply to the average consumption rate of the general population including both consumers and non-consumers.

Ecology has stated that the current risk policy for human health criteria in the state Water Quality Standards, WAC 173-201A-240(6), is intended to apply to the per capita consumption rate of the general population.³³ This was the context of the decision by EPA to extend coverage under the National Toxics Rule (NTR) to Washington. The intent and scope of the state risk policy was further confirmed by EPA in litigation before the United States Circuit Court of Appeals for the Ninth Circuit. The fact that the current risk policy applies to the per capita consumption rate of the general population should be clearly understood in the event the state criteria are disapproved and EPA undertakes to promulgate new human health criteria for the state.

Through the 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. Washington opted to use a 10^{-6} risk level.³⁴ In the context of the NTR, however, this risk level is applicable to the per capita consumption rate of the general population on the assumption that NTR criteria are protective to 10^{-4} for higher consuming subpopulations.

EPA and Washington have never assumed that the 10^{-6} risk policy set forth in WAC 173-201A-240(6) would apply to all consumers of fish. Otherwise, Washington would not have adopted, nor would EPA have approved coverage under the NTR where the criteria are based on

²⁹ See n.19.

³⁰ See n.20, at 7.

³¹ See n.29, at 18.

³² See n.30.

³³ See n.2, 19-20.

³⁴ NTR, 57 Fed. Reg. 60848-01, 60868 (00768-847); 40 C.F.R. §131.36(b)(14)(iii)(00848-860).

a range of acceptable risk levels from 10^{-6} to 10^{-4} .³⁵ EPA described this as a choice “to provide a high level of protection for the average population in order to provide what they [Washington and other states] deem adequate protection for more sensitive populations.”³⁶

The scope and intent of the 10^{-6} risk policy in WAC 173-201A-240(6) was a central issue in a challenge to a dioxin water quality improvement plan or Total Maximum Daily Load (TMDL) allocation developed by EPA for the Columbia River. The dioxin TMDL was based on the same assumptions for the dioxin criterion in the NTR, including a FCR of 6.5 g/day. The TMDL was challenged in federal court on the basis of evidence that actual FCRs on the Columbia River for recreational fishers and Tribes was as high as 150 grams per day. The challengers contended that EPA should have applied WAC 173-201A-240(6) to derive a water quality criterion for dioxin that would protect all fish consumers to a level of 10^{-6} based on the higher FCR. In *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995), the court concluded that Washington did not intend to mandate a 10^{-6} risk level for every fish consumer. The Ninth Circuit held that “the one-in-a-million risk level mandated by the state water quality standards for the general population does not necessarily reflect state legislative intent to provide the highest level of protection for *all* subpopulations but could reasonably be construed to allow for lower yet adequate protection of specific subpopulations.” 57 F.3d at 1524 (emphasis in original).³⁷

In *Dioxin/Organochlorine Center*, EPA successfully argued that the mere fact that actual fish consumption in Washington is greater than the FCR in the TMDL (the same as the NTR) does not mean that the national criteria violate the state risk policy to protect human health under WAC 173-201A-240(6). EPA argued that the FCR and risk levels in the federal criteria are based on consumption of maximally contaminated fish, and are not intended to reflect actual consumption rates.³⁸ EPA also argued that the 6.5 grams per day fish consumption rate was not intended to accurately represent total consumption of fish, but instead the ingestion rate of a given contaminant.³⁹ According to EPA, the fish consumption rate used in the NTR was “intended to represent only a subset of total fish consumption.”⁴⁰ The FCR is the assumed

³⁵ WAC 173-201A-240(6). EPA’s “policy in the NTR [is] to select the risk level that reflect[s] the policies or preferences of CWA programs in the affected States.” 65 Fed. Reg. 31682, 31699 (May 18, 2000)(00861-898).

³⁶ EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000, at 48 (May 31, 1994) (00899-967). EPA argued: “[T]he designated risk level is merely one factor included in the equation for calculating a numeric water quality standard. . . . The risk level chosen by a state is not part of the state’s narrative criteria, nor is it a freestanding ‘standard’ to be applied to the particularized exposure levels of specific individuals or sub-populations. . . . [S]tates may choose to provide a high level of protection for the average population in order to provide what they deem adequate protection for more sensitive populations.” *Id.*

³⁷ The risk policies in the NTR were also affirmed in *Natural Resources Defense Council v. EPA*, 16 F.3d 1395 (4th Cir. 1993)(rejecting argument that 6.5 grams per day FCR failed to protect subpopulations with higher than average fish consumption). EPA’s range of acceptable risk levels was also upheld in other contexts. *E.g.*, *Ohio v. EPA*, 997 F.2d 1520, 1533 (D.C. Cir. 1993)(describing range of 10^{-6} to 10^{-4} as adequately protective of human health).

³⁸ *Natural Resources Defense Council v. EPA*, 16 F.3d 1395, 1402 n.11 (4th Cir. 1993).

³⁹ 16 F.3d 1395 at 1403.

⁴⁰ *See* n.36, at 44.

amount of “maximum residue fish” consumed.⁴¹ EPA further asserted that consuming anadromous fish, like salmon, is unlikely to cause ingestion of contaminants at a rate equal to consuming maximum residue fish.⁴² EPA explained: “[T]he total fish consumption rate of various individuals is not determinative; the central question is whether the actual rate of ingestion [of a contaminant] is greater than that assumed by EPA.”⁴³

An important consideration in understanding the risk policy in the state of Washington is the timing and sequence of the state’s adoption of its risk policy and when the state was formally subject to the NTR. The risk policy, WAC 173-201A-249(5), was promulgated as a state regulation in October 1992.⁴⁴ The promulgation of the regulation referencing the NTR was included with revisions to the state Water Quality Standards, WAC 173-201A-240(6), five years later in November 1997.⁴⁵ In addition to the fact that the NTR does not extend the 10^{-6} risk level to all consumers, there is the intervening ruling in *Dioxin/Organochlorine Center* that the state policy does not reflect any intent to protect high consumers to the 10^{-6} risk level. A basic rule of statutory construction provides that the failure to amend an act following a judicial construction indicates approval of the construction.⁴⁶ Thus, if Ecology believed that the risk policy was intended to more broadly apply in Washington it would have amended the regulation prior to incorporating a reference to the NTR in the state Water Quality Standards.

As adopted and approved by EPA, and in light of the federal court decision, the NTR as applied in Washington does not presume all consumers are to be protected to a level of 10^{-6} .⁴⁷

Comment No. 6: The proposed risk policy is scientifically defensible and consistent with the requirements of the Clean Water Act and EPA regulations.

EPA has recognized that states have the primary prerogative to make risk management decisions in developing human health criteria. EPA guidance allows states, for risk based criteria, to use 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} .⁴⁸ EPA guidance is clear that EPA deems both 10^{-6} and 10^{-5} risk levels as acceptable,⁴⁹ so long as the selection provides at least a 10^{-4} risk level for the greatest consumers

⁴¹ *Id.*

⁴² 16 F.3d at 1403; *see also* n.36, at 44.

⁴³ *See* n.36, at 45. EPA’s water quality criteria guidance includes a margin of safety for water consumption. 65 Fed. Reg. 31682, 31693 (May 18, 2000).

⁴⁴ WSR 92-24-037 (00968-971).

⁴⁵ WSR 97-23-064. (00972-1019).

⁴⁶ *Hangman Ridge Training Stables, Inc. v. Safeco Title Ins. Co.*, 105 Wn.2d 778, 789, 719 P.2d 531 (1986).

⁴⁷ The sequence of all statutes relating to the same subject matter should be considered. *Dep’t of Labor and Industries v. Estate of MacMilan*, 117 Wn.2d 222, 229, 814 P.2d 194 (1991).

⁴⁸ *See* n.34, 60848-01, 60855.

⁴⁹ 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* n.34, 60848-01, 60864. In general, the NTR established AWQC for states based on a 10^{-6} risk level. *Id.* at 60860. A state could ask EPA to remove the state from the rule, and adopt human health

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.”⁵⁰ “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.”⁵¹

EPA guidance addresses the need to consider carefully 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.⁵² That does not mean, however, that 10^{-6} or a one in one million risk level becomes a baseline for environmental justice. EPA 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:

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.⁵³

Ecology has taken an overly conservative approach that goes beyond the requirements of the Clean Water Act and EPA regulations. The state has done this by applying a high Tribal fish consumption rate to a 10^{-5} risk level in deriving the criteria. This approach provides the level of protection associated with the general population under EPA guidance at a consumption rate that reflects the 90th to 95th percentile of Tribal consumption rates of fish. By extension, the proposed risk based criteria extend the level of protection at 10^{-4} to 1,750 grams per day – a consumption rate that encompasses the highest consumption rates documented for Northwest Tribes. It is also a consumption rate that accommodates historic consumption rates such as the 865 grams a day approved for the Spokane Tribe of Indians in 2013.⁵⁴

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.*

⁵⁰ *Id.* at 60855; *see also* n. 35.

⁵¹ *See* n.6, at 1-12; *see also* n.34, NTR, 57 Fed. Reg. 60848, 60863 (describing 10^{-5} level as “adequately protective”).

⁵² *See* n.6, 1-12, 4-25.

⁵³ *See* n.6, at 2-6.

⁵⁴ EPA, Letter approving Spokane Tribe of Indians Water Quality Standards, *Technical Support Document* dated December 11, 2013, at 22 (December 9, 2013)(01020-1071); *see* Attachment A, at 5 (“The default fish consumption rate does not need to be raised to 175 grams per day to protect the people of Washington State from unreasonable risk.”).

Ecology is proposing an additional risk management decision to adopt criteria values that are no less stringent than current criteria values in the NTR.⁵⁵ The CWA and EPA guidance do not require this measure. States have the primary responsibility to determine appropriate risk levels and other variables that go into a risk management decision.⁵⁶ Those risk management decisions may result in criteria that are less stringent than the NTR criteria – as is the case with many of the criteria that Ecology addresses in the draft rule. EPA deems criteria values that result from this type of analysis as scientifically defensible and consistent with the CWA even if the resulting values higher (less stringent) than the NTR criteria values. In 2013, for example, EPA approved human health criteria proposed by the State of New Jersey that are not as stringent as the NTR criteria for a number of chemicals. EPA nonetheless concluded that the New Jersey criteria are “scientifically defensible, protective of designated uses and consistent with the Clean Water Act and EPA’s implementing regulations at 40 C.F.R. § 131.11.”⁵⁷ EPA Region 10 has advised Washington and Idaho to consider EPA decisions on other state water quality standards in the state risk management decisions.⁵⁸ Based on the EPA approval of the New Jersey criteria, it is clear that the Clean Water Act clearly does not require the risk policy decision by the Governor to set current NTR criteria values as a floor for the proposed criteria.

Comment No. 7: EPA guidance on the acceptable range of risk for human health criteria is supported by the best available science that it provides an insignificant risk of cancer.

In adopting a final rule Ecology should consider the background and history of the EPA guidance on risk policy. The policy has deep roots in the regulation of human health exposure to carcinogens. It reflects an underlying assumption that there is no safe or threshold level for exposure to carcinogens. Across EPA and FDA programs exposures at the level of risk between one in one million and one in ten thousand are deemed acceptable because they represent an insignificant and essentially zero increased risk of cancer.⁵⁹

Attachment A prepared by Arcadis provides a summary of health risk assessment decisions under the Clean Water Act and other environmental regulations. NWPPA incorporates this analysis in its comments on the draft rule.

Ecology has noted in the rule development process that the accepted range of risk of one in one million to one in ten thousand reflects a broader regulatory consensus that this range protects to an insignificant level of risk that is essentially a zero increased risk of incurring cancer.⁶⁰ It is important for Ecology to consider the basis for the current EPA guidance on risk policy as part of its final action on the proposed criteria. EPA Region 10 has specifically stated that the rationale for the risk policy is a factor that should be considered in the development of

⁵⁵ See n.2, at 4.

⁵⁶ See n.2, 16-18; n.34.

⁵⁷ 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, 4-5 (2012)(01072-1085).

⁵⁸ L. Macchio, Letter to D. Essig, Idaho DEQ (January 20, 2015)(01086-1088).

⁵⁹ See Attachment A, at 12.

⁶⁰ See n.2, at 18.

human health criteria. This statement was made in a letter to the Idaho Department of Environmental Quality on January 20, 2015.⁶¹

The abiding principle in the regulation of exposure to carcinogens is 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 toxics in toxic amounts.⁶² 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.⁶³ This led to adoption by EPA and FDA of the Mantel-Bryan equation that 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 on risk levels at levels of insignificance that would reflect an essential zero risk of cancer at exposures considered in the resulting criteria.⁶⁴ 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} .⁶⁵

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.⁶⁶ To achieve this goal FDA made an early proposal based on the one in one-hundred-million risk level.⁶⁷ 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.”⁶⁸

⁶¹ To underscore the importance of this factor, EPA originally transmitted a comment letter to Idaho stating that the basis for the risk policy was not relevant, Letter to IDEQ (January 20, 2015). This letter was replaced within thirty minutes affirming the relevance of this discussion. L. Macchio Emails to D. Essig (January 20, 2015)(01089-1096).

⁶² Calabrese, Edward J. “Origin of the Linearity No Threshold (LNT) Dose-Response Concept.” *Archives of Toxicology* 87.9 (2013): 1621-633 (01097-1109).

⁶³ Graham, John D. “The Legacy of One in a Million” *Risk in Perspective* 1.1 (1993): 1-2 (01110-1111).

⁶⁴ Hutt, Peter B. “A Brief History of Risk Assessment,” *FDA Oral History* (November 2000)(01112-1132).

⁶⁵ 33 Fed. Reg. 19226, 19226 (July 19, 1973)(01133-1137).

⁶⁶ *Id.*

⁶⁷ *Id.* at 19227

⁶⁸ FDA, Compounds used in Food-Producing Animals, 38 Fed. Reg. 19227 (July 19, 1973). 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 can’t confidently assert a one in one-hundred thousand risk level would adequately protect the general public). FDA, Cosmetics; Proposed Ban on the Use of

It is important for Ecology 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.”⁶⁹ 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.⁷⁰

EPA engaged in a similar public discussion as the FDA through Federal Register notices in the 1970s and 1980s.⁷¹ EPA recognized that absolute criteria for carcinogens could not be established given uncertainties including variances of sensitivities and exposure levels.⁷² Instead, EPA presented a range of concentrations associated with risk levels of 10^{-5} , 10^{-6} , and 10^{-7} .⁷³ EPA’s objective in deriving these water quality criteria was to estimate concentrations “which do not represent a significant risk to the public.”⁷⁴

As discussed above, the EPA risk policy 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). At issue was whether EPA can 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

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). (01138-1280).

⁶⁹ See n.63 at 17.

⁷⁰ *Id.*

⁷¹ 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 regards to Superfund (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). (01281-1742).

⁷² 45 Fed. Reg. 79318, 79347 (Nov. 28, 1980)(01743-1767).

⁷³ *Id.* at 79348. See also Attachment A, at 12. (“[10^{-6}] does not represent a level of residues ‘approved’ for introduction into the human diet.”)

⁷⁴ *Id.*

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).

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 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.

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.

997 F.2d 1520, 1533.

The national policy on acceptable risk is based on an extended scientific evaluation and has withstood legal challenges.⁷⁵ 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} .⁷⁶ EPA clearly 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.”⁷⁷

The risk policy proposed is accordingly scientifically defensible and consistent with the Clean Water Act.

Comment No 8: EPA has not revised its current policy.

Ecology should note that EPA has not revised its risk policy since its development for use in the NTR in 1992. As discussed above, that decision was based on an extended consideration of appropriate risk levels for water quality human health criteria. EPA has revised and updated its guidance on human health criteria many times since 1992 but has not undertaken any revision to its guidance on risk policy. EPA has also affirmed its risk policy in recent approvals of state standards.

EPA published its guidance on methodologies for deriving human health criteria in 2000. As discussed above, that guidance adopted and applied the same risk policy developed after many years of deliberation for the NTR. EPA has updated this guidance several times since 2000 but has never changed the basic range of risk levels that are deemed protective of public health.

In 2014 EPA published updated national recommendations for human health criteria.⁷⁸ The proposed criteria for carcinogens are based on the consumption rate of the general population at a risk level of one in one million.⁷⁹ EPA is quite clear in this filing that its recommended water quality criteria are “scientifically derived numeric values that protect

⁷⁵ See Attachment A, 11-12.

⁷⁶ See n.34, at 60855; see also n.6 at 1-12.

⁷⁷ See n.6 at 2-6; see also Attachment A, 13-14.

⁷⁸ EPA, *Updated National Recommended Water Quality Criteria for the Protection of Human Health*, 79 Fed. Reg. 27303 (May 13, 2014)(01768-1771).

⁷⁹ EPA, *Human Health Ambient Water Quality Criteria: Draft 2014 Update*, EPA-820-F-14-003, at 2 (May 2014)(01772-1774).

aquatic or human health from the deleterious effects of pollutants in ambient water.”⁸⁰ The proposed updates to the recommended criteria are based on a fish consumption rate of 22 grams per day and a risk policy of one in one million.⁸¹ EPA did not accordingly vary its acceptable range of risk from one in one million to one in ten thousand. EPA specifically cited its 2000 guidance, and has not therefore varied, its long standing guidance that states may protect the general population’s exposure at one in one million or one in one hundred thousand as long as the median consumption rate for higher consuming populations is protected to one in ten thousand.⁸²

EPA has also affirmed the existing risk policy in approving the human health criteria for state on the Great Lakes⁸³, the California Toxic Rule, 40 C.F.R. § 131.38, and the state of Oregon human health criteria. The 2011 Technical Support Document for the Oregon criteria unequivocally states:

EPA has identified a risk level range of 1×10^{-6} (1:1,000,000) to 1×10^{-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.⁸⁴

More recently EPA approved human health criteria submitted by the state of Maine except as to the application of the criteria in Indian Lands. The Maine criteria are based on the consumption rate applicable to the general population at a risk level of one in one million except for the arsenic criteria which are based on a 99th percentile consumption rate and risk level of one in ten thousand.⁸⁵ EPA disapproved the Maine criteria as applied to “Indian Lands” based on the unique circumstance where the Tribes within the state of Maine lack jurisdiction to set water

⁸⁰ *Id.*, at 2.

⁸¹ *See* n.75, at 2.

⁸² *Id.*

⁸³ EPA, *Final Water Quality Guidelines for the Great Lakes System*, 60 Fed. Reg. 15375 (March 23, 1995)(01775-1907).

⁸⁴ 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)(01908-2010).

⁸⁵ EPA, *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*, Attachment A to Responses to Public Comments Relating to Maine’s January 14, 2013 Submission to EPA for Approval of Certain of the State’s New and Revised Water Quality Standards (WQS) That Would Apply in Waters Throughout Maine, Including Within Indian Territories or Lands, at 42 (February 2, 2015)(January 30, 2015)(02011-2117).

quality standards.⁸⁶ The state of Washington is not in this unique position – consistent with the basic principles of federal Indian law the state of Washington has no regulatory authority to set water quality standards for Tribes.⁸⁷ Indeed a number of Tribes in Washington have same as state status and have or have applied for approval of Tribal water quality standards.⁸⁸

There is nothing in the Maine determination that varies the long standing guidance and scientifically accepted view that there is no difference between a risk level of one in one million and one in one hundred thousand. Washington is accordingly proposing criteria that are scientifically derived and consistent with the Clean Water Act and EPA regulations. This is particularly true where the state is proposing the additional conservativeness in using a fish consumption rate that is well in excess of Tribal consumption rates of fish impacted by potential pollutants in state waters. In this sense Washington is proposing criteria that are consistent with the direction of EPA to the state of Maine on human health criteria applicable to Indian Waters in that state.⁸⁹

Comment No. 9: The proposed criteria are consistent with the principles of environmental justice and respectful of Tribal treaty rights.

Water Quality Standards developed in compliance with the Clean Water Act by definition comply with the principles of environmental justice. EPA Region 10 was clear on this point in response to comments in 2014 on draft NPDES permits for Idaho municipalities. Region 10 was unequivocal in response to the assertion that the permits violated Tribal trust responsibilities in regard to toxics. EPA stated, “[b]ecause the permits comply with the [Clean Water Act] and applicable federal regulations, the EPA has met its trust responsibility to the Spokane Tribe.”⁹⁰

⁸⁶ *Id.*, at 2. The EPA decision document refers to “Indian Lands” in the context of receiving water. “Indian waters” are described as including “waters adjacent to land held in trust by the Secretary of the Interior and lands in the Tribes’ reservations.” *Id.* at 6.

⁸⁷ *Id.* 14-15.

⁸⁸ Ecology, *Fish Consumption Rates Used in Human Health Criteria Calculations* (September 9, 2013)(02118-2122).

⁸⁹ Ecology is not only proposing to “target” a high Tribal consumption rate but is doing so for criteria that apply statewide not just to “Indian Lands.” In the event EPA disapproves this approach, Ecology should thoroughly review its risk management decisions on fish consumption rates and risk level. This will be critical as there is no discussion in the Maine decision that substantiates the remarkable shift in risk policy presented by EPA. EPA proclaims “[Tribes] are not a highly exposed or high-consuming population in their own lands; they are the general population for which the federal set-aside of these lands and waters was designed.” *Id.*, at 36. This makes no sense in the context of the long standing policy across FDA and EPA programs as to what constitutes an acceptable range of risk levels for regulating exposure to carcinogens. The EPA determination on Maine water quality standards fails to provide any scientific basis for moving from a long held understanding of what constitutes a range of exposures that is insignificant, the equivalent of zero additional risk, and therefore an acceptable range of risk to protect all consumers of fish. Ecology should note that the State of Maine has announced its intention to seek judicial review of the EPA partial disapproval of the state HHC. *See* J. Mills, Letter to G. McCarthy (March 17, 2015)(04733-4737)

⁹⁰ EPA, *Response to Comments on the Draft NPDES Permits for the City of Coeur d’Alene, City of Post Falls and the Hayden Area Regional Sewer Board*, at 39 (September 31, 2014)(02123-2230).

EPA Region 10 staff has confirmed that there is no stand-alone environmental justice analysis in developing water quality standards.⁹¹

The legal position of EPA Region 10 regarding its trust responsibilities was affirmed in *Sierra Club v. McLerran*, No 11-CV-1759-BJR, slip op. 22-24 (March 16, 2015). In that action the Spokane Tribe of Indians alleged that EPA had violated a trust responsibility by failing to disapprove a constructive submission of a PCB TMDL. The Tribe specifically alleged that its status as a state for establishing water quality standards and the EPA approval of the Tribal water quality standards imposed a heightened trust obligation on the EPA. EPA argued that the Tribe must point to specific statutes and regulations that establish and define such a trust responsibility:

Thus the only cognizable breach of trust claim is one founded upon a definite and express fiduciary duty imposed on the federal government by administrative regulation of Act of Congress. *United States v. Navajo Nation*, 537 U.S. 488, 511 (2003); *United States v. White Mountain Apache Tribe*, 537 U.S. 465, 477 (2003). Accordingly, the federal common law trust duties applicable to private beneficiaries, which the Tribe seeks to impute to the federal government, *see* Tribe br., at 15, do not provide independent bases for the claims asserted by the Tribe. *See Pacific Coast Fed'n of Fisherman's Ass'ns v. United States BLM*, 2005 U.S. Dist. LEXIS 36035, *34 (N.D. Cal. Mar 8, 2005).⁹²

The Court granted EPA summary judgment on this issue concluding that, “In the absence of a specific right or obligation, the EPA’s responsibilities amount to no more than a bare trust obligation, which can be discharged by complying with generally applicable law.”⁹³ Ecology has accordingly met and exceeded the demands of environmental justice and any Federal trust responsibilities by proposing criteria that are scientifically derived and consistent with the Clean Water Act and EPA regulations. Ecology is not required to adopt criteria using the highest Tribal consumption rates at the most conservative risk levels in EPA guidance. This has been conceded by Region 10. On 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.”⁹⁴ Christine Psyk, Associate Director for Region 10, responded that “**EPA would not because that requirement does not appear in EPA regulations or guidance.**”⁹⁵

Aside from EPA regulations and guidance, the central fallacy in the concept that subsistence fishers should be protected to the same extent as the general population is that it is

⁹¹ A. Chung, Email (June 19, 2014)(02231-2232).

⁹² EPA, *Consolidated Brief (A) In Support of Its Cross-Motion for Summary Judgment and (B) In Opposition to Plaintiffs’ and Intervenor-Plaintiff Tribe of Spokane Indians’ Respective Motions for Summary Judgment*, Case No. 2:11-cv-01759-BJR, at 39 (January 29, 2014)(02233-2282).

⁹³ *Sierra Club v. McLerran*, No 11-CV-1759-BJR, slip op. at 23 (March 16, 2015)(citing *Gros Ventre Tribe v. United States*, 469 F.3d 801,812 (9th Cir. 2006))(02283-2307).

⁹⁴ D. Ostermann, Letter to EPA, at 2 (January 9, 2013)(02308-2310).

⁹⁵ *Id.* (emphasis added).

not possible – unless they eat the same type of fish. Even if Ecology used the 99th percentile of Tribal consumption rates, or even the single highest documented Tribal consumption rate, and set criteria at a one in one million risk level, the general population would still be protected at a more protective risk level. That is why EPA and FDA programs have long addressed exposures within an acceptable range.

EPA has consistently defended this range as protective of the entire population. 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.⁹⁶

EPA has also considered the accepted range of risk levels as a matter of environmental justice in establishing 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.

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,

⁹⁶ See n.79.

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.⁹⁷

EPA affirmed the accepted range of risk in its 2014 “Plan EJ 2014 Legal Tools” guidance. EPA states in this 2014 guidance that “EPA’s recommended water quality criteria generally are expressed as ambient numeric pollutant levels that EPA considers to be protective of the intended use of the water (*e.g.*, consumption of fish).”⁹⁸ This guidance further states that for “the protection of overburdened communities, EPA’s methodology specifically considered ‘the States’ and Tribes’ need to provide adequate protection from adverse health effects to highly exposed populations such as recreational and subsistence fishers’.”⁹⁹ This reference speaks to the preference of local data over EPA default fish consumption rates but does not vary in any way the long-standing acceptable range of risk levels that are appropriate for deriving human health criteria. That guidance calls for consideration of more conservative risk levels applied to the general population only if highly exposed populations are not protected to a risk level of one in ten thousand. EPA guidance thus deems environmental justice to be met when states adopt an alternative risk policy “where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded.”¹⁰⁰

Ecology’s risk management decision to protect highly exposed populations at a level of 10^{-5} is based on a long-standing consensus of insignificant risk. It is therefore scientifically derived and exceeds EPA regulations and guidance. Any decision by EPA to disapprove Washington’s proposed human health criteria on the grounds that the criteria utilize a risk factor of 10^{-5} would be contrary to accepted science and the Clean Water Act.

Comment No. 10: There is no scientific or public health policy basis for criteria based on a FCR of 175 g/day and risk policy of one in one million.

Ecology is required to develop criteria that are scientifically defensible and based on the agency determinations for risk management – decisions under the Clean Water Act that are the prerogative of the state, not EPA. There has been a persistent misunderstanding or misrepresentation that a one in one million risk policy is a threshold or baseline for the protection of human health. This is exemplified by the statements from the EPA Region 10 Administrator

⁹⁷ EPA, *California Toxics Rule Response to Comments Report*, CTR-002-005a (Dec. 1999) (emphasis added)(02311-3812).

⁹⁸ EPA, *Plan EJ 2014 Legal Tools*, at 24 (December 2011)(03813-3932).

⁹⁹ *Id.* citing EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, at 4-25 (October 2000).

¹⁰⁰ *See* n.2, at 2-6.

that “everyone should be protected to the same level.”¹⁰¹ This statement ignores the fact there is no reasonable basis to protect everyone to same level – across any population there will always be a range of exposures and therefore a range of risk. There is also no basis in the long history of the regulatory management of cancer risk by EPA and the FDA that supports the contention that all fish consumers in Washington must be protected to a risk level of one in one million.

The real question posed by demands to regulate the highest Tribal consumption rates at one in one million is whether Ecology should adopt a more stringent risk policy than required under the Clean Water Act and EPA guidance. If Ecology considered this demand, the effective risk policy would be in the range from one in one hundred million or one in ten million to one in one million. On this critical issue – whether Washington needs to adopt a more conservative range for its risk policy than EPA guidance – the Northwest Tribes and EPA Region 10 have been silent.

Ecology presented the risk policy issue to EPA Region 10 on numerous occasions over the past two years. The origins and basis for the one in one million risk policy were the subjects of several emails to EPA regional staff in January and February 2013.¹⁰² We believe that EPA staff attended the February 8, 2013, and March 28, 2013, Policy Forum meetings where the current risk policy in Washington and EPA guidance on risk policy were discussed.¹⁰³ EPA staff never indicated in response to these emails or provided any indication at the meetings that there has been any change in EPA policy – or any circumstances that require 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.¹⁰⁴ 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?

Angela Chung: EPA can't answer that now.¹⁰⁵

¹⁰¹ D. McLerran, Pers. Communication to NWPPA Members (April 9, 2013).

¹⁰² C. Niemi, Email to L. Kissinger (January 2, 2013)(03933-3934).

¹⁰³ See Attendance Lists for Meetings on June 24, 2013, November 6, 2013, and July 2014 (03935-3943).

¹⁰⁴ See n.13.

¹⁰⁵ *Id.*

Ecology raised this issue with EPA staff again in emails and meetings in October and November 2013.¹⁰⁶ 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, 2013.¹⁰⁷ 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 that were 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, Dennis McLerran, EPA Regional Administrator, apparently declared that “175 grams a day at 10^{-6} is a baseline for environmental justice.”¹⁰⁸ Mr. McLerran apparently 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?**¹⁰⁹

Dan Opalski, from EPA Region 10, responded to this email and confirmed that there is no such statement. 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.”¹¹⁰ This admission reinforces the long standing range of acceptable risk levels in EPA guidance remain applicable to the development of human health criteria by the state.

¹⁰⁶ M. Gildersleeve, Email to A. Chung and M. Szelag (October 1, 2013)(03944).

¹⁰⁷ Preliminary Draft – HHC Tools Summary, Water Quality Standards Rule Making, Human Health Criteria, Summary, November 6, 2013 (03945).

¹⁰⁸ See n.13.

¹⁰⁹ *Id.* (emphasis added)

¹¹⁰ 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 Sen. 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.”¹¹¹ Three weeks later Dennis McLerran responded with a letter that was not responsive to this question.¹¹² Sen. Erickson 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.”¹¹³ 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?¹¹⁴

On July 1, 2014, Mr. McLerran responded and misstates that Washington is reducing “the level of cancer risk protection for the entire state.”¹¹⁵ EPA knows that the current risk policy in Washington, WAC 173-201A-240(5), is intended to apply a one in one million risk level to the per capita consumption rate of the general population and not to more highly exposed subpopulations. EPA established this as a matter of law in *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995). EPA also knows that EPA guidance does not distinguish between a one in one million risk and one in one hundred thousand risk.¹¹⁶ Ecology is in fact reducing the cancer risk in the proposed criteria.

Mr. McLerran also asserts in the July 1, 2014, letter that certain “groups could be provided less protection than they have now” if Washington uses a one in one hundred thousand risk policy.¹¹⁷ There is no merit to this contention where the state is proposing to increase the consumption rates protected within the long accepted range of insignificant risk at 10^{-4} from 650 grams per day under the NTR to 1750 grams per day under the draft criteria and where the state is proposing criteria that will be no less stringent than the current NTR criteria. Ecology is not

¹¹¹ D. Ericksen, Letter to D. McLerran (April 3, 2014)(03947-3948).

¹¹² D. McLerran, Letter to D. Ericksen (April 24, 2014)(03949).

¹¹³ D. Ericksen, Letter to D. McLerran (May 28, 2014)(03950-3951).

¹¹⁴ *Id.*

¹¹⁵ D. McLerran, Letter to D. Ericksen (July 1, 2014)(03952-3953).

¹¹⁶ See n.80, at 27 (“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.”)

¹¹⁷ See n.115.

required to be this conservative under the Clean Water Act. Nor is Ecology required to set the current NTR criteria as floor for its proposed criteria.

EPA itself has recognized that states may adopt criteria that are numerically less stringent as the NTR criteria. This is precisely what EPA did in approving human health criteria for the state of New Jersey. There the state derived criteria for some chemicals of the risk policies used for the Safe Drinking Water Act. EPA deemed the criteria scientifically defensible and therefore no less stringent than the NTR.¹¹⁸ There is no basis for the Regional Administrator to conclude that proposed criteria will provide less protection. Nor is there any basis, as alleged in the July 1, 2014, letter for EPA to impose additional considerations based on environmental justice. EPA Region 10 conceded on March 11, 2014¹¹⁹, and June 19, 2014¹²⁰, that there is no separate environmental justice review in assessing compliance with the requirement for scientifically defensible criteria that are consistent with the Clean Water Act and EPA regulations.

The July 1, 2014, letter offers another rationale for Mr. McLerran's recommended risk policy that he "supports regional consistency among Region 10 states" to protect downstream waters under 40 C.F.R. § 131.10(b).¹²¹ NWPPA supports consistency with EPA regulations. 40 C.F.R. § 131.10(b) simply 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 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 standards.¹²² This was an issue in the New Jersey criteria approved in 2013 where EPA approved criteria less stringent than downstream criteria based on a narrative provision in the New Jersey water quality standards.¹²³ Ecology has satisfied the requirements of 40 C.F.R. § 141.10(b) by expressly providing in the rule that "All waters shall maintain a level of water quality when entering downstream waters that provides for the attainment and maintenance standards of those downstream waters, including waters of another state." Amendatory Section WAC 173-201A-240(5)(b).

NWPPA has not seen any indication that Northwest Tribes have provided a scientific and public health basis for adoption of a risk policy of one in one million applied to a high Tribal consumption rate. The Tribes mostly declined the opportunity to be part of the public process Ecology employed for the development of human health criteria.¹²⁴ Ecology has nonetheless met

¹¹⁸ See n.57.

¹¹⁹ See n.110.

¹²⁰ See n.91.

¹²¹ See n.115.

¹²² 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).")(03954-3965).

¹²³ See n.57.

¹²⁴ See Letters from Yakama, Lummi, Squaxin, Kalispel, Pt. Gamble, Spokane, Suquamish and Swinomish Tribes declining invitations to be part of the delegates' table. (03966-3980).

with Tribal representatives on numerous occasions.¹²⁵ Following the presentation of policy options in November 2013, Ecology heard for the first time from some Tribal interests that the state should not use a risk factor of one in one hundred thousand. An example of these communications is an email from the Northwest Indian Fisheries Commission dated March 18, 2014, asserting that Northwest Tribes were entitled to a zero additional risk of cancer from eating seafood and that a one in one million risk level would be a compromise position on this issue.¹²⁶ A similar claim on behalf of the Columbia River Inter-Tribal Fish Commission was discussed in a comment letter in the Idaho rulemaking process.¹²⁷

The Tribal demands for zero risk share the central basis of the existing guidance on risk policy as applied by EPA and the FDA across numerous human health regulations. It has been firmly established that there is no feasible way to actually regulate to zero – a point that is conceded in the letters. That is why EPA guidance on risk policy recommends a range of risk levels that are deemed to provide an insignificant degree of risk that is the functional equivalent of zero risk.

The Northwest Tribes and EPA have failed throughout this process to provide any basis for a risk policy that would be the equivalent of 10^{-8} to 10^{-6} . The Northwest Tribes have also failed to acknowledge the compounding effect of conservative factors used in calculating human health criteria.¹²⁸ The effect of compounded conservatism is to derive criteria that are protective to at least a 10^{-6} cancer risk for all consumers.¹²⁹ The National Council for Air and Stream Improvement (NCASI) has separately filed comments on the draft rule that provide additional technical review of the compounded conservatism in the methodology used by Ecology to derive the proposed criteria. NWPPA incorporates the NCASI comments by this reference.

EPA guidance allows states to adopt a more stringent criteria but Ecology must comply with its rulemaking obligations including the significant legislative rule provisions of the state Administrative Procedures Act. To adopt a more restrictive risk policy is an enormous scientific and public policy decision that is beyond the scope of this rulemaking. NWPPA believes changes to risk policy should be a matter addressed by EPA on a national level and in the context of all of its programs that relied on the current and long accepted risk policy. NWPPA does not, however, believe that there has been any demonstration of scientific, technical or policy information that justifies a change in national policy.

¹²⁵ Emails and attendance lists from Tribal meetings (October 11, 2011, November 16, 2011, January 3, 2012, February 8, 2012, February 21, 2012, May 4, 2012, October 10, 2012, and October 28, 2013)(03981-3996).

¹²⁶ See n.14.

¹²⁷ C. O'Neil, Comment Letter on HHC Risk Policy (January 20, 2014)(03997-4015).

¹²⁸ See Attachment A, at 24-25.

¹²⁹ Id.

EPA Region 10 Responsibilities in Review Proposed Criteria

Comment No. 11: EPA Region 10 has no authority to vary the requirements of the Clean Water Act and EPA guidance.

As explained above, the EPA Regional Administrator does not have the authority to impose rules or standards more restrictive than those set by the national EPA. EPA Region 10 suggestions to the contrary, whether contained in emails, letters, or guidance documents, are of no force and effect and are not in any way binding in Washington.

The EPA Administrator has delegated the EPA's mandatory duty to approve or disapprove of state-adopted water quality standards to each of the ten EPA Regional Administrators. EPA Delegations Manual, § 2-10 Water Quality Standards (January 28, 1976). In Region 10, the Regional Administrator has re-delegated this duty to the Director of the Region 10 Office of Water and Watersheds. EPA Delegations Manual, R10 § 2-10 Water Quality Standards (October 28, 2004). Region 10's role is thus to review and either approve or disapprove of water quality standards adopted by Washington, and to do so based on the CWA's requirement that the standards protect designated uses. If they are protective, Region 10 must approve the standards, and in the event of disapproval must articulate why it has determined that the standards are not in compliance with the CWA, and what changes are necessary to assure compliance.

In contrast to the limited review and approval/disapproval authority delegated to the regional offices, the EPA Administrator retains the authority to actually promulgate state water quality standards in two defined circumstances. First, if a Regional Administrator disapproves of water quality standards and directs a state to make specific changes to those standards, and the state fails to do so within 90 days, then the EPA Administrator must propose and promulgate a water quality standard for that state. CWA § 303(c)(3); 303(c)(4)(A); 40 C.F.R. § 131.22(a). Second, the EPA Administrator retains the discretionary authority to propose and promulgate a regulation, applicable to one or more states, setting forth a new or revised standard upon determining that such a standard is necessary to meet the requirements of the CWA. CWA § 303(c)(4)(B); 40 C.F.R. § 131.22(b). EPA's 1992 promulgation of human health water quality criteria in the NTR, made applicable to several states and promulgated pursuant to federal notice and comment rulemaking procedures, is an example of the exercise of this authority by the Administrator. *See* n.34, at 60857.

In contrast, the EPA Regional Offices have not been delegated the authority to promulgate or establish rules of national applicability under the CWA. *Pennsylvania Municipal Authorities Ass'n v. Horinko*, 292 F. Supp.2d 95, 104 (D. C. Cir. 2003). Nor do EPA Regional Administrators have the authority to impose rules or standards more restrictive than those promulgated by the national EPA. *Id.* (citing EPA Delegations Manual 1-21.2a(1), which "authorizes EPA Regions to 'make non-substantive changes to previously published documents [and] amend or change regulations without affecting their stringency, applicability, burden of compliance, or compliance costs.'").

In the course of rejecting attempts by states and regulated entities to challenge EPA regional guidance documents, federal courts have emphasized the limits of authority delegated to

EPA regional offices, as well as the non-binding nature of regional guidance documents. *E.g.*, *American Paper Institute, Inc. v. U.S.E.P.A.*, 882 F.2d 287, 289 (7th Cir. 1989) (Where EPA Region V issued a policy statement setting stricter limits on dioxin tolerances in NPDES permits than that set out in published national EPA policy, the region’s policy statement was merely a “go-it-alone document” with no legal effect, as it was not promulgated by the Administrator as part of federal rule-making: “Region V does not demand that any firm change its conduct now; Region V has no authority to do so”); *American Paper Institute, Inc. v. U.S.E.P.A.*, 726 F. Supp. 1256 (S.D. Alabama 1990) (Region IV policy regarding NPDES permit limitations on dioxin was not binding, and the states were under no obligation to comply with it). As one court stated:

The states may or may not choose to implement the Region IV suggestions in whole or in part. Under the CWA, EPA may not force the states to implement the policy it suggests. Instead, EPA may choose to disapprove state action on individual permits, water quality standards or short lists and substitute its own policies. Only at the [sic] point does the policy become final, and at that point EPA must follow rulemaking procedures.

Id. at 1260.

The participation of Region 10 in the rule development process in Washington has been frustrating – there has been a consistent lack of clarity and transparency as to the applicable EPA regulations and guidance. There appears to be an obvious agenda but not one that is supported by accepted science and the Clean Water Act. NWPPA strongly believes Ecology should adhere to duly published EPA guidance, case law and the precedent of water quality standards approved for other states.

PCB Criteria

Comment No. 12: Ecology should not apply the Governor’s risk policy to deriving PCB criteria.

Polychlorinated biphenyls (PCBs) present a unique environmental challenge in the state of Washington. Although banned and phased out in manufacturing after 1979, PCBs are persistent in airborne deposition. EPA regulations continue to allow incidental PCB concentrations in certain products and in fish feed used in hatcheries. The burden on regulated entities to comply with stringent PCB water quality criteria is not justified by the potential cost and limited benefit due to the inability to test or treat to extremely low criteria as well as the ongoing sources of PCBs from airborne deposition and products. Over regulation of PCBs could also lead to a regulatory stalemate resulting in a ban on any new or expanded discharges until Washington waters achieve impossibly low criteria, a suspension of federal, state and Tribal hatchery programs, a complex TMDL process and management of the NPDES permit process through variances and compliance schedules. This regulatory commitment would likely come at the expense of efforts that could actually reduce PCBs in the environment through sediment cleanup actions and other hazardous waste cleanup actions, source control, implementing the

recently approved PCB Chemical Action Plan¹³⁰ as well as continued pressure on EPA to reform its TSCA regulations.

Ecology is well within EPA guidance to address the unique challenges of PCBs through a risk policy based on the state Department of Health methodology for establishing fish advisories.¹³¹ EPA has approved state standards using alternative risk methodologies – most recently for the state of New Jersey.¹³² The methodology used by Ecology to derive the PCB criteria is scientifically defensible and does not require the modification based on the Governor’s policy direction that no criteria in the rule should be less stringent than the corresponding criteria in the NTR.

Like Ecology, EPA has struggled on how to regulate PCBs. The 2014 draft update to human health water quality criteria by EPA does not address a number of chemicals including PCBs, Arsenic and Methylmercury. EPA withheld action on these chemicals “due to outstanding technical issues, including new toxicity factors and bioaccumulation factors.”¹³³ EPA has also acknowledged the “complex issues” regarding PCBs in declining to enforce current EPA limits on inadvertent generation of PCBs in products.¹³⁴ EPA has further declined to reduce allowed levels of inadvertently generated PCBs due to “policy and scientific challenges.”¹³⁵ Ecology is more than justified to treat PCBs differently in deriving new criteria and should consider withdrawing the application of the Governor’s policy to PCBs. NWPPA believes that total PCB criteria should be set at 0.00029 µg/L consistent with the methodology and risk management decisions made by Ecology.

Arsenic Criteria

Comment No. 13: Proposed Arsenic criteria are consistent with requirements of Clean Water Act.

NWPPA supports Ecology’s methodology for deriving the proposed criteria for Arsenic. Ecology has thoroughly explained that nearly half the states use a similar approach and that EPA did not promulgate human health criteria for Arsenic in the 2000 California Toxics Rule.¹³⁶ Ecology should additionally note that EPA approved Arsenic criteria for Maine based on the 99th percentile consumption rate at a risk level of 10⁻⁴ and that EPA deferred action on Arsenic in its 2014 draft update to human health criteria.¹³⁷

¹³⁰ Ecology and Department of Health, *PCB Chemical Action Plan*, Publication No. 15-07-002 (February 2015)(04016-4238).

¹³¹ See n.2, at 39.

¹³² See n.57 at 6.

¹³³ See n.78.

¹³⁴ D. McLerran, Letter to A. Borgias (February 24, 2015)(04239-4241).

¹³⁵ *Id.*

¹³⁶ See n.2, 43-44.

¹³⁷ See n.78.

Mercury Criteria

Comment No. 14: Deferring development of Mercury criteria is appropriate and allowed under the Clean Water Act.

Ecology has properly deferred action on deriving new state human health criteria for Mercury. As with PCBs and Arsenic, EPA has acknowledged technical issues that justify a delay in updating the national ambient human health water quality criteria.¹³⁸ Ecology properly notes that it will take additional time to assess the appropriate methodology for deriving criteria including an evaluation of how to implement EPA guidance for Methylmercury limits based on fish tissue concentrations.¹³⁹ Pending that regulatory review, the state already has in place chronic aquatic life criteria, based on protection of human health, that are more protective than the NTR criteria.¹⁴⁰

Relative Source Contribution

Comment No. 15: Relative Source Contribution.

Ecology has made a scientifically defensible decision to use a Relative Source Contribution (RSC) of 1.0 in deriving criteria. It is important, however, for Ecology to be clear in its rule development that this decision is based on an overt risk management decision to use a high Tribal fish consumption rate that includes salmon and all other sources of fish consumption documented in the Tribal studies. Ecology should not be subject to a disapproval decision by EPA that approves the fish consumption rate proposed in Amendatory Section WAC 173-201A-240(5)(b) but disapproval of the RSC. If the RSC is not approved, Ecology will need to re-evaluate the inclusion of marine fish, including salmon, and store-bought fish in the consumption rate. Otherwise, the state would be forced to essentially double count salmon in the calculation of criteria.

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. This endorsement is set forth in a letter dated September 5, 2014, from EPA to the state of Idaho.¹⁴¹ EPA Region 10 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.”¹⁴²

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

¹³⁸ *Id.*

¹³⁹ *See* n.2, 49-51.

¹⁴⁰ *Id.*

¹⁴¹ L. Macchio, Letter to D. Essig (September 5, 2014)(04242-4244).

¹⁴² *Id.*, at 2.

preferred means to account for salmon consumption compared to a lower or fractional RSC.¹⁴³ EPA Region 10 has urged Northwest states to consider EPA action on water quality standards for other states.¹⁴⁴ EPA Region 10 has further endorsed the Oregon approach as “the right outcome.”¹⁴⁵

Ecology properly notes that there is significant difference between risk assessment in other programs such as the Safe Drinking Water Act (SWDA) and Superfund Clean Program.¹⁴⁶ The SWDA uses a RSC of 20% and 80% of exposure but does so in terms of goals, not water quality criteria.¹⁴⁷ The SWDA is using this range of RSC for establishing Maximum Contaminant Level Goals that are not by definition regulatory goals.¹⁴⁸ This is in contrast to criteria in approved water quality standards that must be enforced through TMDLs and end of the pipe effluent limits in discharge permits.¹⁴⁹

Social, Economic and Political Concerns

Comment No. 16: The draft rule is supported by appropriate consideration of social, economic and political concerns.

Ecology properly notes that under EPA guidance risk management is a process that requires considerations of social, economic and political considerations.¹⁵⁰ The proposed criteria reduce the risk of exposure to toxics in Washington waters. For non-carcinogens the criteria are as conservative as the state of Oregon criteria and in fact more conservative where the state is setting the current NTR as a floor under the Governor’s policy direction. For carcinogens, Ecology is going much farther than it is required to under the Clean Water Act by using a high Tribal consumption rate at a risk level under EPA guidance that is typically applied to the general population.

Adopting the Oregon carcinogen criteria would be devastating to the Ecology Water Quality Program. There is a long standing rationale as to why human health criteria are not based on zero risk – there is no meaningful basis for regulation to zero criteria. Ecology and permittees would have no ability to monitor or treat to zero. The same applies to criteria based on a more conservative range of exposure risk of 10^{-8} to 10^{-6} . That is precisely why EPA and the

¹⁴³ See n.15, at 9. Oregon used RSC values recommended by EPA for 15 of 17 chemicals and a RSC value of 1.0 for all other non-carcinogens.

¹⁴⁴ See n.58.

¹⁴⁵ See n.13. (“Dennis thinks the Oregon outcome is the right outcome.”)

¹⁴⁶ See n.2, at 22.

¹⁴⁷ *Id.*; see also n.54, at 25 (EPA approved the use of a RSC of 1.0 for the 2013 Spokane Tribe of Indians water quality standards).

¹⁴⁸ Ecology, *Draft Comments from Washington and Idaho on EPA 2013 FAQ* (April 17, 2013)(04245-4256).

¹⁴⁹ See n.138; see also *American Paper Institute, Inc. v. EPA*, 996 F.2d 346, 350 (D.C.Cir.1993)(Once a water quality standard has been promulgated, section 301 of the CWA requires all NPDES permits for point sources to incorporate discharge limitations necessary to satisfy that standard.”)

¹⁵⁰ See n.2, 16-17 (citing n.6, at 2-3).

FDA rejected criteria at this risk level – it affords no meaningful additional protection for public health.¹⁵¹ In Montana, the state has long regulated PCB discharges in hatchery with effluent limits based on the state PCB human health criteria.¹⁵² It would likely be impossible to maintain hatchery operations if the Oregon criteria were applied in hatchery discharge permits in Washington.

There certainly would be little benefit to the more conservative risk level. Ecology illustrated this in a table of NTR chemicals and existing NPDES permit data provided during the public forum process. Very few of the chemicals are found in permit effluent and even fewer can be detected at the levels of the Oregon criteria.¹⁵³

Ecology would nonetheless have to strictly enforce the more stringent criteria. That would have an enormous adverse impact on the state of Washington. Ambient water quality monitoring in Puget Sound indicates that most of Puget Sound would meet the current NTR PCB criteria but not the Oregon PCB criteria.¹⁵⁴ This would potentially result in all of Puget Sound being subject to listing as an impaired water body under section 303(d) of the Clean Water Act. This would result in a prohibition of new or expanded surface water discharges until Puget Sound achieves standards that have no meaningful additional benefit to public health. *Friends of Pinto Creek v. EPA*, 504 F.3rd 1007 (9th Cir. 2007); 40 C.F.R. § 122.26.

Ecology should consider the impact of this result on its Water Quality Program. Dischargers would face an impossible task of compliance with standards that cannot be measured in the absence of viable treatment technology. The potential costs for compliance are staggering as documented by the 2013 HDR study and local governments.¹⁵⁵ The impact on the Water Quality Program would be equally devastating. In Oregon, the state has slipped to the last position in the ability to review and issue new and renewed NPDES permits.¹⁵⁶ Ecology is likely then to lose one of the most effective tools – the NPDES permit – in maintaining and improving water quality.

Ecology should also consider the impact of Oregon criteria on other programs that are intended to reduce toxic loading. The Water Quality Program would have to manage the need for extensive variances and, where it could engage in permitting decisions, would have to manage complex mixing zone analyses, compliance schedules, and intake credits. The TMDL

¹⁵¹ See n.67 and n.68. This is a continuing concern as documented in a NOAA Fisheries *Draft EIS for Joint State and Tribal Management Plans for Puget Sound Salmon and Steelhead Hatchery Program*. NOAA Fisheries, Draft EIS, Appendix K (July 2014)(04257-4273).

¹⁵² Montana DEQ, Concentrated Aquatic Animal Production General Permit, page 3 (July 1, 2011)(04274-4288).

¹⁵³ Ecology, *Washington NTR Criteria versus Oregon Human Health Criteria* (September 11, 2013)(04289-4296).

¹⁵⁴ Ecology, *Control of Toxic Chemicals in Puget Sound, Assessment of Selected Toxic Chemicals in the Puget Sound Basin, 2007-11, Quality Assurance Project Plan for Phase 3: Characterization of Toxic Chemicals in Puget Sound and Selected Major Tributaries*, Publication No. 11-03-055 (November 2011)(04297-4593).

¹⁵⁵ HDR, *Treatment Technology Review and Assessment*, Association of Washington Business Association of Washington Cities, Washington State Association of Counties (December 14, 2013)(04594-4661).

¹⁵⁶ News article, *Underwater: Oregon's Agency Responsible for Monitoring Waterway Polluters Is The Most Backlogged in the Country*. Street Root News (February 24, 2015)(04662-4668).

program would be heavily impacted and it is likely to reduce the effectiveness of this program over time. Ecology should also consider the impact of more stringent criteria on its sediment cleanup efforts and on its Chemical Action Plan process.

Ecology should also consider the impact of the Oregon criteria on federal, state, Tribal and other private hatchery programs in Washington. Ecology has identified returning salmon as contributing up to 10% of the PCB loading to Puget Sound.¹⁵⁷ In 2006 Ecology published a report documenting the PCB loadings associated with hatcheries.¹⁵⁸ This is a statewide problem as illustrated by Ecology's section 401 certification for the Leavenworth Federal Fish Hatchery.¹⁵⁹

Comment No. 17: While the rule is scientifically defensible taken as a whole, it is more stringent and thus more burdensome than some alternatives as defined by RCW 34.05.328.

Ecology exercised its policy discretion in a multitude of areas to develop the proposed numeric criteria and implementation tools. NWPPA believes the rule is scientifically defensible taken as a whole, but some numeric criteria are overly stringent due to compounded conservatism that results from the use of multiple conservative exposure and risk management factors (drinking water intake, body weight etc.) used to derive the criteria using a deterministic approach.

There is an alternative calculation method acceptable to EPA that can be used to derive scientifically sound and protective numeric criteria called probabilistic risk assessment (PRA). Ecology could have chosen to exercise its discretion and employ the PRA calculation method, which could have reduced compounded conservatism thus reducing stringency and resulted in an alternative rule that was less burdensome to the public – while still being protective of beneficial uses and meeting EPA guidance.

Comment No. 18: Submitting the rule package for EPA approval containing both numeric criteria and implementation tools is appropriate under state law and consistent with Ecology's prior commitments.

Ecology has reiterated its intent to submit a rule package containing both numeric and narrative criteria and implementation tools for water permits on numerous occasions in the public process. It is extremely helpful for all parties to see the complete path toward implementation as the rule proposal moves through the state and federal approval processes. Under no circumstances should the rule proposal components be divided up and moved separately through the federal approval process. Appropriate rule language should be included to ensure all components remain together similar to “the numeric criteria in Table 240(3) become effective when the water quality standards implementation policies in revised WAC 173-201A-

¹⁵⁷ See n.154.

¹⁵⁸ Ecology, *Persistent Organic Pollutants in Feed and Rainbow Trout from Selected Trout Hatcheries*, Publication No. 06-03-017 (April 2006)(04681-4732).

¹⁵⁹ Ecology, *Final 401 Certification for the Leavenworth National Fish Hatchery*, Order No. 7192 (January 7, 2010)(04669-4680).

420 *Variances*, -460 *Intake Credits*, and -510(4) *General Allowance for Compliance Schedule*, are approved by EPA.”

Comment No. 19: Rule implementation plan must consider the regulatory framework will evolve over time and not be a static “snap shot” of year 2015; the current plan fails to demonstrate logical conclusions.

Ecology’s support documents should be designed to implement the proposal considering the evolution over time of regulations and laws, the built environment and science. Nothing will remain static as this rule proposal is implemented across Washington. We provide a list of factors that will change over time and no one issue is more important than others. First, analytical test methodologies will likely advance and have lower quantification levels leading to more stringent water quality based effluent limits as allowed for by WAC 173-201A-260(3)(h). Second, water permit holders will likely change as populations shift and manufacturing changes. Third, Section 303(D) lists of waters impaired by pollutants under the Clean Water Act will likely change. Fourth, additional large and complex TMDLs will need to be developed in populous areas of Washington. Fifth, applications and drafting water quality permits will become more complex and require additional Ecology staff-time and scientific support activities. Sixth, large-scale treatment technology is likely to advance beyond 2015 technology limitations. Seventh, case law and also legal precedents from the Pollution Control Hearings Board will change, for example, the practical implications of PCHB No. 11-184 for future water permits. Finally, when all is said and done, the situation will likely be chaotic and factors surrounding water permitting will not evolve at the same pace.

As a result the questions for Ecology are: at what pace will the evolution in each sector occur; and, how will Ecology respond to the challenge of developing appropriate implementation policies. NWPPA encourages Ecology to build a plan based on realistic assessments of available data, implementation tools and science while building in flexibility to meet these challenges.

Comment No. 20: Preliminary Cost-Benefit and Least-Burdensome Alternative Analyses is incomplete and fails to adequately quantify the complex phase-in costs of the human health rule.

Ecology’s Preliminary Cost-Benefit Analysis inadequately addresses the complex and evolving nature of regulatory costs that will be phased in over time for the human health rule proposal. The Analysis fails to quantify all regulatory costs across sectors for “prospectively impacted entities.” This qualitative approach fails to identify and quantify regulatory costs drivers for the private and public sectors and provide information to the public. The analysis should address future federal actions on analytical test methodologies; future PCHB decisions; an increased number of impaired water listings under the Clean Water Act; Ecology staff costs for preparation and implementation of additional complex TMDLs; incrementally higher remediation costs as the complete program is implemented; and, lost economic opportunities for the public due to increased compliance costs and regulatory uncertainty

NWPPA believes that if Ecology is required to adopt more stringent criteria, it will have to substantially review and revise its preliminary cost benefit analysis.

Comment No. 21: Variances are necessary and appropriate implementation tools for the rule proposal in WAC 173-201A-420 and allowed by the Clean Water Act.

NWPPA supports variances as essential tools for implementing the human health proposal. A variance is an undesirable but likely necessary implementation tool for the human health rule package. It is a serious tool that modifies a water quality standard and undergoes rigorous evaluation by both the state and EPA and includes public comment. Regulated entities will absolutely require the option of a variance to provide regulatory certainty and a path forward to compliance in certain water permitting situations.

Comment No. 22: Ecology must carefully consider any changes to variance rule language and the rule implementation plan to ensure successful implementation of variances for public and private entities.

The variances application process should be a defined path with clear expectations for both the regulated entities and the public. Ecology must develop and disseminate information to assist in applying for a variance with defined steps and timelines to reduce regulatory uncertainty and build trust with the public.

Any changes to the proposed variance language should be carefully analyzed to ensure a fair and balanced process with checks and balances. A variance should not be a regulatory roadblock to achieving water quality improvements. Ecology should assess whether decisions to initially grant a variance can be adopted through RCW 34.05.350 *Emergency Rule* procedures to allow compliance in specific water permitting situations rather than wait for 12 to 24 months in a typical rule process.

Comment No. 23: Waterbody-specific variance language and implementation plans must be retained in WAC 173-201A-420.

NWPPA supports waterbody specific variances as essential tools for implementing the human health proposal. Ecology must retain and sharpen their plans for water-body specific variances rules to not only mitigate regulatory compliance costs, but to also provide certainty to regulated entities and the public. A waterbody variance could establish a framework for improving water quality in a geographical area. It could provide benefits beyond initial compliance as the variance overlay attracts further study, evaluation, and actions by all sectors contributing to impairment of the waterbody.

Comment No. 24: Compliance schedules are necessary and appropriate implementation tools for the rule proposal in WAC 173-201A-510(4) and allowed under the Clean Water Act and their important role is recognized in RCW 90.48.605.

NWPPA supports compliance schedules as well-established and essential tools for implementing the human health rules. Compliance schedules allow facilities the necessary time to come into compliance with more stringent criteria and encourages Ecology to maintain the proposal without modifications. If a facility needs to change their manufacturing processes, or modify their treatment facility or perform research – a compliance schedule is the appropriate

tool to allow the time to come into compliance with criteria and new regulations especially in a situation governed by a TMDL.

NWPPA supports the rule recognizing the statutory direction for allowing a compliance schedules to exceed ten years. RCW 90.48.605. In some complicated water quality impairment situations it is necessary to take actions benefitting water quality across the landscape. An extended compliance schedule is a win-win implementation tool allowing the flexibility to come into compliance with more stringent regulations while allowing facilities a path to comply with the criteria rather than seek a variance to the criteria.

Comment No. 25: Intake credits are necessary and appropriate implementation tools for the rule proposal in WAC 173-201A-460 and are allowed by the Clean Water Act and should be rewritten to be broader in scope, practical and administratively simple.

NWPPA supports intake credits as essential tools for implementing the human health rules. However, the specific provisions of the intake credit proposal must be improved upon to guarantee future success. Ecology must rethink and revise the essential intake credit implementation tool to make it workable for the regulated community.

As it now stands, the proposal is hard to understand and confusing, which will lead to a less effective and perhaps useless implementation tool. Ecology should revise the proposed language to provide meaningful consideration of background pollutants and an understandable administrative process. The final rule should be broadly applicable and useful to assist facilities with compliance in situations where they are not contributing to water quality impairments but bringing a pollutant into their process in their intake water that already exceeds water quality criteria.

NWPPA requests to work with Ecology to answer any questions on modifying the rule to be more practical, simple and useful for improving Washington's water quality.