

Water Quality Risk Policy for the Protection of Human Health

I. Introduction and Summary

- The Washington Department of Ecology (Ecology) is considering the development of state water quality human health criteria. An important factor in deriving human health criteria for carcinogens is the acceptable risk level used to calculate the criteria.
- The existing Ecology risk policy protects the general population to a one-in-one million (10^{-6}) increased risk of cancer as long as subpopulations are protected to a level that is no less than a one-in-ten-thousand (10^{-4}) increased risk of cancer. This policy is embodied in two provisions of the Washington Water Quality Standards, WAC 173-201A-240(5) and 240(6).
- Pursuant to this policy the human health criteria applicable to Washington under the National Toxics Rule are based on a fish consumption rate of 6.5 grams per day (g/day) for the general population while higher consuming subpopulations are protected up to a fish consumption rate of 650 g/day.
- The existing human health criteria are protective of subpopulations in Washington based on Ecology's Fish Consumption Rate Technical Support Document (TSD), No. 11-09-050 (Sept. 2011). The TSD identified tribal fish consumption rates of between 157 and 267 g/day. *Id.*, at 7. The current criteria are roughly three times as protection of high fish consumers documented in the TSD.
- EPA guidance continues to support deriving human health criteria based on protection of the general population to a risk level of 10^{-6} as long as subpopulations are protective to at least 10^{-4} .¹
- EPA guidance further recommends that states revise their human health criteria, or in the case of Washington, develop human health criteria, where there is evidence that subpopulations are not protected to 10^{-4} .² There is no evidence that the current criteria applicable in Washington fall below this level of protection.

II. Background on State Water Quality Standards and Criteria for Toxic Contaminants

Under the Clean Water Act (CWA)³, states are responsible for establishing water quality standards.⁴ EPA's method for deriving state water quality standards to protect

¹ "EPA believes that both 10^{-6} and 10^{-5} may be acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level." EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, at 2-6 (Oct. 2000).

² EPA, *Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health*, EPA-822-B-00-004 (Oct. 2000) at 2-6.

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

⁴ 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 "ambient water quality criteria"), along with an antidegradation

human health involves consideration of the FCR—the rate at which adults consume fully contaminated fish over a lifetime. Along with various factors including the acceptable risk level, the FCR is used to derive “ambient water quality criteria” (AWQC). AWQC are amounts of substances “designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and consumption of fish obtained from surface waters.”⁵ Regulatory agencies translate water quality criteria into point source permit limits in NPDES permits.⁶

In 1987, Congress amended the CWA to require states to adopt criteria for those toxic pollutants that could interfere with designated uses of state waters.⁷ EPA promulgated guidance to assist states in the adoption of criteria for these pollutants.⁸

EPA allowed states to establish risk levels “in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations.”⁹ Citing the slow pace at which states were adopting criteria, EPA adopted the National Toxics Rule (NTR) in 1992. The NTR established AWQC for states (including Washington) that had not yet established their own numeric ambient criteria for toxic pollutants.¹⁰

III. Washington’s Water Quality Standards and the National Toxics Rule

Through the NTR process, EPA offered states the option of AWQC calculated based on either a 10^{-6} or 10^{-5} risk level for the general population. EPA regards both risk

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).” EPA, METHODOLOGY FOR DERIVING AMBIENT WATER QUALITY CRITERIA FOR PROTECTION OF HUMAN HEALTH, EPA-822-B-00-004 (Oct. 2000) at 1-4.

⁵ EPA, METHODOLOGY FOR DERIVING AMBIENT WATER QUALITY CRITERIA FOR PROTECTION OF HUMAN HEALTH, EPA-822-B-00-004 (Oct. 2000) at 1-11.

⁶ CWA, Section 301(b)(1)(C); 303(e)(3)(A); National Toxics Rule (NTR), 57 FR 60848-01, 60851.

⁷ CWA, Section 303(c)(2)(B).

⁸ NTR, 57 Fed. Reg. 60848-01, 60853.

⁹ NTR, 57 Fed. Reg. 60848-01, 60855.

¹⁰ NTR, 57 Fed. Reg. 60848-1; 40 C.F.R. § 131.36. The FDA was the first federal administrative agency to adopt 10^{-6} as a risk level. The FDA sought to establish amounts of carcinogenic compounds that when present as residue in human food would be consistent with “a zero tolerance (no residue)” policy. 33 Fed. Reg. 19226, 19226 (July 19, 1973). FDA proposed a one in one-hundred-million risk level. *Id.* at 19227. In its final rule, FDA determined a one-in-a-million risk was “essentially zero.” 42 Fed. Reg. 10412 (Feb. 22, 1977). Given uncertainties including variances of sensitivities and exposure levels, absolute criteria could not be established. 45 Fed. Reg. 79318, 79347 (Nov. 28, 1980). Instead, EPA presented a range of concentrations associated with risk levels of 10^{-5} , 10^{-6} , and 10^{-7} . *Id.* at 79348. EPA’s objective in deriving these water quality criteria was to estimate concentrations “which do not represent a significant risk to the public.” *Id.* at 79347.

levels as acceptable,¹¹ so long as the selection provides at least a 10^{-4} risk level for the greatest consumers of fish. “EPA generally regulates pollutants treated as carcinogens in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations.”¹² “EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10^{-4} level.”¹³

Washington opted to use a 10^{-6} risk level.¹⁴ In the context of the NTR, however, this risk level is applicable to 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 a range of acceptable risk levels from 10^{-6} to 10^{-4} .¹⁵ EPA described this as a choice “to provide a high level of protection for the average population in order to provide what [Washington deemed] adequate protection for more sensitive populations.”¹⁶

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 also known as a Total Maximum Daily Load allocation (TMDL) approved by EPA for Columbia River. The dioxin TMDL was based on the same assumptions for the dioxin criterion in the NTR, including an FCR of 6.5 g/day. The TMDL was challenged in federal court on the basis of evidence that actual FCR on the Columbia River for recreational fishers and

¹¹ 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} . NTR, 57 FR 60848-01, 60864. In general, the NTR established AWQC for states based on a 10^{-6} risk level. 57 Fed. Reg. 60848-1, 60860. A state could ask EPA to remove the state from the rule, and adopt human health criteria for a carcinogen at a 10^{-5} risk level. 57 Fed. Reg. 60848-1, 60860. 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.” 57 Fed. Reg. 60848-1, 60860.

¹² NTR, 57 Fed. Reg. 60848-01, 60855; *see also* 65 Fed. Reg. 31682, 31699 (May 18, 2000).

¹³ EPA, Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health, EPA-822-B-00-004 (Oct. 2000) at 1-12; *see also* NTR, 57 FR 60848-01, 60863 (describing 10^{-5} level as “adequately protective”).

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

¹⁵ 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).

¹⁶ EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994), at 48. 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.*

tribes was as high as 150 g/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} assuming 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).¹⁷

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.¹⁸ 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.¹⁹ The AWQC is a range of concentrations associated with specified incremental lifetime risk levels.²⁰ According to EPA, the FCR was “intended to represent only a subset of total fish consumption.”²¹ The FCR is the assumed amount of “maximum residue fish” consumed.²² 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.²³ 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.”²⁴

¹⁷ 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).

¹⁸ *Natural Resources Defense Council v. EPA*, 16 F.3d 1395, 1402 n.11 (4th Cir. 1993).

¹⁹ *Natural Resources Defense Council v. EPA*, 16 F.3d 1395, 1403.

²⁰ EPA, Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health, EPA-822-B-00-004 (Oct. 2000) at 1-2, 1-3.

²¹ EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994), at 44.

²² EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994), at 44.

²³ *Natural Resources Defense Council v. EPA*, 16 F.3d 1395, 1403 (4th Cir. 1993); EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994), at 44.

²⁴ EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994), at 44. EPA’s water quality criteria guidance includes a margin of safety for water consumption. 65 Fed. Reg. 31682, 31693, col. 3 (May 18, 2000).

An important consideration in understanding the risk policy in the state of Washington is the timing and sequence of when the state adopted its risk policy and when the state formally adopted the NTR. The risk policy, WAC 173-301A-249(5), was promulgated as a state regulation in October 1992.²⁵ The promulgation of the regulation adopting the NTR as part of the state Water Quality Standards, WAC 173-201A-240(6), came five years later in November 1997.²⁶ 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.²⁷ Thus, if Ecology believed that the risk policy was intended to more broadly apply in Washington it would have amended the regulation prior to adoption of the NTR. As adopted and in light of the federal court decision, the NTR as applied in Washington does not presume that all consumers are to be protected to a level of 10^{-6} .²⁸

EPA has also considered the accepted range of risk levels as a matter of environmental justice. This was raised in 2000 when EPA approved the California Toxics Rule in 2000. EPA specifically rejected several comments that the 10^{-6} to 10^{-4} risk policy constituted 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, after attainment of water quality criteria in ambient waters, no group is subject to increase 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

²⁵ WSR 92-24-037.

²⁶ WSR 97-23-064.

²⁷ *Hangman Ridge Training Stables, Inc. v. Safeco Title Ins Co.*, 105 Wn.2d 778, 789, 719 P.2d 531 (1986).

²⁸ 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).

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.²⁹

In a 2000 guidance document, EPA affirmed its national policy on the acceptable risk level for human health criteria. In that guidance document EPA describes the choice of a default consumption rate and acceptable cancer risk as a risk management decision that integrates the risk assessment with engineering data, social, economic and political concerns.³⁰ EPA encourages states in the guidance to adopt an alternate FCR from EPA guidance “where fish consumption among highly exposed population groups is of a magnitude that a 10⁻⁴ risk level would be exceeded.”³¹ EPA has not revised the national policy on the acceptable range of risk levels reflected in the 1992 NTR, the 1995 *Dioxin/Organochlorine Center* decision or the 2000 guidance document for deriving human health criteria.

IV. Conclusion

The fish consumption rate used to derive Washington’s water quality standards was not intended to accurately reflect actual fish consumption in Washington. In EPA’s words, the “central question is whether the actual rate of ingestion” for any *contaminant* is greater than that assumed by the state and EPA,³² not whether Washington residents consume a particular quantity of fish. A disparity in actual fish consumption relative to the FCR does not alone render the FCR unlawful or indefensible. It does not mean that high fish-consuming populations are not protected from an increased risk of cancer. Without evidence that the risk level for Washington fish consumers is less than 10⁻⁴, a revision to the FCR should be understood as driven by a policy choice (to extend a 10⁻⁶ risk level to a greater percentage of the Washington population), and not driven by the CWA or environmental justice. There has been no discussion at the federal or state level as to how the current accepted risk policies are in any way inadequate to protect all consumers from exposure to carcinogens.

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²⁹ EPA, *California Toxics Rule Response to Comments Report*, CTR-002-005a (Dec. 1999). http://water.epa.gov/lawsregs/rulesregs/ctr/upload/2009_03_26_standards_rules_ctr_responses.pdf

³⁰ EPA defined risk management as “Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision.” EPA, *Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health*, EPA-822-B-00-004 (Oct. 2000) at 2-4.

³¹ EPA, *Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health*, EPA-822-B-00-004 (Oct. 2000) at 2-6.

³² EPA, *Brief for the Defendant-Appellees, Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994), at 45.