

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

ASSOCIATION OF WASHINGTON BUSINESS, NORTHWEST PULP & PAPER ASSOCIATION, AMERICAN FOREST & PAPER ASSOCIATION, GREATER SPOKANE, INC., and FOOD NORTHWEST,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and

MICHAEL S. REGAN, in his official capacity as Administrator of the U.S. Environmental Protection agency,

Defendants.

Civil Action No. 23-cv-3605

**COMPLAINT**

Plaintiffs Association of Washington Business, Northwest Pulp & Paper Association, American Forest & Paper Association, Greater Spokane, Inc., and Food Northwest hereby allege as follows:

**I. Introduction**

1. This is a challenge to a final rule promulgated by the U.S. Environmental Protection Agency (EPA) imposing water quality standards (WQS) on the State of Washington that are so stringent that compliance cannot even be measured, much less achieved. EPA arrived at these impossible standards by populating the variables in the relevant standards-setting formula with values that are unscientific, conflict with EPA guidance, and have no basis in real-world data. Among other errors, EPA treated a small and speculative subpopulation of tribal subsistence fishers as the “general population,” even though its own guidance distinguishes between the

general population and highly exposed subpopulations when calculating these standards. To justify that assumption, EPA purported to give effect to tribal treaties that EPA has no reason—or legal authority—to interpret. EPA compounded that error by relying on an assumption about that subpopulation’s rate of fish consumption that the agency *admits* is inconsistent with present-day realities. And EPA substituted its own preferences for Washington’s in selecting an acceptable cancer risk level for certain chemicals—even though Washington’s policy choice was fully consistent with EPA’s guidance. In adopting these flawed inputs, EPA reversed its own prior determination—made just a few years earlier—that these inputs were *unlawful* and based on improper, nonscientific concerns involving tribal rights. EPA cited no new scientific evidence to justify its about face. In the end, EPA’s arbitrary assumptions produced absurd standards that fall below even background levels of the relevant pollutants in many water bodies, rendering Washington’s communities and businesses powerless to comply. EPA added insult to injury by justifying the rule in part using a flawed economic analysis that purported to find the standards are *cost-free*. Because reasoned decisionmaking requires far more than that, this Court should vacate the 2022 rule.

2. The Clean Water Act (CWA) “anticipates a partnership between the States and the Federal Government, animated by a shared objective: ‘to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.’” *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992) (quoting 33 U.S.C. § 1251(a)). This “program of cooperative federalism,” *New York v. United States*, 505 U.S. 144, 167 (1992) (citation omitted), tasks the States with developing water quality standards and the EPA with issuing guidance and reviewing state standards for consistency with the CWA and its implementing regulations. If EPA determines that a State’s

standards are inconsistent with the CWA, it must conduct its own analysis and promulgate federal standards that comply with the statute's requirements.

3. In August 2016, the State of Washington submitted a set of water quality standards to EPA after an extensive process of scientific analysis and public input. Washington used a "fish consumption rate" higher than EPA's national recommendation and pollutant-specific "cancer risk levels" within the recommended range set out in EPA's longstanding guidance. After analyzing these inputs, Washington developed target concentrations for the pollutants at issue.

4. In November 2016, EPA partially disapproved Washington's water quality standards. EPA based this decision not on reasonable interpretations of the CWA or its implementing regulations, however, but on a novel legal theory with sweeping implications: That EPA had the authority to interpret treaties between the United States and tribes located in Washington, and that "harmonizing" its interpretation of those treaties with the CWA required EPA to reject some of Washington's standards.

5. Pursuant to this theory, EPA treated "tribal subsistence fishers" as the "target general population" rather than as a highly exposed subpopulation; required a more stringent "cancer risk level" for a key pollutant than the State deemed appropriate; and imposed federal water quality standards that were as much as 25 times more stringent than the State's. In fact, EPA's standards for polychlorinated biphenyls (PCBs) were so stringent that modern technology cannot even detect the pollutant at EPA's selected level.

6. In 2019, after receiving a petition for reconsideration by a coalition of Washington businesses and others (some of which are Plaintiffs here), EPA revisited its decision and reversed course, approving the State of Washington's August 2016 proposed standards, finding them to be scientifically sound and protective of human health and the environment, and withdrawing the

November 2016 federal standards that EPA had imposed on the State. EPA acknowledged that its prior tribal rights theory had no basis in the CWA or EPA regulations, and reaffirmed its position that States have primary responsibility to make risk-management decisions in setting water quality standards.

7. In 2022, however, EPA reversed its reversal, returning to and relying on much of the same discredited rationale of the November 2016 EPA rule and re-imposing the federal standards on Washington, claiming that the State's standards were not based on sound science. In reality, EPA's 2022 decision relied on its unsupported and unlawful tribal-rights rationale. Despite commenters' identification of the serious flaws with EPA's approach in a round of notice and comment, EPA offered no further justification for its asserted tribal-rights authority, and did not explain adequately why EPA's rejection of that authority in 2019 was no longer correct. In support of its impossibly stringent 2022 standards, EPA offered an economic analysis asserting that the 2022 rule imposed *no costs* on regulated parties, including small entities, because the State's role in complying with the federal standards through the permitting process made estimating those costs "highly speculative."

8. In reality, EPA's 2022 rule imminently threatens severe injuries to regulated parties in Washington—including many of Plaintiffs' members—by imposing pollutant concentration thresholds that are unduly burdensome and, by all accounts, impossible to measure and achieve using available detection and treatment technologies. As a direct result of EPA's unlawful action, Plaintiffs' members will incur billions of dollars in additional compliance costs, and endure regulatory uncertainty that disrupts their investment-backed reliance on EPA's longstanding prior policies.

9. As alleged in greater detail below, EPA's 2022 rule is unlawful for a number of independent reasons.

10. *First*, EPA's abrupt, unexplained, and complete reversal of the 2019 rule in its 2022 decision is arbitrary and capricious and violates the Administrative Procedure Act (APA). Less than three years after expressly disclaiming the tribal-rights rationale for selecting a high consumption subpopulation as a target general population, an unreasonably high fish consumption rate, and a more stringent cancer risk level, EPA's 2022 rule changed tack by finding that the 2019 standards were not based on sound science and, relying on this baseless rationale, imposed unduly stringent, and unnecessary, federal standards. In doing so, EPA failed to explain or demonstrate why the 2019 rule was not based on sound science or was not sufficiently protective of human health and the environment; despite bald assertions to the contrary, EPA's 2022 rule still relies on its groundless tribal-rights rationale. Agencies may abandon prior positions and adopt new ones so long as the change is "reasonable and reasonably explained." *Biden v. Texas*, 142 S. Ct. 2528, 2543 (2022). Because EPA's 2022 rule is neither, it violates the APA.

11. *Second*, EPA's 2022 rule violates the APA by relying on a risk analysis that departs from the agency's own longstanding guidance. Rather than analyze risk based on Washington's population, EPA considered tribal subsistence fishers as the target general population in setting the federal standards—an analytical choice with no basis in law that does not reflect population realities and has no relation to the sound science requirement that EPA purported to apply in disapproving Washington's standards. Based on this improper assumption, EPA then triple-counted the need to protect its chosen target general population by: (1) failing to consider that anadromous fish such as salmon have lower pollutant concentrations than freshwater or estuarine fish; (2) setting an unsupported and unreasonably high fish-consumption rate of 175 g/day; and

(3) choosing a more stringent cancer-risk level than even that recommended by EPA’s guidance—which remains in force.

12. *Third*, EPA’s 2022 rule further violates the APA by imposing a target concentration level for PCBs that is unmeasurable and unworkable. As EPA was forced to admit, its PCB limit of 7 parts per quadrillion (or 0.00007 micrograms per liter) is so low that modern technology literally cannot detect or measure the pollutant at EPA’s selected concentration. Background PCB levels in many Washington waters already exceed this standard. Yet EPA expects regulated parties to comply with this limit through as-yet-unknown technologies at enormous expense. That is arbitrary and capricious, and it violates the APA.

13. *Fourth*, EPA’s economic analysis in support of the 2022 rule came to the incredible and implausible conclusion that its impossible target level for PCBs imposes *no costs* on regulated parties, despite receiving ample evidence to the contrary from those parties. For an administrative agency to estimate unduly low costs is one thing; but to say a regulation imposes no costs at all is astounding. Despite proceeding to impose the federal standards for PCBs and scores of other pollutants, EPA asserted that the costs of that approach were too “speculative” to evaluate before forcing Washington and regulated parties to comply. But Washington regulators are already compelling the City of Spokane to comply, generating costs of around \$19 million per gram of PCB removal. Further, contrary to EPA’s view, EPA should consider costs when setting water quality standards under these circumstances. EPA’s mistaken legal premise is itself reason to vacate and remand. And when an agency performs a cost-benefit analysis, that analysis must be reasonable. EPA’s is not, and that violates the APA.

14. *Fifth*, EPA’s 2022 rule is unreasonable in light of the Regulatory Flexibility Act (RFA) for much the same reasons. Like its decision not to assess costs at all, EPA failed to perform

any regulatory flexibility analysis. It failed to do so despite the rule's evident impact on small entities, instead certifying that costs would flow not from the 2022 rule but from Washington's permitting decisions. But it is the 2022 rule that overrode the 2019 standards, forcing regulated parties, including small entities, to comply with an impossibly low limit, and EPA was required to consider economic impacts on small entities when issuing its federal standards. That failure undermined the notice and comment process, and it is arbitrary and capricious.

15. *Sixth*, EPA's 2022 rule exceeds the agency's statutory authority under the CWA. States retain primacy in developing water quality standards, with EPA authorized to step in only when "necessary." Given Washington's protective standard and sound scientific basis for those standards under longstanding regulatory guidance, imposing federal criteria was unnecessary. Moreover, EPA's claimed authority to interpret tribal treaties with the United States and to use its own interpretation to impose more stringent requirements on the States has no basis in the CWA, its implementing regulations, or longstanding EPA policy. Recognizing this fact, EPA only *later* issued a proposed rule to codify its supposed tribal-rights authority into law. But that approach is neither required, nor authorized, by the CWA.

16. For these reasons and more, the Court should vacate EPA's unlawful 2022 rule and allow Washington's water quality standards to go into effect by operation of law.

## **II. Parties**

17. Plaintiff Association of Washington Business (AWB) is a non-profit association headquartered in Olympia, Washington, that represents nearly 7,000 businesses with over 700,000 employees, approximately one-quarter of Washington's workforce. 90% of its members are small businesses employing fewer than 100 people, and many of its members are subject to CWA National Pollutant Discharge Elimination System (NPDES) permitting requirements administered by the Washington Department of Ecology (Ecology) under EPA supervision. AWB represents

its members' interests on state and federal policy issues, including environmental stewardship, water resources, climate change, and land use, as a key part of its mission. As relevant here, AWB and its members directly participated in the formulation of the human health criteria developed by Ecology and disapproved by EPA, and AWB commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

18. Plaintiff Northwest Pulp & Paper Association (NWPPA) is a trade association headquartered in Olympia, Washington, that represents 12 members in the paper products industry employing over 10,000 people at pulp and paper mills in Washington, Oregon, and Idaho. Many of its members are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. NWPPA represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. As relevant here, NWPPA and its members actively participated in Ecology's development of the human health criteria disapproved by EPA, including through the Governor's Informal Advisory Group, and commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

19. Plaintiff American Forest & Paper Association (AF&PA) is a trade association headquartered in Washington, D.C., that represents member companies that make about 87% of the pulp, paper, paper-based packaging, and tissue products made in the United States, including in Washington. The forest products industry accounts for approximately 5% of the total U.S. manufacturing GDP, manufactures about \$350 billion in products annually and employs about 925,000 people. AF&PA membership includes small businesses employing fewer than 100 people, and several AF&PA members are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. AF&PA represents its members' interests on



legislative and regulatory issues at the federal and state level, including environmental and energy policy, as a key part of its mission. As relevant here, AF&PA and its members commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

20. Plaintiff Greater Spokane, Inc., is a non-profit corporation headquartered in Spokane, Washington, that represents hundreds of businesses in the greater Spokane area. Many of its members are small businesses employing fewer than 100 people, and many are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. Greater Spokane represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. As relevant here, Greater Spokane and its members commented extensively on the EPA rulemaking challenged in this case to urge adoption of a more reasonable standard.

21. Plaintiff Food Northwest is a trade association headquartered in Portland, Oregon, that represents over 350 members in the food-processing industry located in Washington, Oregon, and Idaho. Many of its members are small businesses employing fewer than 100 people, and many are subject to CWA NPDES permitting requirements administered by Ecology under EPA supervision. Food Northwest represents its members' interests on legislative and regulatory issues at the federal and state level, including environmental policy, as a key part of its mission. Food Northwest's members will be required to expend millions of dollars in an effort to comply with the challenged rule, which sets an impossibly high standard.

22. Defendant U.S. Environmental Protection Agency is an executive department of the United States.

23. Defendant Michael S. Regan is the Administrator of the U.S. Environmental Protection Agency and the official charged by statute with administering the CWA. *See* 33 U.S.C. §§ 1313, 1361. Defendant Regan is named in his official capacity only.

### **III. Jurisdiction and Venue**

24. This action arises under the CWA, 33 U.S.C. §§ 1311 *et seq.*, the APA, 5 U.S.C. §§ 500 *et seq.*, the RFA, 5 U.S.C. §§ 601 *et seq.*, and EPA rules and regulations.

25. This Court therefore has jurisdiction under 28 U.S.C. § 1331.

26. Plaintiffs have associational standing to bring this suit on behalf of individual members who have standing because their members' individual participation is not required and because the issues in this case are germane to Plaintiffs' organizational missions. Plaintiffs' individual members include holders of and applicants for NPDES permits issued by Ecology under EPA supervision, are subject to CWA permitting requirements and the unlawful water quality standards imposed by the challenged EPA rule, and will, as a result of the challenged EPA rule, incur additional compliance costs, bear additional fees and expenses associated with applications for permits and variance development that would otherwise have been unnecessary, and endure regulatory uncertainty that disrupts their investment-backed reliance on EPA's prior policies.

27. Venue is proper in this district under 28 U.S.C. § 1391(e) because Defendants EPA and Regan reside in this judicial district, and no real property is involved in this action.

### **IV. Allegations**

#### **A. The CWA**

28. The Clean Water Act requires States to adopt water quality standards regulating discharges of pollutants into navigable waters.

29. Water quality standards incorporate the "designated uses" for the water body at issue (*e.g.*, supporting aquatic life or recreational use) and the "water quality criteria" necessary to

protect those uses, which are typically specified as the maximum concentration of a pollutant that may be present in the water. 33 U.S.C. § 1313(c)(2)(A); *see also* 40 C.F.R. §§ 131.3(b), 131.11(a).

30. Water quality criteria include human health criteria representing specific levels of chemicals or conditions in a water body that are not expected to cause adverse effects to human health. Such criteria “must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use.” 40 C.F.R. § 131.11(a)(1).

31. States must periodically submit proposed water quality standards to EPA for review and approval. 33 U.S.C. § 1313(c).

32. To guide States in promulgating such standards, EPA publishes criteria recommendations for States to consider when adopting water quality criteria for particular pollutants based on “the latest scientific knowledge.” 33 U.S.C. § 1314(a). Among other pollutants, EPA has published criteria recommendations for PCBs.

33. States may, but are not required to, adopt criteria recommendations identical to EPA’s federal criteria. They also may adopt criteria modified to reflect site-specific conditions, or other scientifically defensible methods. 40 C.F.R. § 131.11(b)(1).

34. This case principally concerns Washington’s water quality standards for PCBs—“a group of man-made organic chemicals consisting of carbon, hydrogen and chlorine atoms.” EPA, Learn About Polychlorinated Biphenyls (Apr. 12, 2023), <https://www.epa.gov/pcbs/learn-about-polychlorinated-biphenyls>. For much of the twentieth century, PCBs were used in hundreds of industrial and commercial applications, including in electrical equipment, as plasticizers in paints, plastics, and rubber products, and in pigments, dyes, and carbonless copy paper. *Id.*

35. In 1979, Congress banned PCBs in the Toxic Substances Control Act (TSCA). While no longer commercially produced in the United States, however, PCBs may still be present

in products and materials—including in common items like electrical equipment, cable insulation, caulking, and floor finish—that were produced before the 1979 PCB ban. PCBs remain present in air, water, and soil.

36. PCBs have been well studied for both their carcinogenic and non-carcinogenic effects. EPA has never recommended that States adopt a water quality criteria permitting zero PCBs, rejecting that level as “not . . . attainable.” EPA, Ambient Water Quality Criteria for Polychlorinated Biphenyls vii (Oct. 1980), <https://www.epa.gov/sites/default/files/2019-03/documents/ambient-wqc-polychlorinatedbiphenyls-1980.pdf>.

37. In 2000, EPA published guidance—“EPA’s Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health” (2000 Methodology)—that “is used in the development of EPA’s recommended criteria and offered as guidance for states and tribes in developing their own criteria.” EPA, Human Health Water Quality Criteria and Methods for Toxics (Oct. 2, 2023), <https://epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics>. The 2000 Methodology recommends specific inputs to the formulas used in determining human health criteria for particular pollutants.

38. Those inputs include the cancer risks associated with the presence of a particular pollutant in surface water. In evaluating carcinogenic effects, EPA recommends a formula with, as relevant here, two major sub-inputs: (1) cancer risk level (CRL), an excess lifetime cancer risk in the population used to derive an acceptable concentration of a pollutant in water; and (2) fish-consumption rate (FCR), a measure of the amount of fish consumed by the target general population on average per day over a lifetime. EPA also considers as other sub-inputs exposure through the ingestion of contaminated surface water and a relative source contribution—the percentage of a reference dose (the amount of a chemical that a person can ingest every day for a lifetime that is

not anticipated to cause harmful noncancer health effects) to be attributed to ambient water and freshwater and estuarine fish consumption. EPA, Water Quality Standards Handbook, Chapter 3, § 3.3.1 (2014), <http://www.epa.gov/wqs-tech/water-quality-standards-handbook>.

39. The 2000 Methodology provides that human health criteria “based on a  $10^{-5}$  [cancer] risk level”—*i.e.*, the acceptable pollutant concentration should reflect a probability of no more than one additional case of cancer in a population of one hundred thousand—“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.” 2000 Methodology 1-12.

40. The 2000 Methodology further specifies that “[t]he default fish consumption value for the general adult population . . . is 17.5 grams/day, which represents an estimate of the 90th percentile consumption rate for the U.S. adult population,” and is a default value “chosen to be protective of the majority of the general population.” 2000 Methodology 1-12.

41. The 2000 Methodology acknowledged, however, that these choices were not entirely scientific decisions. While “[s]ome decisions” for relevant inputs to the human health criteria formula “are more grounded in science,” EPA explained, “others are more obviously *risk management* decisions (such as the determination of default fish consumption rates and cancer risk levels).” 2000 Methodology 2-4 (emphasis added).

42. States are required to propose water quality standards pursuant to 33 U.S.C. § 1313(c)(1).

43. If EPA determines that a State’s proposed standards satisfy the CWA’s requirements, “such standard[s] shall thereafter be the water quality standard[s] for the applicable waters of that State.” 33 U.S.C. § 1313(c)(3).

44. The CWA thus gives States primary responsibility for establishing water quality standards and regulating their waters, and EPA may step in only if it determines that a State's water quality standards are inconsistent with the Act. 33 U.S.C. § 1313(c)(3).

45. If a State fails to adopt standards that meet the Clean Water Act's requirements and EPA "determines that a revised or new standard is necessary to meet the requirements" of the Act, EPA must "promptly prepare and publish proposed regulations setting forth a revised or new water quality standard." 33 U.S.C. § 1313(c)(4)(B). EPA's federal standards must be "in accordance with the applicable requirements" of the Act and, as with all agency action subject to the APA, must involve reasonable analysis, arrive at a reasonable result, and be reasonably explained. *Id.* § 1313(b)(1); *Biden*, 142 S. Ct. at 2543.

46. Whether ultimately adopted as state or federal standards, approved water quality standards are used to set effluent limits in the permits that dischargers must obtain to discharge pollutants from a point source into waters covered by the CWA. 33 U.S.C. § 1342; *see* 40 C.F.R. § 122.44(d)(1).

47. Under regulations issued by EPA, States may also seek a variance from approved water quality standards—the so-called "base" water quality standards—if compliance with such standards is shown to be infeasible. *See* 40 C.F.R. § 131.14. But EPA and States with delegated authority rarely grant variances. Indeed, Washington State has never been granted a variance. EPA may approve a variance only if the State can demonstrate that compliance with the base water quality standards is not feasible for one of several enumerated reasons. *Id.* §§ 131.10(g), 131.14(b)(2)(i)(A). Moreover, "new sources are ineligible for variances from performance standards," which are "potentially available" only "to existing sources." *Nat. Res. Def. Council, Inc. v. EPA*, 822 F.2d 104, 112 (D.C. Cir. 1987). Even once granted, a variance provides only

a narrow, time-limited exemption from the base water quality standards, applicable to specific pollutants and to specific dischargers or a particular water body. 40 C.F.R. §§ 131.3(o), 131.14(a).

**B. Washington’s 2016 Water Quality Standards**

48. In 2015, EPA determined that updated human health criteria (HHC) were “necessary” to protect Washington residents and invoked its authority to establish new federal water quality standards. 80 Fed. Reg. 55,063, 55,066 (Sept. 14, 2015). EPA proposed criteria for 99 CWA-listed toxic pollutants, including PCBs. *Id.* at 55,067. The agency calculated these standards using an FCR of 175 g/day and a CRL of  $10^{-6}$  for all chemicals, including PCBs. *Id.* at 55,067–68. This FCR far surpassed the 2000 Methodology’s FCR of 17.5 g/day; EPA adopted this higher value because it stated that 175 g/day reflected the “95th percentile consumption rate of surveyed tribal members.” *Id.* at 55,067. EPA’s chosen CRL of  $10^{-6}$  was an order of magnitude more stringent than the 2000 Methodology’s CRL for PCBs; EPA adopted this more stringent value only by mischaracterizing its own Methodology as requiring it. *Compare* 81 Fed. Reg. 85,417, 85,420 & n.10 (Nov. 28, 2016) (“Criteria based on a  $10^{-5}$  risk level are acceptable . . .”), *with id.* at 85,427 (“EPA issued its 2000 Methodology, which states that when promulgating water quality criteria for states and tribes, EPA intends to use the  $10^{-6}$  cancer risk level, which reflects an appropriate risk for the general population.”).

49. In August 2016, before EPA finalized its proposed federal standards, Washington adopted its own HHC following, in EPA’s words, “an extensive public process.” *Toxic Substances—WAC 173-201A-240*, Wash. State Legislature (2019), <https://apps.leg.wa.gov/wac/default.aspx?cite=173-201a-240>; 87 Fed. Reg. 69,183, 69,187 (Nov. 18, 2022). In all, the State’s Department of Ecology promulgated 188 new criteria. The State used its discretion to make risk management decisions for its waters by incorporating several of EPA’s proposed inputs, including

the unusually high FCR and CRL, while using a different CRL level of  $10^{-5}$  for PCBs. *Toxic Substances—WAC 173-201A-240, supra*, at tbl. 240 & nn.B, E.

50. In 2016, EPA approved 45 and disapproved 143 of Washington’s HHC, finding they were not adequately supported by sound science. 81 Fed. Reg. at 85,419. Specifically, EPA rejected the State’s PCB standards because it erroneously concluded that any CRL below  $10^{-6}$  for that chemical would be insufficiently protective. When paired with the State’s inflated fish consumption rate, these inputs produced a remarkably low (and therefore stringent) PCB target level (7 parts per quadrillion, or  $7 \times 10^{-6}$  micrograms per liter). *Id.* at 85,431.

51. EPA’s November 2016 rule acknowledged that its 2000 Methodology authorizes a  $1.0 \times 10^{-5}$  CRL (close to, and in reality, due to the theoretical nature of these values, indistinguishable from the value Washington had used,  $2.3 \times 10^{-5}$ ), as long as “more highly exposed subgroups”—like “subsistence fishers”—were protected at a  $10^{-4}$  CRL. 81 Fed. Reg. at 85,420 & n.10. But the agency moved the goalposts, defining “tribal subsistence fishers” as the “target general population” and combining it with a  $10^{-6}$  CRL. To exacerbate its error, EPA not only identified the wrong group as the “general population” (it is a gross misuse of the terms of the CWA to designate an extremely small subpopulation as the “general population”), but also used an inflated estimation of that population’s fish consumption rate. *Id.; id.* at 85,424. In promulgating the 2022 rule, EPA “appl[ied] the same rationale here as the agency articulated . . . in the 2016 federal rule.” 87 Fed. Reg. 19,046, 19,054 (Apr. 1, 2022) (noting this point in connection with selection of FCR); *id.* at 19,055 (noting that selected CRL “is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels”). This definitional shift effectively protects the actual general population of Washington at a  $10^{-8}$  risk level—one additional case of cancer in a population of *one hundred million*. *Nw. Pulp & Paper*



Ass'n Comment Letter on EPA Proposed Human Health Water Quality Criteria for Washington 23, Dkt. No. 2015-1089 (Apr. 1, 2022). There is absolutely no basis under the CWA for EPA to impose on a State a rule with such a risk level; the CWA gives States and tribes discretion whether to adopt such an extremely conservative (and likely unprecedented) standard. 81 Fed. Reg. at 85,420.

52. EPA's only explanation for its change in position is that the 2000 Methodology did not "speak to or envision the unique situation of setting WQS [water quality standards] that cover areas where tribes have treaty-reserved rights to practice subsistence fishing"—even though the Methodology used the phrase "subsistence fishers." 81 Fed. Reg. at 85,424–25. While purporting to disapprove Washington's standards for scientific reasons, EPA in fact predominantly relied on a tribal-rights theory that has no basis in applicable regulations or EPA's longstanding Methodology and is not a scientific consideration.

53. Both the CRL and high FCR rested on EPA's assumption of authority to "harmonize treaty-reserved fishing rights with the CWA." 81 Fed. Reg. at 85,424. The agency decided that even though "[t]he CWA generally assigns to a state the responsibility of determining the designated uses of its waters . . . , through treaties, tribes reserved specific fishing rights . . . including the right to take fish from such waters for their subsistence." *Id.* EPA then construed this "subsistence fishing" right to require that the agency treat tribes as the "target general population." *Id.*

54. According to the U.S. Census Bureau, 1.6% of Washington state's population were American Indian and Alaska Native in 2020. *Race and Ethnicity*, U.S. Census Bureau (2023), <https://data.census.gov/profile/Washington?g=040XX00US53#race-and-ethnicity>. Not all of these individuals are tribal members, and even fewer fish for subsistence. Moreover, a substantial

number of tribal members who do fish for subsistence likely live on tribal reservation land and fish in whole or in part in tribal reservation waters, which expressly are *not* governed by EPA's WQS or Washington's HHC. *See* 81 Fed. Reg. at 85,422 & n.27 ("This rule applies to waters under the State of Washington's jurisdiction, and not to waters within Indian country"). Thus, EPA's rule applied to all waters in the State and the entire population of Washington—even though likely less than 1% of the population consumes the amount of fish on which the fish consumption rate was based.

55. Shortly after its promulgation, a coalition of Washington businesses and others petitioned EPA to reconsider the 2016 rule. Compl. Ex. 1, Pet. for Rulemaking, *Washington v. EPA*, No. 2:19-cv-00884-RAJ (W.D. Wash. June 6, 2019). The petitioners urged that EPA change course for three reasons: (1) The CWA required EPA to approve state standards that met statutory requirements, as Washington's did, "improperly usurp[ing] the primary role of the state to make risk management decisions"; (2) EPA's new standards were arbitrary and capricious because they would "devastat[e the State's] local communities and businesses"; and (3) the federal criteria offered "no benefit to public health over the Washington-submitted standards." *Id.* at 2–3.

### **C. EPA's Reconsideration**

56. In 2019, EPA approved all but two of Washington's HHC after determining that its partial disapproval had improperly infringed on Washington's authority under the CWA to make its own risk-management decisions based in sound science. Letter from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Wash. Dep't of Ecology 8 (May 10, 2019), [https://www.epa.gov/sites/default/files/2019-05/documents/wawqsletter\\_td\\_dated\\_may\\_2019.pdf](https://www.epa.gov/sites/default/files/2019-05/documents/wawqsletter_td_dated_may_2019.pdf) ("EPA Approval").

57. Applying the 2000 Methodology, EPA determined that Washington's cancer risk level of  $2.3 \times 10^{-5}$  for PCBs satisfied CWA requirements, was based on sound science, and was

protective of the general population and high-consuming subpopulations. EPA Approval at 21. EPA confirmed that the CWA does not require States to meet or exceed each of EPA's recommended criteria so long as the submission's risk-management decisions are "based on sound science and the resulting criteria protect the designated uses," consistent with the 2000 Methodology. *Id.* at 24.

58. EPA also determined that the partial disapproval had departed from longstanding EPA policy by requiring Washington as a matter of sound science to treat tribal subsistence fishers as the "target general population." EPA Approval at 21–23. As EPA explained, it was "improper and unnecessary" under the CWA and existing regulations to purportedly "harmonize" tribal treaty rights with the CWA under a new theory not found in the statute or EPA regulations. *Id.* at 22–24. EPA further explained that the partial disapproval had relied on an interpretation of treaty rights that "was not consistent with Washington's interpretation of its designed use[s]." *Id.* at 22.

59. In 2020, EPA allowed Washington's approved HHC to go into effect by finalizing its withdrawal of the relevant federal WQS for Washington through notice-and-comment rulemaking. 85 Fed. Reg. 28,494 (May 13, 2020). EPA restated its longstanding position that "EPA prefers that states maintain primary responsibility and establish their own WQS in keeping with the text and structure of the CWA." *Id.* at 28,495. EPA explained that because Washington's HHC satisfied all statutory requirements, "the cooperative federalism structure of the CWA" required the agency "to withdraw the federal WQS to enable the EPA-approved state WQS to become the applicable WQS for CWA purposes." *Id.* at 28,496.

60. In doing so, EPA affirmed its view that "Washington's HHC are based on sound science and are protective of Washington's designated uses." 85 Fed. Reg. at 28,496. EPA noted in response to comments that "some of Washington's HHC are less stringent than the federal HHC,

and some are more stringent.” *Id.* As EPA explained, the CWA entitled Washington to make such risk-management decisions because its inputs for doing so were based on sound science. *Id.*

#### **D. EPA’s 2022 Rule**

61. In 2022, following a change in administration, EPA again reversed its position and proposed to determine that Washington’s HHC were not based on sound science and therefore not protective of the designated uses in Washington. 87 Fed. Reg. at 19,051. EPA finalized that determination several months later and imposed federal WQS for Washington nearly identical to those promulgated in EPA’s November 2016 rule. 87 Fed. Reg. at 69,183. EPA again noted that federal WQS for Washington do not apply to “waters within Indian country.” *Id.* at 69,188 & n.52.

62. In the 2022 rule, EPA purported to rely on science but in fact relied on the same rationale used in the 2016 rule to arrive at the same analytical inputs and similar federal WQS. 87 Fed. Reg. at 69,188–89. Without addressing the contrary findings in the agency’s 2020 rule and 2019 approval, EPA once again determined that “tribal subsistence fishers” *must* be treated as the “target general population” when setting the fish consumption rate and cancer risk level in States with tribal reserved treaty rights. 87 Fed. Reg. at 19,054–55 (applying “same rationale” to determine fish consumption rate as 2016 Rule, and emphasizing that as “in EPA’s 2016 final rule,” “EPA’s selection of a  $10^{-6}$  CRL is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels”); *see also* 87 Fed. Reg. at 69,188–90. Specifically, EPA again adopted a  $10^{-6}$  CRL for PCBs and a 175 g/day fish consumption rate. 87 Fed. Reg. at 69,188–90.

63. Relying on these inputs, EPA finalized the extraordinarily low target level for PCBs of 7 parts per quadrillion (0.000007 micrograms per liter). 87 Fed. Reg. at 69,193. Despite insisting that this target level was required by the CWA, EPA acknowledged that the existing detection limit for PCBs under EPA-approved testing methodologies is 170 parts per quadrillion

(0.00017 micrograms per liter), almost 25-times higher than EPA’s target level for PCB concentrations. *Id.* at 69,195. Nevertheless, EPA asserted that “it is important that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods.” *Id.* at 69,196.

64. EPA also relied on an economic analysis that estimated the 2022 rule would impose no costs at all on permit holders and only \$100,000 to \$182,000 in administrative costs on the State. 87 Fed. Reg. at 69,195–96. EPA found that it would be “highly speculative to attempt to estimate potential costs” because, for example, the PCB target level is well below existing detection capabilities. *Id.* at 69,195.

65. Finally, EPA certified that the 2022 rule “will not have a significant economic impact on a substantial number of small entities under the [Regulatory Flexibility Act].” 87 Fed. Reg. at 69,196. EPA asserted that it was not required to conduct a regulatory flexibility analysis because “the State will have a number of choices associated with permit writing” while implementing the federal WQS. *Id.*

**Count One (All Defendants):**

**EPA’s Unjustified Change In Position Violates The APA.**

66. Plaintiffs incorporate by reference the allegations above.

67. Abruptly reversing longstanding policy by disapproving the 2019 standards (which were based on the State of Washington’s August 2016 proposed standards) and enacting the 2022 rule based in part on the purportedly scientific need to protect tribal subsistence fishers as the “target general population,” EPA changed its position without adequate justification and without considering the reasonable, investment-backed reliance of regulated parties in the State. EPA again failed to offer any valid reason why the sound science standard or any applicable statutory

or regulatory requirements mandated its disapproval and imposition of infinitesimally low values for the federal standards. That unexplained departure is arbitrary and capricious and warrants vacatur of the 2022 rule.

68. The CWA and its implementing regulations enumerate specific requirements for state criteria, including the use of sound science. *See* 33 U.S.C. § 1313; 40 C.F.R. §§ 131.1 *et seq.* None requires, or even mentions, any role for tribal reserved rights in determining the “target general population,” fish consumption rate, and cancer risk level in setting and reviewing WQS. EPA has since admitted in a proposed rule that “EPA’s existing WQS regulation” and applicable guidance “do[] not . . . explicitly address how WQS must protect tribal reserved rights.” 87 Fed. Reg. 74,361, 74,365 (Dec. 5, 2022).

69. As recently as 2019, EPA has explained to States and regulated parties that “[t]he existence of tribal treaties with reserved fishing rights does not grant the EPA authority to recharacterize a state’s designated uses or otherwise skew the federal-state balance of the CWA towards the federal government” and that “[n]othing in the CWA or the EPA’s regulations and guidance, including the 2000 Methodology, requires a state to set a FCR based on an estimate of unsuppressed consumption.” EPA Approval of the State of Idaho’s New/Revised Human Health Water Quality Criteria for Toxics and Other Water Quality Standards Provisions 12, 27 (Apr. 4, 2019), [https://www.epa.gov/sites/default/files/2019-04/documents/04042019\\_cover\\_letter\\_approval\\_of\\_deq\\_human\\_health\\_criteria\\_signed.pdf](https://www.epa.gov/sites/default/files/2019-04/documents/04042019_cover_letter_approval_of_deq_human_health_criteria_signed.pdf).

70. In 2019 and 2020, EPA reiterated the same view in its decisions approving Washington’s August 2016 WQS and withdrawing EPA’s November 2016 WQS and explained that “EPA prefers that states maintain primary responsibility and establish their own WQS in keeping with the text and structure of the CWA.” 85 Fed. Reg. at 28,495.

71. EPA failed to adequately justify or explain its change in position when superseding the existing, 2019 standards with new federal standards, noting only that it was returning in part to the rationale of EPA's November 2016 WQS and that, without explaining why, the agency preferred chemical-specific cancer risk levels to be consistent across pollutants. 87 Fed. Reg. at 69,189. There is no basis in the CWA or implementing regulations to require States to adopt the same cancer risk level for all human health criteria.

72. Tellingly, EPA did not even mention the contrary policy that EPA itself adopted in 2019 and 2020 (which correctly applied EPA's longstanding approach) regarding the role of reserved tribal fishing rights in setting WQS, let alone justify its new policy based on the text, structure, and regulatory history of the CWA in light of the extensive contrary reasoning in its 2019 and 2020 decisions and many prior decisions approving water quality standards in Washington and other States without application of its novel tribal-treaty approach. Instead, EPA purported to rely on a sound-science rationale, although its reversal was based on its novel and unsupported tribal-rights rationale. And when, as here, an agency repeatedly changes its interpretation of a statute, its interpretation should receive little (if any) deference. *See INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987).

73. Moreover, EPA completely failed to acknowledge the reliance interests of States and regulated parties. Instead, as alleged herein, EPA unreasonably asserted that costs to regulated parties would be zero and estimated an absurdly low cost to Washington in implementing the new federal WQS at between \$100,000 and \$182,000. 87 Fed. Reg. at 69,195–96.

**Count Two (All Defendants):**

**EPA's Risk Analysis Violates The APA.**

74. Plaintiffs incorporate by reference the allegations above.

75. EPA relied on a risk analysis to promulgate the 2022 rule that is arbitrary, capricious, and otherwise unlawful in multiple ways in violation of the APA. 5 U.S.C. § 706(2).

76. *First*, as it did in its November 2016 rule, EPA began its analysis with the insupportable conclusion that hypothetical tribal subsistence fishers consuming fish at a speculative “unsuppressed” rate must be considered the “target *general* population for protection, rather than a subpopulation,” for “the purposes of setting risk levels to protect the subsistence fishing use.” 81 Fed. Reg. at 85,424 (emphasis added); 87 Fed. Reg. at 69,189 (“EPA is applying the same rationale here as the agency articulated to support its use of those inputs in the 2016 Federal rule. . . . As noted in EPA’s 2016 final rule for Washington, several tribes in Washington have treaty-reserved rights to fish on waters throughout the State.” (footnote omitted)). EPA’s choice of FCR for that population necessarily—and unjustifiably—presupposes an “unsuppressed” rate because EPA selected a value well above the 90th percentile of consumption in its survey data. And EPA failed to adequately justify that choice based on sound science, instead merely piggybacking off the “FCR . . . that Washington used in 2016 and that EPA used in its 2016 federal rule.” EPA Response to Public Comments, *Restoring Protective Human Health Criteria in Washington* 50, Dkt. No. EPA-HQ-OW-2015-0174 (2022).

77. EPA’s position relies on an erroneous understanding of federal duties imposed by reserved tribal rights and is based on speculation, not science or EPA’s expertise as an environmental regulator. Specifically, EPA exceeded its authority under the CWA by purporting to interpret the Stevens-Palmer Treaties with the Washington Tribes to impose affirmative obligations on the United States to guarantee “water quality sufficient under the CWA to ensure that tribal members can safely eat the fish for their own subsistence.” 81 Fed. Reg. at 85,423.



78. Nothing in the CWA delegates to EPA the authority to interpret treaties between the United States and Indian Tribes, much less to use such treaties to impose affirmative environmental obligations on States and regulated parties. EPA invokes its authority to make an Administrator’s Determination, 33 U.S.C. § 1313(c)(4)(B), but that provision is limited to a determination that water quality standards are “not consistent with the applicable requirements of *this Act*”—not with treaties, *id.* § 1313(a)(1)–(3) (emphasis added).

79. EPA points to no other treaty text or statutory provision that is sufficiently clear to support EPA’s expansive claim of authority to impose billions of dollars of costs on regulated parties. *See West Virginia v. EPA*, 142 S. Ct. 2587, 2604 (2022) (Congress must have clearly authorized rule that would, among other things, “entail billions of dollars in compliance costs”). The provision that the CWA “not be construed as . . . affecting or impairing the provisions of any treaty of the United States,” for example, is not a grant of authority at all; it is merely a rule of construction. 81 Fed. Reg. at 85,422 & n.31 (quoting 33 U.S.C. § 1371(a)). And nothing in that ancillary provision or elsewhere suggests that the treaties may be used as the basis for EPA to set impossible-to-attain water quality standards.

80. Even assuming EPA could interpret the scope of obligations imposed by treaty, it clearly erred in interpreting the Stevens-Palmer Treaties as imposing affirmative regulatory obligations under the CWA. “Whether the Government has expressly accepted such obligations ‘must train on specific rights-creating or duty-imposing’ language in a treaty, statute, or regulation.” *Arizona v. Navajo Nation*, 143 S. Ct. 1804, 1813 (2023) (quoting *United States v. Navajo Nation*, 537 U.S. 488, 506 (2003)). By its plain terms, language in the Stevens-Palmer Treaties reserving rights “of taking fish at usual and accustomed places, in common with all citizens of the Territory” does not impose a duty on EPA to supplant state water quality standards

in order to treat tribal subsistence fishers as the “target general population.” *See id.* at 1814 (similar language did not impose affirmative duties with respect to providing water to the Navajo Nation).

81. Moreover, EPA’s attempt to “harmonize” its interpretation of the Stevens-Palmer Treaties with the CWA falls well outside the agency’s expertise and is not entitled to deference. 81 Fed. Reg. at 85,423 & n.39. EPA cites no statutory authority or established practice authorizing the agency to interpret tribal reserved rights or to take these rights into account when evaluating WQS submitted by the States. Indeed, EPA has since admitted in a notice of proposed rulemaking that “EPA’s existing WQS regulation” and relevant agency guidance on methodologies “do[] not . . . explicitly address how WQS must protect tribal reserved rights.” 87 Fed. Reg. at 74,365.

82. Perhaps recognizing that this approach is unlawful, EPA contends that it “determined that a  $10^{-6}$  CRL was appropriate independent of treaty rights,” 87 Fed. Reg. at 69,189, and that it derived its new inputs based instead on a “finding that Washington’s criteria are not scientifically sound,” EPA 2022 Response to Public Comments, *supra*, at 50. But EPA expressly conceded “that it does not have new data or information suggesting a need to revisit the inputs utilized in the 2016 rule,” 87 Fed. Reg. at 69,189, cited no new scientific data to support its return to the rationale for EPA’s November 2016 rule, and did not explain how the “science” somehow supported reaching precisely the same number it had previously adopted under a flawed legal rationale. Notwithstanding its reflexive recitation of the sound-science standard, EPA’s unsupported tribal-rights rationale was critical to its decision—and it is not a scientific consideration.

83. *Second*, EPA adopted a fish consumption rate for its “target general population” of 175 g/day, that is based on an overly conservative assumption that this amount of fish is consumed every day, for seventy years, a three-fold increase from even the 90th percentile fish consumption

rate of 53 g/day. 87 Fed. Reg. at 69,188–89; 81 Fed. Reg. at 85,426–27. Because EPA arrived at this figure based on speculation rather than sound science, its use renders the 2022 rule arbitrary and capricious.

84. In selecting its fish consumption rate, EPA relied on “heritage tribal consumption reports” estimating fish consumption rates between 63 and 995 g/day under “traditional tribal practices, prior to contact with European settlers.” 81 Fed. Reg. at 85,426 & n.53. These reports are inherently speculative estimates of behavior in the absence of real-world data that cannot take the place of the sound science required by the CWA and its implementing regulations.

85. Although purporting to rely on “local and regional FCR surveys,” EPA actually disregarded them on the grounds that “[t]here is no local survey of contemporary fish consumption in Washington adjusted specifically to account for suppression, and no survey is a clear representation of current unsuppressed consumption for all tribes in Washington.” 81 Fed. Reg. at 85,426. EPA provides no statutory, regulatory, or scientific justification for “adjust[ing]” this undisclosed data to account for “unsuppressed” rates beyond its reliance on speculative “heritage” data. Ultimately, EPA in part defers selection of its fish consumption rate to the Washington tribes, which “have generally agreed that 175 g/day is acceptable for deriving protective criteria at this time.” *Id.* That subdelegation is not authorized by statute or regulation and fails to reflect “sound science.”

86. In addition, EPA points to Oregon’s approved fish consumption rate of 175 g/day as supporting the same rate for the general population in Washington without explaining why one State’s choice would be required for setting federal standards in another. EPA’s reliance on 40 C.F.R. § 131.10(b) similarly is misplaced, as that provision does not require either EPA or upstream States to adopt the same or even more stringent water quality standards as downstream

States. EPA also fails to mention, or take into account, that Idaho’s more recently approved WQS used a fish consumption rate of 66.5 g/day for the general population. *See* EPA Idaho Approval, *supra*, at 28. And EPA’s allusion to “maintaining consistency between the fish consumption values in this rule with Washington’s other HHC that are not affected by the rule,” EPA 2022 Response to Comments, *supra*, at 26—without any explanation for why such consistency is important enough to override EPA’s obligation to base its FCR on sound science—also fails to provide an adequate basis for EPA’s decision.

87. *Third*, EPA assumed without justification that anadromous fish species, including salmon, which spend most of their life cycle in non-nearshore ocean waters, have the same pollutant concentrations “as those in inland and nearshore fish.” 87 Fed. Reg. at 69,190. EPA failed to consider in setting the FCR that anadromous fish have significantly lower pollutant concentrations than fish that spend the entirety of their life cycles in inland and nearshore waters. The failure to consider this aspect of the problem is material because, as repeatedly emphasized in the sources cited by EPA, salmon are the primary traditional fish food source of tribes in the Pacific Northwest. *See Washington v. Wash. State Com. Passenger Fishing Vessel Ass’n*, 443 U.S. 658, 663 (1979).

88. *Fourth*, EPA failed to explain why it did not use the National Cancer Institute (NCI) method (or EPA’s simplified variant of the same method)—a sounder method than EPA’s chosen approach—for estimating the FCR. EPA, *National Health and Nutrition Examination Survey 21–22* (Apr. 2014), <https://19january2017snapshot.epa.gov/sites/production/files/2015-01/documents/fish-consumption-rates-2014.pdf>. These methods account for the reality that most people do not eat the same amount of fish every day over their entire lives. *Id.* If EPA chose not to adjust the numbers this way, as it has acknowledged that it should, the agency should have justified that

choice. It failed to do so. *See id.*; 87 Fed. Reg. at 69,185–86 (discussing the FCR data from 2003 through 2010 without discussing the newer NCI methodology in EPA’s FCR publication in 2014); 81 Fed. Reg. at 85,426 (same); EPA Response to Public Comments, *Restoring Protective Human Health Criteria in Washington* 159–60, Dkt. No. 2015-0174-0427 (2016) (explaining the FCR calculation without mentioning the NCI method); *id.* at 145–46, 149–52 (same); *id.* at 174 (acknowledging a commenter’s suggestion that EPA use the NCI method to process the fish consumption data). Using the NCI method would have lowered the FCR for the 2022 rule. Nw. Pulp & Paper Ass’n Comment Letter, *supra*, at 21–22.

89. *Fifth*, EPA triple-counted its unwarranted assumptions by selecting an irrational chemical-specific CRL of  $1 \times 10^{-6}$  for PCBs based on the purported need to protect reserved tribal fishing rights, although that consideration was already reflected in the selection of subsistence fishing communities as the “target general population” and the adoption of an inflated, counterfactual FCR. 87 Fed. Reg. at 69,189; 81 Fed. Reg. at 85,427. EPA offers no scientifically defensible rationale for overriding Washington’s CRL of  $2.3 \times 10^{-5}$  for PCBs—a level deemed sufficient in EPA’s own 2000 Methodology—and instead relies on the unreasonable and erroneous tribal-reserved-rights rationale described above. EPA’s efforts to disclaim reliance on this rationale are incompatible with what it actually did in the 2022 rule.

90. EPA asserted that Washington’s selected CRL was not sound because it purportedly failed to account for carcinogenic health effects. But consistent with the 2000 Methodology, Washington’s CRL is protective of the general population’s consumption rates within a range of risk factors from  $10^{-6}$  and  $10^{-5}$ , while protecting tribal consumption rates at better than  $10^{-4}$ . EPA points to no *science* mandating a  $10^{-6}$  CRL—and it has no authority to second-guess Washington’s

risk-management decision. *See* 2000 Methodology 2-4 (describing choice of CRL within range as principally a risk-management decision).

91. EPA's unscientific and *ultra vires* rationale is arbitrary and capricious.

**Count Three (All Defendants):**

**EPA's Unreasonable PCB Standard Violates The APA.**

92. Plaintiffs incorporate by reference the allegations above.

93. EPA admits that the 2022 rule's 7 parts-per-quadrillion (ppq) limit is neither measurable nor attainable with current technology.

94. *First*, EPA lacks any tools to measure whether 7 ppq of PCBs exist in a given water sample. As the agency admits, "EPA has completed a multi-laboratory validation of a new analytical method for PCBs (method 1628) that has an average analytical quantitation limit for each PCB congener of approximately 2,000 [ppq], which is a substantial improvement over the current regulatory method, but still well above either the criterion currently in place or EPA's criterion." 87 Fed. Reg. at 69,195–96. EPA has not even hinted that its standard would be measurable with any technology lurking on the horizon, much less any existing pilot projects.

95. *Second*, the standard is unachievable, even with cost-prohibitive control technology. Washington acknowledged in a public presentation that currently installed municipal-treatment systems cannot achieve 7 ppq of PCBs, even with advanced methods like reverse osmosis, activated carbon, or advanced oxidation. *Workshop on PCB Variances for Spokane River Dischargers* 83 (Nov. 14, 2019), [https://www.ezview.wa.gov/Portals/\\_1962/Documents/SpokaneRiverCleanWater/VarianceWorkshop\\_All.pdf](https://www.ezview.wa.gov/Portals/_1962/Documents/SpokaneRiverCleanWater/VarianceWorkshop_All.pdf). According to a study conducted by AWB, even the highest-performing treatment systems in Washington can reduce PCBs only to 100 ppq. Nw. Pulp & Paper Ass'n Comment Letter, *supra*, Attach. C at 36.

96. *Third*, EPA has not justified its 7 ppq standard in the face of its own chemical regulations. EPA’s rules under TSCA allow PCB concentrations of up to 50 ppm in manufactured goods, recycled fluids and used oils, and other items. 40 C.F.R. § 761.20; *id.* § 761.3 (“Excluded PCB products,” subsections (1)–(4)). It is arbitrary and capricious to allow 50,000,000,000 ppq concentrations in products in commerce, while requiring other regulated entities to limit PCBs to an infinitesimal 7 ppq level. The inconsistency between these two regulations creates arbitrary and capricious burdens on CWA-regulated entities as compared to TSCA-regulated ones. EPA proffered two reasons for this discrepancy: (1) that TSCA regulations are based on the levels required for chemicals in products instead of surface water that the CWA regulates; and (2) EPA’s interpretation that it cannot consider costs in setting CWA water quality standards. EPA 2016 Response Letter, *supra*, at 106; EPA 2022 Response to Public Comments, *supra*, at 109 & n.255. But those explanations do not excuse the agency’s failure to grapple with TSCA’s effects on PCBs in the environment and the burden that EPA shifts to CWA sources to reduce PCB concentrations below background levels. And EPA’s understanding of its duty to consider costs under the CWA is mistaken: EPA *must* consider costs in setting water quality standards.

**Count Four (All Defendants):**

**EPA’s Failure To Consider Costs Violates The APA.**

97. Plaintiffs incorporate by reference the allegations above.

98. EPA has broad discretion to weigh costs and benefits in implementing its regulatory statutes, and it generally must do so unless the statutory text precludes it. *See Michigan v. EPA*, 576 U.S. 743, 752 (2015). Here, nothing in the Clean Water Act’s open-ended directive that the Administrator determine that a new federal standard must be “necessary” to meet the requirements of the Act forecloses consideration of costs and benefits in setting water quality standards. To the

contrary, because such costs affect whether a new standard is “necessary,” ignoring compliance costs would be arbitrary and capricious.

99. EPA, however, proceeded on the mistaken legal premise that it could *not* consider such costs in setting water quality standards. EPA 2022 Response to Public Comments, *supra*, at 109 & n.255 (explaining that costs cannot be considered in the “development of water quality criteria such as HHC under the CWA”). Even if the CWA does not require it, EPA at minimum has *discretion* to consider costs. But EPA’s mistaken premise led it to ignore costs altogether—or at least to arbitrarily zero them out.

100. Agency action that “stands on a faulty legal premise” is arbitrary and capricious. *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985). When an agency erroneously disclaims discretion that it possesses, vacatur and remand is required so that the agency may consider whether and how to exercise that discretion.

101. EPA’s standards are especially arbitrary and capricious in light of the enormous costs EPA’s criteria would impose on regulated entities. EPA’s failure to consider the costs involved blinded the agency to an important aspect of the problem.

**Count Five (All Defendants):**

**EPA’s Unreasonable Economic Analysis Violates The APA.**

102. Plaintiffs incorporate by reference the allegations above.

103. To the extent EPA did conduct and rely upon an economic analysis, EPA’s economic analysis is arbitrary and capricious under the APA. 5 U.S.C. § 706(2).

104. When an agency conducts and relies upon an economic analysis in promulgating a rule, the APA requires that the analysis be reasonable and reasonably explained.



105. EPA conducted an economic analysis in setting Washington’s standards. *See* 87 Fed. Reg. at 69,194–96. To the extent EPA relied on this analysis in determining that its proposed standards are “necessary” to meet the Clean Water Act’s requirements, EPA’s analysis is neither reasonable nor reasonably explained.

106. EPA arbitrarily attributed *no* incremental costs to any major point sources. EPA explained that it did so not because there are no such costs, but because EPA believed it would be too “speculative” to estimate the costs of developing new technologies to measure pollutants at lower levels, even below current levels of detection, or for major facilities to change facility operations and practices to comply with EPA’s new standards. The APA does not permit EPA to treat such costs as nonexistent, or to refuse to make any effort to quantify them, merely because the costs present some uncertainty or cannot be precisely quantified.

107. EPA also failed to adequately address commenters’ specific cost estimates. Commenters explained that the rule would impose enormous compliance costs, providing specific estimates, and that the standards are unattainable even with cost-prohibitive control technology.

108. Available data indicates that large segments of state waters would qualify as impaired under the CWA for failing to meet the PCB criteria, based on EPA’s 2022 standards, and almost every publicly owned wastewater treatment plant in Washington and other dischargers would therefore need to adopt tertiary membrane filtration treatment or other tertiary treatment technology to address PCBs. Notwithstanding this, there are no known combinations of treatments that would actually achieve EPA’s PCB criteria.

109. One commenter estimated that the incremental cost for such treatment, including construction costs and operation and maintenance costs, would be between \$53 and \$82 million for a plant that processes 500,000 gallons of wastewater per day, with a net present value unit cost

of between \$106 and \$262 per gallon per day. This will amount to a range of compliance costs from nearly \$6 billion to over \$11 billion just for the major permits identified by EPA. Another commenter estimated costs of a similar magnitude. EPA ignored substantial record evidence by failing to explain why these cost estimates were wrong and by failing to consider the cost implications of lower analytic limits.

110. Pursuant to EPA's 2022 rule, Washington Department of Ecology is already compelling the City of Spokane to spend funds to use a more rigorous testing method to address PCB levels (Method 1668) that purports to accurately measure PCBs in the low parts per quadrillion range. An expansion of the City's wastewater treatment plants to add additional tertiary treatment to address PCBs, the City estimates, would cost \$19 million per gram of additional PCB removal.

111. In the face of these crippling compliance costs, EPA's estimate of zero compliance costs is arbitrary and capricious and is evidence that the agency failed to apprehend important aspects of the problem it attempted to address.

**Count Six (All Defendants):**

**EPA's Regulatory Flexibility Act Certification Violates The APA.**

112. Plaintiffs incorporate by reference the allegations above.

113. Many of Plaintiffs' members are "small entit[ies]," including "small business[es]" as defined in the RFA and incorporated regulatory definitions promulgated by the Small Business Administration. 5 U.S.C. § 601(3), (6); *see also* 15 U.S.C. § 632(a); 13 C.F.R. § 121.201.

114. EPA was required by law to promulgate the 2022 rule through notice-and-comment rulemaking under the APA. *See* 5 U.S.C. §§ 553, 603(a), 604(a).

115. EPA is a "covered agency" under the RFA subject to additional consultation requirements for engaging in reasoned agency rulemaking. 5 U.S.C. § 609(d)(1).

116. EPA failed to ensure participation by small entities, including small businesses and small governmental jurisdictions, in the comment period for the 2022 rule by noting the potential small-entity impacts of the rule in the notice of proposed rulemaking or taking any steps to notify, directly or indirectly, small entities, including small businesses, of the potential impacts of the proposed rule. *See* 5 U.S.C. § 609(a).

117. EPA failed to comply with the RFA's requirement that "a covered agency" notify the Small Business Administration and convene a small entity impact review panel prior to publishing the proposed 2022 rule. *See* 5 U.S.C. § 609(b).

118. EPA failed to prepare, consider, and publish for comment an initial regulatory flexibility analysis of the compliance costs imposed by the 2022 rule on small businesses and other small entities or of regulatory alternatives that would minimize any significant impact on small entities while achieving the agency's objectives. *See* 5 U.S.C. § 603.

119. EPA failed to prepare, consider, or publish a final regulatory flexibility analysis responding to small-business-related and other small-entity-related comments, justifying the choice to finalize the 2022 rule as opposed to regulatory alternatives with lesser impacts on small businesses, and describing the steps the agency has taken or will take to minimize the economic impact of the 2022 rule on small businesses. *See* 5 U.S.C. § 604.

120. EPA's purported certification that the 2022 rule "will not have a significant economic impact on a substantial number of small entities" because they are "not directly regulated by this rule," 87 Fed. Reg. at 69,196, is invalid, arbitrary and capricious, contrary to the factual record, and insufficient to evade the agency's reasoned-decisionmaking duties under the APA.

121. EPA's purported certification demonstrates that the agency failed to consider the 2022 rule's economic impact on small entities, failed to consider reasonable alternatives that would

have lessened those economic impacts, and failed to explain why the 2022 rule was justified despite those economic impacts, in violation of the APA.

**Count Seven (All Defendants):**

**EPA Exceeded Its Statutory Authority Under The CWA.**

122. Plaintiffs incorporate by reference the allegations above.

123. EPA exceeded its statutory authority under the CWA when it concluded that superseding Washington state’s standard was “necessary” to meet the requirements of this chapter. 33 U.S.C. § 1313(c)(4)(B). States retain primacy in developing water quality standards. Federal Water Quality Coalition Comment on EPA’s Proposal “Restoring Human Health Criteria in Washington” 3 n.6, Dkt. No. EPA-HQ-OW-2015-0174 (May 31, 2022) (collecting authority).

124. The Act’s requirements are both procedural and substantive. Procedurally, States must submit timely water quality standards, 33 U.S.C. § 1313(b), after public hearings, *id.* § 1313(c)(1). Substantively, the standards must “consist of the designated uses” for the waters, “water quality criteria” for such uses, and those designations must “protect the public health or welfare, enhance the quality of water . . . tak[e] into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and . . . their use and value for navigation.” *Id.* § 1313(c)(2)(A).

125. EPA never raised procedural problems with Washington’s standard and it acknowledged that Washington’s “designated uses” for its waters “include fish and shellfish harvesting.” 81 Fed. Reg. at 85,424.

126. As a substantive matter, EPA exceeded its statutory authority vis-à-vis tribal treaties. The CWA mandates only that its provisions shall not “affect[ ] or impair[ ] the provisions of any treaty of the United States.” 33 U.S.C. § 1371(a). From these words, EPA presumes the power to regulate more stringently based on *its own interpretation* of tribal treaties. There are at least

two problems with this approach: EPA assumes interpretive authority over tribal treaties and, based on that, greater regulatory authority for itself. The CWA grants neither. And EPA’s power-grab undermines its statutory duty to revise state criteria only when “necessary.” *Id.* § 1313(c)(4)(B).

127. EPA’s revisions are also not “necessary.” 33 U.S.C. § 1313(c)(4)(B). EPA contends only that Washington’s criteria should be “set at levels that will adequately protect Washington residents, including tribes.” 81 Fed. Reg. at 85,417. But Washington’s original rule was extremely protective, setting a technology-forcing 170 ppq PCB standard. *Toxic Substances—WAC 173-201A-240, supra.*

128. EPA used nearly the “same inputs to derive its proposed PCB HHC as Washington used, with the exception of the [CRL].” EPA 2022 Response to Public Comments, *supra*, at 116. But the CRL that EPA used in this rulemaking ( $10^{-6}$ ) exceeded its 2000 Methodology ( $10^{-4}$ ), which Washington followed. Nw. Pulp & Paper Ass’n Comment Letter, *supra*, at 9. Moreover, States need not even follow every aspect of the 2000 Methodology; it is only guidance and was never promulgated as a rule. Federal Water Quality Coalition Comment, *supra*, at 4. In short, EPA has failed to show that the CWA requires its newly adopted cancer risk level, such that federal standards were “necessary” to displace state standards. EPA’s new federal standards are *ultra vires* and defy the CWA’s deference to state standards.

### **Count Eight (All Defendants):**

#### **EPA’s Failure To Follow Regulations Violates The APA.**

129. Plaintiffs incorporate by reference the allegations above.

130. EPA’s water quality standards violate the APA’s procedural requirements and well-settled principles of administrative law because they fail to follow EPA’s own rules for promulgating such standards.

131. Like the Clean Water Act, EPA’s implementing regulations authorize EPA to “promulgate a new or revised standard when *necessary* to meet the requirements of the Act.” 40 C.F.R. § 131.5(b) (emphasis added). Because no EPA action is “necessary” if existing standards already satisfy the Act’s requirements, EPA’s authority to promulgate WQS is triggered only if existing state standards are unlawful.

132. As relevant here, Washington must have “adopted criteria that protect the designated water uses based on sound scientific rationale,” and Washington must have “followed applicable legal procedures for revising or adopting standards.” 40 C.F.R. § 131.5(a)(1)–(2), (6). As EPA itself has explained, “[i]f the EPA finds the state WQS are based on sound science and protect the state’s designated uses, the CWA requires the EPA to approve those state WQS.” 85 Fed. Reg. at 28,495.

133. In May 2019, EPA concluded that “Washington’s HHC are based on sound science and are protective of Washington’s designated uses.” 85 Fed. Reg. at 28,496. That determination was based on a finding that Washington’s HHC were based on already “conservative inputs,” which “appropriately balanced risks and resulted in HHC that are based on sound science and are protective of Washington’s designated uses, consistent with the rationale provided in Ecology’s submittal.” EPA Approval at 18.

134. In addition to failing to adequately explain its departure from its prior findings, EPA had no authority to promulgate new regulations. Because the state standards were sufficiently protective, EPA’s own regulations forbid it from promulgating more stringent standards.

135. Plaintiffs are therefore entitled to relief under the APA and other applicable law.

### **Prayer for Relief**

136. Plaintiffs pray for an order and judgment:

- a. Declaring that EPA violated the APA in finalizing the 2022 rule because its risk analysis, economic analysis, and unattainable PCB water quality standard are arbitrary and capricious; that EPA violated the APA and the CWA by failing to consider costs, to compare the costs to the incremental benefits likely to result, and to consider reasonable alternatives; that EPA violated the APA in finalizing the 2022 rule without analyzing and accounting for its impact on small entities, including small businesses, as required by applicable law, including the APA and RFA; and that EPA exceeded its statutory authority under the CWA and failed to follow its own regulations in disapproving Washington's WQS and promulgating federal WQS based on an invalid tribal reserved rights rationale.
- b. Declaring that any attempt to force Washington to implement or enforce the 2022 rule violates the APA and CWA;
- c. Vacating and setting aside the 2022 rule;
- d. Issuing all other process necessary and appropriate to postpone further implementation of the 2022 rule pending the conclusion of this case;
- e. Awarding Plaintiffs their reasonable costs, including attorneys' fees, incurred in bringing this action under 28 U.S.C. § 2412 or other applicable law; and
- f. Granting such other and further relief as this Court deems just and proper.

Dated: December 4, 2023

Respectfully submitted,

/s/ Helgi C. Walker

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

ASSOCIATION OF WASHINGTON BUSI-  
NESS,

1414 Cherry Street, S.E.  
Olympia, Washington 98501

NORTHWEST PULP & PAPER ASSOCIA-  
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212 Union Avenue, S.E.  
Olympia, Washington 98501

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Washington, D.C. 20005

GREATER SPOKANE, INC.,

801 W. Riverside, Suite 200  
Spokane, Washington 99201

and FOOD NORTHWEST,

8338 NE Alderwood Road, Suite 160  
Portland, Oregon 97220

Plaintiffs,

v.

Civil Action No. 23-cv-3605

UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY,

1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

and MICHAEL S. REGAN, in his official ca-  
pacity as Administrator of the U.S. Environ-  
mental Protection Agency,

1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

Defendants.

**COMPLAINT**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

ASSOCIATION OF WASHINGTON BUSI-  
NESS, et al.,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY, et al.,

Defendants.

Civil Action No. 23-cv-3605

**NOTICE OF ERRATA**

Plaintiffs hereby submit this Notice of Errata relating to the caption on the Complaint (Dkt. 1) and the format of the corporate disclosure certificates (Dkts. 2–6) previously filed in the above-captioned case. Attached as Exhibit A is the corrected caption for the Complaint, which includes residential addresses for all parties as required by Local Civil Rule 5.1(c). Attached as Exhibits B through F are the corporate disclosure certificates required by Local Civil Rule 26.1 in a non-fillable PDF format. As instructed by the Court, Plaintiffs hereby substitute the first page of the Complaint and the corporate disclosure certificates previously filed.

Dated: December 5, 2023

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

ASSOCIATION OF WASHINGTON  
BUSINESS, et al.,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY, et al.,

Defendants.

Civil Action No. 23-cv-3605

**PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

Plaintiffs Association of Washington Business, Northwest Pulp & Paper Association, American Forest & Paper Association, Greater Spokane, Inc., and Food Northwest hereby move for summary judgment on all claims pursuant to Federal Rule of Civil Procedure 56(a) and Local Civil Rule 7(h). In support of the motion, Plaintiffs rely on the administrative record, *see* Dkt. 38, and the memorandum of points and authorities and declarations filed concurrently with this motion. Plaintiffs respectfully request that the Court grant the motion for the reasons set out in the accompanying memorandum.

Dated: May 13, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

Pursuant to Local Civil Rule 5.3, I hereby certify that on May 13, 2024, I caused the foregoing Motion for Summary Judgment and supporting materials to be served on counsel of record for Defendants via this Court's CM/ECF system.

Dated: May 13, 2024

/s/ Helgi C. Walker  
Helgi C. Walker

**IN FIN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

ASSOCIATION OF WASHINGTON  
BUSINESS, et al.,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY, et al.,

Defendants.

Civil Action No. 23-cv-3605

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF  
MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

This is a challenge to a final rule promulgated by the U.S. Environmental Protection Agency (“EPA”) imposing federal water quality standards (“WQS”) on the State of Washington that are so stringent that compliance cannot even be measured, much less achieved. EPA used a permissible formula to set these standards, but it populated the variables in that formula with values that are unscientific, conflict with EPA guidance, and have no basis in real-world data—thereby producing an impossible-to-meet and irrational standard.

Among other errors with respect to the inputs, EPA treated a small subpopulation of tribal subsistence fishers as the “general population,” even though its own guidance distinguishes between the general population and highly exposed subpopulations for the purpose of calculating standards. To justify that leap, EPA purported to give effect to tribal treaties that EPA has no expertise, much less authority, to interpret. EPA compounded that error by assuming a rate of fish consumption—one of the key variables in the standard-setting formula—by a subpopulation of tribal subsistence fishers that EPA has conceded is inconsistent with present day realities. EPA selected a consumption rate that amounts to about *fifteen* three-ounce filets of salmon per week, on the unsupported theory that this rate tracks the “unsuppressed” level of consumption by tribal subsistence fishers before contact with European settlers. And EPA substituted its own preferences for Washington’s in selecting an acceptable cancer risk level for certain chemicals—even though Washington’s choice was consistent with sound science and EPA’s own guidance.

Worse still, in adopting these flawed inputs, EPA reversed its own prior determination—made only two years earlier—that these very same inputs were unlawful and based on improper, nonscientific concerns involving tribal rights. EPA cited no new scientific evidence to justify its

about-face. EPA then added insult to injury by justifying the rule in part using a flawed economic analysis that purported to find the standards are entirely cost-free for regulated parties.

In the end, EPA’s arbitrary assumptions resulted in irrational and unlawful standards that are lower than the background pollutant levels in many receiving water bodies throughout the State, and that are impossible to achieve with available or reasonably foreseeable technologies, rendering Washington’s communities and businesses powerless to comply. Because reasoned decision-making requires more, this Court should vacate the 2022 rule.

## **BACKGROUND**

### **I. Statutory and Regulatory Background**

In the Clean Water Act (“CWA” or “Act”), Congress adopted a “policy” of “protect[ing] the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution.” 33 U.S.C. § 1251(b). To advance that policy, the Act “anticipates a partnership between the States and the Federal Government,” *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992), with States bearing “primar[y] responsib[ility] for creating and revising water quality standards” that reflect “the purpose for which a particular body of water is used,” *City of Dover v. EPA*, 36 F. Supp. 3d 103, 108 (D.D.C. 2014).

Water quality standards are central to the CWA’s statutory framework because they “set the permissible level of pollution in a specific body of water.” *City of Arcadia v. EPA*, 411 F.3d 1103, 1105 (9th Cir. 2005). In turn, these standards are implemented through permits issued under the National Pollutant Discharge Elimination System (“NPDES”). The CWA prohibits the “discharge of any pollutant” by “any person” from any “point source” to navigable waters unless authorized by an NPDES permit. 33 U.S.C. §§ 1311(a), 1342. Each NPDES permit sets “specific limits that apply to individual polluters.” *Arcadia*, 411 F.3d at 1105; *see also* 40 C.F.R. § 122.44(d)(1).

States bear the primary role in setting these standards, subject to circumscribed EPA oversight. States must periodically propose standards for EPA approval that identify “[1] the designated uses of the navigable waters involved and [2] the water quality criteria for such waters based upon such uses” that “protect the public health or welfare.” 33 U.S.C. § 1313(c)(2)(A); *see id.* § 1251(d) (vesting oversight authority in “the Administrator of the Environmental Protection Agency”); *see also* 40 C.F.R. §§ 131.3(b), 131.11(a). Standards “shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation.” 33 U.S.C. § 1313(c)(2)(A); *see id.* § 1251(a)(2). The CWA does not dictate precisely how a State must weigh each factor, so long as the resulting standards are protective.

A State’s submitted standards take effect if the Administrator finds that the submission “meets the requirements” of the CWA. 33 U.S.C. § 1313(c)(3). To support States in this process, EPA issues recommended criteria for particular pollutants. *Id.* § 1314(a). States, however, are not required to follow EPA’s recommendations and may adopt criteria that reflect site-specific conditions, 40 C.F.R. § 131.11(b)(1), so long as they are “based on sound scientific rationale” and “contain sufficient parameters or constituents to protect the designated use,” *id.* § 131.11(a)(1).

In addition to its specific criteria recommendations, EPA has also promulgated general guidance to States in setting criteria. In 2000, EPA published its “Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health” (“2000 Methodology”), which “is used in the development of EPA’s recommended criteria and offered as guidance for states and tribes in developing their own criteria.” EPA, Human Health Water Quality Criteria and Methods for Toxics (Oct. 2, 2023), <https://epa.gov/wqc/human-health-water-quality-criteria->



and-methods-toxics. EPA recommends using a formula that considers, among other things, two major inputs for each pollutant: (1) the cancer risk level (“CRL”), *i.e.*, the excess lifetime cancer risk in the population; and (2) the fish consumption rate (“FCR”), *i.e.*, the daily average measure of freshwater and ocean fish that the general target population consumes. The 2000 Methodology authorized a CRL of  $10^{-5}$  for the general population—a probability of no more than one additional cancer case in a population of one hundred thousand—and  $10^{-4}$  for more highly exposed subgroups like subsistence fishers or sport fishers. 2000 Methodology at 1–12. EPA determined the default FCR that was protective for the general population to be 17.5 grams/day, the 90th percentile consumption rate. *Id.* And EPA explained that while some of these input decisions were “grounded in science,” others were “more obviously *risk management* decisions (such as the determination of default fish consumption rates and cancer risk levels).” *Id.* at 2–4 (emphasis added). EPA has not rescinded the 2000 Methodology and continues to rely on it in other actions.

The CWA authorizes the EPA Administrator to override state standards with federal ones only in one of two situations. The Administrator may disapprove state standards and supply federal ones if the State’s submission is “not ... consistent with the applicable requirements” of the CWA. 33 U.S.C. § 1313(c)(4)(A). Or, through an “Administrator’s determination,” the Administrator may *sua sponte* “determin[e] that a revised or new standard is necessary to meet the requirements” of the CWA. *Id.* § 1313(c)(4)(B).

Finally, if compliance is not feasible, States may seek “variances” from EPA-approved standards, which authorize permitting authorities to establish less stringent effluent limits for the period of the variance. 40 C.F.R. § 131.14(a). But EPA and States rarely grant variances; Washington’s Department of Ecology has *never* granted a variance. EPA may approve a variance only if the State can demonstrate that compliance with the water quality standards is not feasible

for one of several enumerated reasons. *Id.* §§ 131.10(g), 131.14(b)(2)(i)(A). And the variance process is only available to existing sources, not “new sources.” *Nat. Res. Def. Council, Inc. v. EPA*, 822 F.2d 104, 112 (D.C. Cir. 1987). Even if a variance is approved, it is time-limited and narrowly applicable to specific pollutants entering particular bodies of water. 40 C.F.R. §§ 131.3(o), 131.14(a). And variances also are subject to third-party challenges via the CWA’s citizen-suit provision. 33 U.S.C. § 1365.

## **II. Factual Background**

This case concerns the State of Washington’s water quality criteria for polychlorinated biphenyls, or PCBs—a set of organic chemicals used for much of the twentieth century in common industrial and commercial applications, such as electrical equipment, plastics, and rubber products. *See* EPA, Learn About Polychlorinated Biphenyls (Apr. 2, 2024), <https://www.epa.gov/pcbs/learn-about-polychlorinated-biphenyls>. Banned by Congress in the Toxic Substances Control Act of 1976, PCBs may still be present in the environment and found in materials that were produced before the ban.

The water quality standards at issue here arrive at the Court after a winding path before the agency. In 2016, EPA disapproved a number of Washington’s water quality criteria—including for PCBs—based on EPA’s erroneous premise that the State’s already protective inputs were insufficient to protect tribal treaty rights. Four years later, EPA reconsidered its disapproval and permitted Washington’s criteria to take effect. In a carefully reasoned decision, EPA found that Washington’s standards were grounded in sound science and reflected reasonable risk management decisions. Yet in 2022, in the rule challenged here, EPA again reversed course, reinstating criteria almost identical to EPA’s 2016 rule under the “same rationale” that “the agency articulated ... in ... 2016.” 87 Fed. Reg. 69,183, 69,189 (Nov. 18, 2022) (the “2022 rule”).

### A. Washington’s Water Quality Standards and EPA’s 2016 Disapproval

Between 2012 and 2016, Washington’s Department of Ecology undertook the process of revising its criteria, including for PCBs. While Washington’s rulemaking process was ongoing, the EPA Administrator *sua sponte* determined in 2015 that Washington’s existing criteria “no longer protect the relevant designated uses of Washington’s waters” and proposed federal criteria for Washington, including for PCBs. *See* 80 Fed. Reg. 55,063, 55,066 (Sept. 14, 2015) (invoking power to make Administrator’s determination under 33 U.S.C. § 1313(c)(4)(B)). Washington ultimately completed its rulemaking process in 2016 and promulgated 188 new criteria. *See* 87 Fed. Reg. at 69,187; *Toxic Substances—WAC 173-201A-240*, Wash. State Legislature (2019), <https://apps.leg.wa.gov/wac/default.aspx?cite=173-201a-240>. Exercising its discretion to make risk management decisions, the State used inputs to calculate its criteria that included a CRL of  $2.3 \times 10^{-5}$  for PCBs, and an unusually high FCR that attributed fish consumption levels for high-consuming subpopulations to the general population. *Toxic Substances—WAC 173-201A-240*, *supra*, at tbl. 240 & nn.B, E. Based on these inputs, Washington adopted a highly protective limit for PCBs of 170 parts per quadrillion (ppq) (or  $170 \times 10^{-6}$  micrograms per liter). 81 Fed. Reg. 85,417, 85,431 (Nov. 28, 2016) (the “2016 rule”). A part per quadrillion is 1/1,000,000,000,000,000.

Shortly after Washington promulgated its criteria, EPA finalized most of the proposed federal standards pursuant to the 2015 Administrator’s determination. *See* 81 Fed. Reg. at 85,417. “Concurrent with th[e] final rule,” the Administrator approved 45 and disapproved 143 of Washington’s new criteria. *Id.* As a result, EPA’s federal criteria took effect in place of “those [state] criteria that EPA disapproved.” *Id.*

EPA’s 2016 rule rejected Washington’s PCB criterion on the ground that any CRL below  $10^{-6}$  for that chemical would be insufficiently protective. *See* 81 Fed. Reg. at 85,427. EPA’s

conclusion ran contrary to its own guidance—the 2000 Methodology’s conclusion that a CRL of  $10^{-5}$  would present an acceptable level of risk for PCBs when all other inputs are taken into account. *See* 2000 Methodology at 2–6 (“Adoption of a  $10^{-6}$  or  $10^{-5}$  risk level ... represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes.” (emphasis added)). EPA also adopted an FCR of 175 g/day, which far surpassed the 2000 Methodology’s FCR of 17.5 g/day and reflected the “95th percentile consumption rate” of fish not among *the general population*, but among “surveyed tribal members.” 81 Fed. Reg. at 85,426. These highly protective inputs yielded remarkable outputs, including a PCB limit of only 7 *ppq*—an infinitesimally small number. *Id.* at 85,431.

The 2016 rule acknowledged that EPA’s 2000 Methodology authorizes criteria “based on a  $10^{-5}$  risk level”—just as Washington had selected—as long as “more highly exposed subgroups” like “subsistence fishers” are protected at a  $10^{-4}$  CRL. 81 Fed. Reg. at 85,420 & n.10. But the agency moved the goalposts, reclassifying “tribal subsistence fishers” from a highly exposed subpopulation to the “target general population” solely for the purpose of the rule. This choice of “general population” was significant, because water quality criteria must be more stringent to protect specific groups exposed to higher concentrations of carcinogens at the same cancer risk level as a less exposed, broader group. By defining the tribal subsistence fisher subpopulation as the “general population,” EPA effectively sought to protect the *actual* general population of Washington (as defined by the 2000 Methodology) at a  $10^{-8}$  cancer risk level—one additional case of cancer in a population of *one hundred million*. *See* EPA-HQ-OW-2015-0174-1089 at 14 (Nw. Pulp & Paper Comment Letter May 31, 2022) (“Nw. Pulp & Paper Letter”). That is an astronomically small risk—orders of magnitude smaller than the risk of being killed by an asteroid. *See* New Scientist, *The Word: Torino Scale* (Oct. 19, 2005),

<https://www.newscientist.com/article/mg18825221-900-the-word-torino-scale>. EPA deployed the same sleight of hand to justify its choice of FCR. And EPA further inflated the FCR by picking a so-called “unsuppressed” rate of fish consumption based on counterfactual “heritage tribal consumption reports”—educated guesses of historical tribal consumption practices—rather than actual data about current consumption. 81 Fed. Reg. at 85,424, 85,426.

In selecting these inputs, EPA’s only explanation for departing from the 2000 Methodology is that the Methodology did not “speak to or envision the unique situation of setting WQS that cover areas where tribes have treaty-reserved rights to practice subsistence fishing.” 81 Fed. Reg. at 85,424–25. EPA did not attempt to square that assertion with the 2000 Methodology’s express description of “subsistence fishers” as a “highly exposed subgrou[p].” 2000 Methodology at 1–12.

Ultimately, EPA’s selected CRL and FCR rested on its assertion of authority to “harmonize treaty-reserved fishing rights with the CWA”—a power it had never before asserted in the five decades since the CWA’s enactment. 81 Fed. Reg. at 85,424. EPA stated that even though “[t]he CWA generally assigns to a state the responsibility of determining the designated uses of its waters ... , through treaties, tribes reserved specific fishing rights ... including the right to take fish from such waters for their subsistence.” *Id.* EPA then construed this “subsistence fishing” right to require the agency to treat tribes as the “target general population.” *Id.* Thus, EPA concluded, “where treaty-reserved tribal fishing rights apply to particular waters, it would be unreasonable to

expose the communities exercising those rights to levels of risk above what would be reasonable for the general population of the state.” *Id.* at 85,425.<sup>1</sup>

### **B. EPA’s 2020 Reconsideration and Approval**

In 2017, a coalition of Washington businesses and others petitioned EPA to reconsider the 2016 rule. Compl. Ex. A, Pet. for Rulemaking, *Washington v. EPA*, No. 2:19-cv-00884-RAJ (W.D. Wash. June 6, 2019). The petitioners urged EPA to change course because the rule “improperly usurped the primary role of the state to make risk management decisions,” and threatened to “devastat[e the State’s] local communities and businesses” while offering “no benefit to public health over the Washington-submitted standards.” *Id.* at 1–2.

EPA agreed. In 2019, EPA granted the petition and, upon reconsideration, approved all but two of Washington’s original criteria, reasoning that the 2016 rule had improperly infringed on the State’s CWA authority to make its own risk management decisions within the limits of sound science. *See* Letter from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Wash. Dep’t of Ecology 8 (May 10, 2019) (“EPA 2019 Approval”). Applying

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<sup>1</sup> According to the U.S. Census Bureau, 1.6 percent of Washington State’s population were American Indian and Alaska Native in 2020. *Race and Ethnicity*, U.S. Census Bureau (2023), <https://data.census.gov/profile/Washington?g=040XX00US53#race-and-ethnicity>. Not all of these individuals are tribal members, and even fewer fish for subsistence. Moreover, a substantial number of tribal members who do fish for subsistence likely live on tribal reservation land and fish in whole or in part in tribal reservation waters, which expressly are *not* governed by EPA’s or Washington’s WQS. *See* 81 Fed. Reg. at 85,422 & n.27 (“This rule applies to waters under the State of Washington’s jurisdiction, and not to waters within Indian country”); 87 Fed. Reg. at 69,188 & n.52 (same).

Thus, although EPA’s rule is replete with legalese and scientific terms of art, its sleight of hand is simple. Fish are a source of carcinogens. If population A eats 17 grams of fish per week and subpopulation B eats 175 grams of fish per week, subpopulation B is exposed to more sources of carcinogens. To reduce cancer risk for subpopulation B to the same level that would be appropriate for population A, the level of carcinogens in the water must be reduced far more significantly. And EPA selected “subpopulation B” as the “target general population” that Washington’s standards must protect, even though it is *not* the actual general population of Washington. Impossibly stringent water quality criteria were the inexorable result of that choice.

the 2000 Methodology, EPA determined that Washington's CRL of  $2.3 \times 10^{-5}$  for PCBs satisfied statutory requirements, was based on sound science, and was protective of the general population and high-consuming subpopulations. *Id.* at 21. EPA confirmed that the CWA does not require States to meet or exceed each of EPA's recommended criteria so long as the submission's risk management decisions are "based on sound science and the resulting criteria protect the designated uses." *Id.* at 24.

In a 31-page decision, EPA explained that it was "improper and unnecessary" to purportedly "harmonize" tribal treaty rights with the CWA under a "new legal theory." EPA 2019 Approval 22–24. That approach, EPA reasoned, rested on two related errors: (1) it required States "to provide the same level of protection to tribal treaty fishers as to the State's general population," identifying tribal populations as the "target general population," and (2) "interpret[ed] the State's designated uses to also mean or include subsistence fishing." *Id.* at 22. The 2016 rule thus trenched on the State's prerogative to manage risks and designate uses for its own water bodies. *Id.* Moreover, EPA explained that the 2016 rule "departed from longstanding EPA policy and the Agency's recommendations for setting [criteria], including the 2000 Methodology." *Id.* "[T]he 2000 Methodology speaks directly" to subsistence fishing protections and advises that subsistence fishers should be treated as "highly exposed subgroups." *Id.* at 23. The 2016 rule's new legal theory, in contrast, was "not ... promulgated in any nationally applicable rule or articulated in any national recommended guidance," failing to provide "adequate notice of this framework or ... the Agency's decision to apply this framework to particular state submissions in the first instance." *Id.* at 22. Simply put, tribal treaties "do not expand the EPA's authority under the CWA." *Id.* at 23.

In 2020, EPA promulgated a rule allowing Washington’s approved criteria to take effect. 85 Fed. Reg. 28,494 (May 13, 2020) (the “2020 rule”). EPA restated its longstanding position that “EPA prefers that states maintain primary responsibility and establish their own WQS in keeping with the text and structure of the CWA.” *Id.* at 28,495. EPA explained that because Washington’s criteria satisfied all statutory requirements, “the cooperative federalism structure of the CWA” required the agency “to withdraw the federal WQS to enable the EPA-approved state WQS to become the applicable WQS for CWA purposes.” *Id.* at 28,496. In so doing, EPA affirmed its view that “Washington’s [human health criteria] are based on sound science and are protective of Washington’s designated uses.” *Id.* Recognizing that “some of Washington’s [human health criteria] are less stringent than the federal [human health criteria], and some are more stringent,” EPA concluded that the CWA authorized Washington to make these reasonable risk management decisions. *Id.*

### **C. EPA Proposes the 2022 Rule**

In April 2022, after a change in administration, EPA again reversed course. Administrator Michael Regan determined under Section 1313(c)(4)(B) “that revised [human health criteria] are necessary” for Washington and “propos[ed] new standards for Washington waters” to replace the criteria submitted by Washington in 2016 and approved by EPA in 2019. 87 Fed. Reg. 19,046, 19,051 (Apr. 1, 2022).

The agency received a number of comments, including from Plaintiffs, arguing: (1) that the agency had taken an unjustified change in position; (2) that EPA’s inputs were flawed and inconsistent with its own methodology; (3) that the resulting criteria were unworkable and unattainable; (4) that the agency had failed to consider costs as required under the APA and CWA;



and (5) that the rule’s economic analysis was unreasonable.<sup>2</sup> Commenters, for instance, submitted data showing that the costs of treating water to EPA’s PCB target concentration range from \$53 to \$82 million at a single facility (or \$106 to \$262 per gallon per day), *see* Nw. Pulp & Paper Letter 70, and between \$6 billion and \$11 billion for a subset of the permits identified in EPA’s economic analysis, *see* Am. Forest & Paper Ass’n Letter 4. One municipality, the City of Spokane, explained that in light of the 2022 rule, the Washington Department of Ecology had already required “the City to spend additional money to control PCBs entering the river.” Spokane Letter 2. And expansion of the City’s wastewater treatment plants to further address PCBs, the City estimated, would cost \$19 million per gram of additional PCB removal. *Id.*

#### **D. EPA Finalizes the 2022 Rule**

EPA finalized the federal standards several months later. *See* 87 Fed. Reg. at 69,183. The agency imposed federal WQS for Washington nearly identical to those promulgated in EPA’s November 2016 rule, including the same PCB criterion of 7 ppq. *Id.* at 69,183.

In promulgating the 2022 rule, EPA “appl[ie]d the same rationale ... as the agency articulated ... in the 2016 Federal rule.” 87 Fed. Reg. at 69,189 (noting this point in connection with selection of FCR); *id.* at 69,198 (noting that the selected CRL “is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at the 175 g/day level”). And

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<sup>2</sup> *See* Nw. Pulp & Paper Letter 4–13, 23 (arguing that the EPA used unreasonable inputs that were inconsistent with its own methodology and that the PCB output was unreasonable); EPA-HQ-OW-2015-0174-1092 at 2–4 (Am. Forest & Paper Ass’n Comment Letter June 1, 2022) (“Am. Forest & Paper Ass’n Letter”) (arguing, *e.g.*, that the EPA’s change in position was unjustified in light of the CWA’s deference to States, that the agency failed to reasonably consider costs, that the economic analysis was unreasonable, and that EPA could not invoke a tribal treaty rights theory without clear statutory authorization); EPA-HQ-OW-2015-0174-1084 at 23 (Greater Spokane Comment Letter May 26, 2022) (“Spokane Letter”) (arguing that the PCB standard was unreasonable); *see also, e.g.*, EPA-HQ-OW-2015-0174-1086 (City of Post Falls Comment Letter May 27, 2022) (“Post Falls Letter”); EPA-HQ-OW-2015-0174-1094 (National Mining Association Comment Letter May 31, 2022) (“National Mining Association Letter”).

EPA adopted the same inputs as the 2016 rule, underscoring “that it does not have new data or information suggesting a need to revisit the inputs utilized in the 2016 rule.” *Id.* at 69,189. Thus, doubling down on its previously disavowed tribal treaty rights theory, EPA again adopted a  $10^{-6}$  CRL for PCBs, and a 175 g/day FCR. *Id.* at 69,188–90. EPA chose these inputs purportedly because Washington had selected inputs insufficiently “protective of the State’s designated uses,” including “the tribal subsistence fishing portion of the fish and shellfish harvesting use *as informed by treaty-reserved fishing rights.*” *Id.* at 69,187 & n.38 (quoting Letter from Dan Opalski, Dir. Off. Water & Watersheds to Maia Bellon, Wash. Dep’t of Ecology 26 (Nov. 15, 2016) (emphasis added)). Moreover, because Washington had used a  $10^{-6}$  CRL for other chemicals besides PCBs, EPA added that “it is important to keep these [CRL] values consistent” between specific chemicals “because these values are associated with the population that the criteria are intended to protect and are not pollutant-specific.” *Id.* at 69,189. As before, EPA’s selected FCR assumed that tribal subsistence fishers consume extraordinary numbers of fish from state surface waters every day for seventy years, and that this quantity is representative of the general population. *Id.* Relying on these inputs, EPA finalized the extraordinarily low PCB criterion of 7 ppq. *Id.* at 69,193.

EPA acknowledged that the existing detection limit for PCBs under methods EPA has approved for determining NPDES permit compliance is 2000 ppq—three orders of magnitude higher than EPA’s target level for PCB concentrations. 87 Fed. Reg. at 69,195–96. EPA further recognized that Washington had already set an aggressive target level below this limit—at 170 ppq, given that the highest performing treatment systems in the State can reduce PCBs to only 100 ppq (which can be measured only with highly sensitive, non-EPA approved methods). *Id.* at 69,193; Nw. Pulp & Paper Letter, Attach. C at 36. Nevertheless, EPA asserted that “it is important

that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods.” 87 Fed. Reg. at 69,196.

EPA also relied on an economic analysis that estimated the 2022 rule would impose only \$100,000 to \$182,000 in administrative costs on the State. 87 Fed. Reg. at 69,195–96. Remarkably, EPA concluded that it “did not identify *any* incremental costs to any major point source discharges ... attributable to EPA’s criteria revisions.” *Id.* at 69,195 (emphasis added). EPA did not find that there would actually “be no costs to point sources over time to implement controls or modify processes to meet future permit limits.” *Id.* Rather, EPA’s conclusion equivocated that in the agency’s judgment it would be too “speculative to attempt to estimate potential costs.” *Id.* EPA asserted that it was unclear how permit limits would change as technologies for measuring PCB concentrations improved and that “advanced treatment or other substantial costs [that] arise in the future” could potentially be avoided through “variances,” “alternative permit limits,” and constructive engagement between EPA and stakeholders. *Id.* EPA also discounted commenters’ specific cost studies on the ground that those studies did not assume a proper baseline for calculating marginal costs. The right baseline, according to EPA, is not the *real* status quo, but a counterfactual one of assumed “full compliance with existing (including not yet implemented) criteria.” EPA-HQ-OW-2015-0174-1112 at 139–40 (“EPA 2022 Response to Comments”).

In a separate document addressing comments, EPA made a number of additional assertions in tension with the rule’s preamble. For instance, although the 2022 rule adopted the “same rationale” as the 2016 rule, 87 Fed. Reg. at 69,189, EPA’s response to comments purported to disclaim “reli[ance] on tribal treaty rights” and to rest on “sound science” alone, EPA 2022 Response to Comments 24. Despite acknowledging that it had not identified any “new data or

information,” 87 Fed. Reg. at 69,189, EPA did not even try to explain how it reached the same inputs and outputs as the 2016 rule *without reliance on its previously disavowed tribal rights theory*. Indeed, EPA proposed a *separate* rule just two weeks after it finalized the 2022 rule, proposing to ratify the approach it took in 2016: “WQS must protect tribal reserved rights.” *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*, 87 Fed. Reg. 74,361, 74,365 (Dec. 5, 2022) (discussing EPA’s 2016 rule with approval).<sup>3</sup> Thus, while purporting to disapprove Washington’s standards for scientific reasons, EPA in fact relied on a contrived tribal rights theory that has no basis in applicable regulations or EPA’s longstanding 2000 Methodology.

In addition, EPA explained that “costs” cannot “be considered” in the “development of water quality criteria.” EPA 2022 Response to Comments 109 & n.255. According to EPA, “compliance costs may be considered only when designating the uses to be protected by water quality standards,” but not in setting criteria, which must be “based on sound scientific rationale.” *Id.* (quoting *Upper Mo. Waterkeeper v. EPA*, 15 F.4th 966, 972 n.1 (9th Cir. 2021)).

### **III. Procedural History**

On December 4, 2023, Plaintiffs brought this Administrative Procedure Act (“APA”) suit. On January 25, 2024, Defendants filed a motion to transfer the case to the Western District of Washington, which remains pending. Dkt. 19. Defendants also filed a timely answer with no objection to venue. Dkt. 23. The State of Washington and five Tribes have moved to intervene, and those motions are pending. Dkts. 20, 30, 31.

### **LEGAL STANDARD**

Summary judgment is warranted “if the moving party ‘shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.’” *Toledo*

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<sup>3</sup> EPA finalized that rule on May 2, 2024. *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*, 89 Fed. Reg. 35,717 (May 2, 2024).

*Hosp. v. Becerra*, 621 F. Supp. 3d 13, 22 (D.D.C. 2021). In an APA action, “summary judgment ‘serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.’” *Id.*

Courts will “hold unlawful and set aside” an agency rule that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” or “in excess of statutory jurisdiction, authority, or limitations.” 5 U.S.C. § 706(2)(A), (C), (E). Agency action is arbitrary and capricious if the agency has “entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Agency action thus must be “reasonable and reasonably explained.” *Biden v. Texas*, 142 S. Ct. 2528, 2543 (2022). And an agency may not exceed its statutory authority. *Michigan v. EPA*, 268 F.3d 1075, 1082 (D.C. Cir. 2001).

### **JURISDICTION**

This Court has subject-matter jurisdiction under 28 U.S.C. § 1331.

Plaintiffs have Article III standing. They are associations of Washington businesses whose members operate facilities subject to CWA permitting requirements administered by Washington’s Department of Ecology under EPA oversight. Plaintiffs therefore have associational standing because their members are the “object[s] of the challenged government action” who are suffering concrete injuries traceable to the 2022 rule. *New Jersey v. EPA*, 989 F.3d 1038, 1045 (D.C. Cir. 2021). EPA’s human health criteria are increasing costs, undermining existing investments in facilities and regulatory compliance, and generating harmful regulatory uncertainty. *See, e.g.*, Declaration of Paul R. Noe (“AF&PA Decl.”) ¶¶ 9–12; Declaration of Christian M. McCabe

(“NWPPA Decl.”) ¶¶ 8–11. These harms are traceable to the 2022 rule because EPA’s imposition of more stringent federal criteria subjects existing NPDES permits to modification and results in new requirements for discharge permits that regulated parties must obtain on a periodic basis. *See id.* (citing NPDES Permit WA0003697); *see, e.g.*, NPDES Discharge Permit No. WA0093317, EPA-HQ-OW-2015-0174-1112 at 48, 128 n.327 (“Ecology will reopen the permit should the Human Health Criteria for PCBs be revised.”). Vacating the 2022 rule would redress these ongoing and imminent harms by restoring the status quo ante, *i.e.*, EPA’s prior approval of Washington’s 2016 standards. *See, e.g.*, AF&PA Decl. ¶¶ 12–13.

This action is also germane to Plaintiffs’ missions to advocate for reasonable environmental regulation on behalf of their members in the business community, and the participation of individual members is not required to resolve the questions presented. *See Me. Lobstermen’s Ass’n v. Nat’l Marine Fisheries Serv.*, 70 F.4th 582, 593 (D.C. Cir. 2023); AF&PA Decl. ¶¶ 4–8. Plaintiffs raised serious concerns about EPA’s proposed rule in comments, *see* AF&PA Decl. ¶ 6, NWPPA Decl. ¶ 5, but EPA finalized the rule without material change.

## ARGUMENT

The 2022 rule violates multiple precepts of administrative law. Most fundamentally, the rule is *ultra vires*: EPA overstepped its statutory authority by setting criteria based on an unfounded tribal treaty rights theory. The rule is also arbitrary and capricious. In reversing course from the 2020 rule and the 2000 Methodology, EPA departed from longstanding positions without adequate explanation. Its federal standards are based on non-factual and unreasonable inputs that unsurprisingly produced unreasonable outputs, including an unmeasurable and unattainable PCB criterion. Moreover, EPA erroneously disclaimed authority to consider costs in setting the criteria. Alternatively, to the extent EPA nonetheless relied on a cost-benefit analysis to justify the rule, its

analysis unreasonably assumed that there would be *zero* compliance costs for the regulated community.

**I. EPA Exceeded Its Statutory Authority Under the CWA and Failed to Follow Its Own Regulations.**

Agency action taken without statutory authority “is plainly contrary to law and cannot stand.” *Michigan*, 268 F.3d at 1081. And “it is a well-settled rule that [the] agency’s failure to follow its own regulations is fatal to the deviant action.” *Mine Reclamation Corp. v. FERC*, 30 F.3d 1519, 1524 (D.C. Cir. 1994) (cleaned up).

Here, EPA exceeded its mandate under the CWA and violated its own regulations in imposing unnecessary federal standards on Washington to protect tribal reserved rights under treaties that EPA has no power to interpret or enforce.

1. The CWA “anticipates a partnership between the States and the Federal Government, animated by a shared objective: ‘to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.’” *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992) (quoting 33 U.S.C. § 1251(a)). To advance the “policy” of “protect[ing] the primary responsibilities and rights of States” to control pollution in their waters, 33 U.S.C. § 1251(b), EPA’s role in this process is “limited,” *Nat. Res. Def. Council, Inc. v. EPA* (“*NRDC*”), 16 F.3d 1395, 1399, 1405 (4th Cir. 1993).

Congress evinced this intentional design through the CWA’s procedural and substantive requirements. States are in the driver’s seat from the start, and must submit timely water quality standards after public hearings. *See* 33 U.S.C. § 1313(b), (c)(1). EPA may supersede the States’ standards and impose federal criteria only when “necessary” to meet the requirements of the statute. *Id.* § 1313(c)(4)(B). Thus, “EPA sits in a reviewing capacity of the state-implemented standards, with approval and rejection powers only.” *NRDC*, 16 F.3d at 1399.

Nothing in this reticulated scheme envisions EPA invoking tribal treaties to second-guess States' reasonable risk management decisions. For treaties, the CWA provides only that its provisions shall not "affect[] or impair[] the provisions of any treaty of the United States." 33 U.S.C. § 1371(a). This provision does not compel or empower EPA to take a particular action; rather, it imposes a *limit* on EPA's authority.

Nevertheless, in the 2022 rule, EPA claims authority found nowhere in the CWA or historical practice to interpret tribal treaties for itself and to override state standards under the guise of protecting tribal rights. Treaties between the United States and tribes are not grants of authority to EPA, and EPA's action points to no treaty that would grant EPA the authority it claims. Tribal reserved rights similarly do not limit or prohibit a State or EPA from taking an otherwise lawful action under the CWA. Instead, as a general rule, "th[e] [trust] responsibility is discharged by the agency's compliance with general regulations and statutes not specifically aimed at protecting Indian tribes." *Morongo Band of Mission Indians v. FAA*, 161 F.3d 569, 574 (9th Cir. 1998). In prior litigation, EPA defended the same principle. *See* EPA Consolidated Br. at 40–43, *Sierra Club v. McLerran*, No. 2:11-cv-01759-BJR, Dkt. 91 (W.D. Wash. Jan. 29, 2014). Thus, as EPA itself has previously (and consistently) recognized, *see infra* at 22–23, EPA lacks statutory authority to "harmonize" tribal treaty rights with the CWA. EPA 2019 Approval 22–24.

Even assuming *arguendo* that EPA may generally construe tribal treaty rights, nothing in any relevant treaty compels *specific* water quality standards in Washington. "Whether the Government has expressly accepted [treaty] obligations must turn on specific rights-creating or duty-imposing language in [the] treaty." *Arizona v. Navajo Nation*, 143 S. Ct. 1804, 1813 (2023) (cleaned up). In *Arizona*, the Supreme Court applied this principle to hold that a general treaty provision that "set apart" a reservation for the "use and occupation of the Navajo tribe" did not



impose an affirmative duty to secure water for the tribe. *Id.* at 1813–14; *see id.* at 1816 (explaining that “[t]he 1868 treaty reserved necessary water to accomplish the purpose of the Navajo Reservation” but did not obligate anyone to take “affirmative steps” to provide water).

Here, although EPA generally invoked the Stevens-Palmer Treaties with the Washington Tribes, EPA never identified a plausible textual basis for the purported treaty guarantee of “*water quality sufficient under the CWA* to ensure that tribal members can safely eat the fish for their own subsistence.” 2016 Rule, 81 Fed. Reg. at 85,423 (emphasis added). In support of that asserted right, EPA cited the treaty right to “tak[e] fish at usual and accustomed places” and case law construing that right to require “fish sufficient to sustain” the right. *Id.* at 85,423 & nn.35–39 (collecting cases). But those cases at most hold that the right to take fish implies a right to access fishing grounds. The right thus imposes only a negative duty: It *constrains* States, for instance, from constructing barriers that “obstruc[t] fish passage” and barring tribes from “cross[ing] private property to access [a] traditional fishing ground.” *Id.* at 85,424 n.39; *cf. Arizona*, 143 S. Ct. at 1816. No specific rights-creating language in any treaty gives EPA the *affirmative* authority to dictate water quality standards, much less to require any *specific* criterion—*e.g.*, a PCB criterion of 7 ppq, rather than 170 ppq.

Rather than justify this claim to authority in the 2022 rule, EPA denied that it was relying on treaty rights at all. *See, e.g.*, 87 Fed. Reg. at 69,189 (claiming that EPA’s decision “was appropriate independent of treaty rights”); *id.* at 69,190 (asserting that the 2022 rule was predicated on EPA’s conclusion that “Washington’s PCB [human health criteria] are not protective of Washington’s designated uses because of Washington’s selected chemical-specific CRL, which is not based on a sound scientific rationale”). But EPA’s backtracking is disingenuous. EPA admitted that it had no new data and characterized the 2022 rule as resting on the “same rationale”

as the 2016 rule, which indisputably relied on a treaty rights theory. *Id.* at 69,189. And EPA’s assertion that Washington’s standards were insufficiently protective of the State’s designated uses leaves no doubt that EPA claimed authority to interpret tribal treaty provisions in the 2022 rule. EPA’s *only* explanation for that conclusion was that the State’s designated uses included harvesting “*as informed by treaty-reserved fishing rights.*” *Id.* at 69,187 & n.38 (quoting 81 Fed. Reg. 85,426) (emphasis added). Indeed, EPA just finalized a rule “to ensure that WQS are consistent with treaties,” by purportedly “build[ing] on” EPA’s approach in the 2022 rule. 89 Fed. Reg. at 35,732, 35,744.

Nor can EPA rescue its atextual power-grab by resort to agency expertise or deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Where, as here, an agency repeatedly changes its interpretation of a statute, its interpretation “is entitled to considerably less deference than a consistently held agency view.” *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (cleaned up). EPA’s discovery of a nascent tribal rights authority in the 2016 rule, decades after enactment of the CWA, is not entitled to deference—particularly since the agency later renounced the authority and has yet to reassert it in a reasoned manner. *See, e.g., Chamber of Com. v. Dep’t of Lab.*, 885 F.3d 360, 380–81 (5th Cir. 2018) (no deference where agency’s newly discovered reading came decades after statutory enactment). EPA also never attempted to establish the “genuine ambiguity” necessary to trigger deference by “exhaust[ing] all the ‘traditional tools’ of construction,” and cannot do so for the first time before this Court. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (quoting *Chevron*, 467 U.S. at 843 n.9).<sup>4</sup>

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<sup>4</sup> The Supreme Court is currently considering whether to overrule or narrow *Chevron*. *See Loper-Bright Enterprises v. Raimondo, cert. granted*, No. 22-451 (argued Jan. 17, 2024); *Relentless, Inc. v. Dep’t of Com., cert. granted*, No. 22-1219 (argued Jan. 17, 2024). Plaintiffs preserve all arguments that may arise from those decisions to the extent they limit or overrule *Chevron*.

The 2022 rule eviscerates the CWA’s cooperative federalism regime with one under which EPA has freestanding authority to impose federal standards based on EPA’s understanding of tribal rights. The CWA was enacted over fifty years ago. But until EPA purported to discover the power in the 2016 rule, EPA had never before asserted the authority to invoke tribal treaty rights to supercharge its authority to override state water quality standards. As the Supreme Court recently warned EPA, it must find clear authorization in the statutory text when it claims newfangled authority to regulate in an area where it has “no comparative expertise”—here, in purportedly protecting tribal treaty rights (the domain of the Department of the Interior, not EPA). *West Virginia v. EPA*, 142 S. Ct. 2587, 2612–13 (2022). Congress has not delegated—much less *clearly* delegated—tribal treaty interpretation or enforcement power to the agency, and EPA’s flimsy treaty interpretation underscores its lack of expertise in construing agreements between sovereigns. Because the 2022 rule is *ultra vires*, it must be vacated.

2. Under EPA’s longstanding regulations, too, Washington was entitled to set its own designated uses and water quality criteria that “are consistent with the requirements of the Clean Water Act” and “protect the designated water uses based on sound scientific rationale.” 40 C.F.R. § 131.5(a)(1)–(2). EPA may disapprove state standards and impose federal criteria if, and only if, “*necessary* to meet the requirements of the Act.” *Id.* § 131.5(b) (emphasis added). EPA has repeatedly acknowledged that its *current* regulations do not construe this requirement to authorize the agency to override a State’s standards under a tribal rights theory. *Cf.* EPA 2019 Approval 18. That is why EPA undertook a new rulemaking during the pendency of this case in an effort to establish that very authority. *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*, 89 Fed. Reg. 35,717, 35,718 (May 2, 2024).

EPA nonetheless invoked a tribal treaty rights theory to override state standards here, long

before it promulgated any such rule purporting to authorize it. Even if EPA could now claim the power to harmonize water quality standards with tribal treaty rights (it cannot), no EPA rule authorized it do so *before* EPA asserted that power to override Washington’s standards. *See Nat’l Conservative Pol. Action Comm. v. FEC*, 626 F.2d 953, 959 (D.C. Cir. 1980) (per curiam) (agency action unlawful when issued in a departure from agency regulations without prior notice to affected parties). On that ground alone, the rule is unlawful.

## **II. EPA’s Unjustified Changes in Position Violate the APA.**

In 2019 and 2020, EPA applied well-settled agency policy in thoroughly reasoned decisions that approved Washington’s human health criteria, rescinded the federal standards imposed in 2016 that departed from this longstanding policy, and explained that EPA cannot invoke tribal treaties to expand its authority under the CWA to set water quality standards. Plaintiffs’ members and others reasonably relied on those decisions to make substantial investments in Washington facilities, equipment, and personnel. *See, e.g.*, Spokane Letter 2 (stating that, as of 2022, regulators had already “compel[led] the City to spend additional money to control PCBs entering the river”). Nevertheless, in the 2022 rule, EPA abruptly reversed course without explaining the agency’s own intervening findings and the reasonable reliance they engendered. Because it is “arbitrary [and] capricious to ignore such matters,” the 2022 rule should be vacated. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

When an agency changes position, it must at least “display awareness” of the change and “show that there are good reasons for the new policy.” *Fox*, 556 U.S. at 515. Thus, the APA’s reasoned decision-making requirement “is especially important where, as here, an agency changes course.” *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 644 (D.C. Cir. 2020). EPA violated this requirement by promulgating the 2022 rule without acknowledging or addressing the abrupt policy reversals embodied in four key features of the rule: (1) EPA’s treatment of tribal subsistence

fishers as the general population, (2) EPA's demand for lockstep formula inputs across water quality criteria for all chemicals, (3) EPA's revival of a tribal treaty rights theory it had only recently repudiated, and (4) EPA's recharacterization of Washington's designated water uses to protect tribal fishing rights.

1. *First*, EPA reversed its longstanding position that States may choose criteria that protect the *general* population at a CRL of  $10^{-5}$  and protect tribal subsistence fishers as a highly exposed subpopulation at a CRL of  $10^{-4}$ . As EPA explained when approving Washington's criteria just two years before the 2022 rule, "longstanding EPA policy and the Agency's recommendations for setting [human health criteria], including the 2000 Methodology," authorize States to "consider tribes with reserved fishing rights to be highly exposed [sub]populations, rather than the target general population, in order to derive criteria" using appropriate CRLs and FCRs. EPA 2019 Approval 22–23. EPA further explained that the agency had been "aware" that "certain tribal populations engaged in subsistence fishing practices" for decades, and that the 2000 Methodology "speaks directly" to these populations by recommending that States protect them as "more highly exposed subgroups." *Id.* (quoting 2000 Methodology at 1–12). Noting that Washington appropriately based its standards on the general population while protecting tribes as highly exposed subpopulations, EPA "determined that, looking at the record and the State's approach as a whole, [Washington's human health criteria] meet the requirements of EPA's regulations because their inputs are based on sound science and the resulting criteria protect the designated uses." *Id.* at 24; *see* 85 Fed. Reg. at 28,496 (withdrawing federal criteria for Washington to allow the State's standards to go into effect by operation of law).

That was not a standalone decision. In approving Idaho's standards in 2019, EPA similarly explained that the agency had never before used the term "target general population" and had

reviewed state submissions only for protection of the “general population” and “highly exposed subpopulations.” Letter from Chris Hladick, Regional Administrator, EPA Region 10, to John Tippetts, Director, Idaho Dep’t of Env’t Quality 15 (May 10, 2019) (“2019 Idaho Letter”). Indeed, EPA’s view that States may set criteria based on the general population predates the 2000 Methodology and has survived judicial review. *See, e.g., Dioxin/Organochlorine Ctr. v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995) (rejecting argument that EPA effluent limits for the Columbia Basin insufficiently protected subpopulations by using an FCR for the general population); *NRDC*, 16 F.3d at 1403 (rejecting argument that EPA-approved state standards failed to “protect subpopulations with higher than average fish consumption”).<sup>5</sup>

The 2022 rule broke from this longstanding policy without explanation. Consistent with the 2000 Methodology and decades of EPA guidance, Washington had determined its PCB criterion “based on a  $10^{-5}$  [cancer] risk level” that is “acceptable for the general population” and “ensure[d] that the risk to more highly exposed subgroups ... does not exceed the  $10^{-4}$  level.” 2000 Methodology at 1–12; *see Toxic Substances—WAC 173-201A-240, supra*, at tbl. 240 & nn.B, E. Nevertheless, EPA determined that Washington’s standards “do not protect designated uses because the input values on which they rely are not supported by a sound scientific rationale.” 87 Fed. Reg. at 19,051. The agency imposed a more stringent CRL of  $10^{-6}$ , asserting that only this value “reflects an appropriate risk for the general population” as determined by “tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels.” 87 Fed. Reg. at 69,189. Rather than acknowledge the change in policy, EPA repeatedly insisted, with

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<sup>5</sup> The handful of agency actions taking a contrary position from 2015 to 2017—including the 2016 rule—purported to announce “new designations” that were “not established by regulation in any nationally applicable EPA rulemaking or in a guidance document or statement of policy.” 2019 Idaho Letter at 15.

a flawed and circular explanation, that its 2022 rule “is consistent with EPA’s 2000 Methodology.” *Id.*; see also EPA 2022 Response to Comments 90 (“EPA’s selection of a  $10^{-6}$  CRL is consistent with EPA’s 2000 Methodology, which states that EPA intends to use the  $10^{-6}$  level[.]”).

2. *Second*, EPA reversed its position that States may use chemical-specific inputs in setting water quality criteria. In 2019, EPA concluded that Washington’s “chemical-specific cancer risk rate of  $2.3 \times 10^{-5}$ ” for PCBs “falls within the range of protective risk rates the EPA has recommended since it issued its 2000 Methodology and is protective of the State’s designated uses.” EPA 2019 Approval 19. As EPA explained, “[n]othing in the CWA prevents or prohibits a state from adopting a chemical-specific cancer risk rate, as long as the derived criteria are based on sound scientific rationale and protective of the designated use.” *Id.* at 19–20. Again, this position was not new. For decades, EPA has authorized the use of chemical-specific values and limitations to support States’ discretionary risk management decisions. See 2019 Idaho Letter at 28, 31–32; 2000 Methodology at 2–4 (“The choice of an acceptable cancer risk ... is a risk management decision.”); cf. *Am. Paper Inst., Inc. v. EPA*, 996 F.2d 346, 351 (D.C. Cir. 1993) (rejecting challenge to EPA regulation requiring “chemical-specific limitations on discharges”).

EPA took exactly the opposite position in the 2022 rule, without displaying awareness or acknowledging that it was changing position, let alone weighing the benefits and tradeoffs of such a change or explaining why it believes its new position to be better. Without elaboration, EPA stated that “it is important to keep these [CRL] values consistent” between specific chemicals “because these values are associated with the population that the criteria are intended to protect and are not pollutant-specific.” 87 Fed. Reg. at 69,189. That explanation ignored that cancer risk levels used for water quality criteria vary widely for different chemicals, even though the criteria often apply to the same population. See, e.g., 2019 Idaho Letter at 28, 31–32. Moreover, EPA

gave short shrift to Washington’s own explanation—Washington chose a chemical-specific CRL that corresponded to a 170 ppq PCB criterion in light of Washington’s other highly protective input, an FCR of 175 g/day. Wash. Dep’t of Ecology, *Washington State Water Quality Standards: Human Health Criteria and Implementation Tools* 66–67 (Aug. 2016). Its choice reflected “a chemical-specific risk management decision” not to increase the PCB criterion above EPA’s prior National Toxics Rule value and accorded with “EPA [human health criteria] guidance as well as with precedent from other states” permitting chemical-specific risk levels. *Id.* EPA’s newfound preference for lockstep risk levels does not endow it with authority to set aside a State’s differing risk management approach that accords with sound science and established EPA guidance.

3. *Third*, EPA reversed its prior position that the agency lacks statutory authority to interpret and enforce tribal rights against the States through the CWA standards-setting process, including by recharacterizing the State’s designated uses for its waterways. In approving Washington’s standards in 2019, EPA rejected the argument that it may require States to treat tribal subsistence fishers as the “target general population” because the State’s designated uses “include subsistence fishing.” EPA 2019 Approval 22. EPA further disclaimed authority to “‘effectuate and harmonize’ tribal reserved treaty rights with the CWA when establishing [human health criteria],” *id.* (quoting 80 Fed. Reg. at 55,067), noting that reserved rights “do not expand the EPA’s authority under the CWA,” *id.* at 23. But in the 2022 rule, EPA ignored the reasoning and conclusion of its 2019 Approval, adopting the treaty rights rationale with no mention of the agency’s recent repudiation of that rationale. Instead, as explained above, EPA attempted to downplay reliance on a tribal rights rationale in the 2022 rule, asserting that the rule was based on “sound science” and Washington’s “designated uses.” *See supra* at 14–15, 20–21.

4. *Fourth*, EPA reversed its prior position that the agency lacks authority to substitute



its own designation of water uses for the State's. Until the 2022 rule, EPA consistently recognized that "States have exclusive responsibility to designate water uses," *NRDC*, 16 F.3d at 1405 (citing 40 C.F.R. § 131.10), and EPA therefore may not invoke tribal treaty rights to override or recharacterize the State's designated uses. *See Miss. Comm'n on Nat. Res. v. Costle*, 625 F.2d 1269, 1276 (5th Cir. 1980) ("[T]he specification of a waterway as one for fishing, swimming, or public water supply is closely tied to the zoning power Congress wanted left with the states."); *see also* 40 C.F.R. §§ 131.10(a) ("Each *State* must specify appropriate water uses to be achieved and protected." (emphasis added)), 131.11 (setting out requirements for criteria that protect "the designated use"). In approving Idaho's water quality standards in 2019, for instance, EPA explained that "[t]he existence of tribal treaties with reserved fishing rights does not grant the EPA authority to recharacterize a state's designated uses or otherwise skew the federal-state balance of the CWA towards the federal government" and "do[es] not expand the EPA's authority under the CWA." 2019 Idaho Letter at 30–31. And in withdrawing certain criteria for Indian lands in Maine in 2020, EPA again explained that "the CWA does not provide the Agency with statutory authority to recharacterize the State's general fishing use beyond the meaning intended by the State." Letter from Dennis Deziel, Regional Administrator, EPA Region 1, to Gerald D. Reid, Commissioner, Maine Dep't of Env't Prot., *Re: Withdrawal of Certain of EPA's February 2, 2015 Decisions Concerning Water Quality Standards for Waters in Indian Lands*, Attach. B at 20 (May 27, 2020).

Yet that is precisely what EPA did in the 2022 rule. EPA reversed its approval of Washington's standards by invoking tribal fishing rights to recharacterize Washington's designated uses: According to EPA, Washington's criteria were insufficiently protective of "the State's" designated uses, including "the tribal subsistence fishing portion of the fish and shellfish harvesting use as informed by treaty-reserved fishing rights." 87 Fed. Reg. at 69,187 & n.38

(quoting 81 Fed. Reg. 85,426); *see also* EPA 2022 Response to Comments 36. But the phrases “tribal subsistence fishing” and “treaty-reserved fishing rights” were *EPA’s* additions. As EPA previously recognized, Washington’s designated uses include “Harvesting (fish harvesting),” “Shellfish Harvesting,” and “Harvesting”—without specifying *subsistence* harvesting or discussing tribal fishing rights. EPA 2019 Approval 9 (citing *Toxic Substances—WAC 173-201A, supra*, at 600–10). EPA’s blue-penciling thus trenched on the State’s “*exclusive* responsibility to designate water uses.” *NRDC*, 16 F.3d at 1405 (emphasis added). More to the point, EPA did not even acknowledge its prior position that the agency may not recharacterize the States designated uses, much less explain why it was changing course.

Finally, in changing position, EPA was required to consider the interests of parties (like Plaintiffs’ members) that reasonably relied on EPA’s prior approval of Washington’s standards to “craft[] business models and invest[] significant resources” in Washington facilities, equipment, and personnel. *Nat’l Lifeline Ass’n v. FCC*, 921 F.3d 1102, 1114 (D.C. Cir. 2019); *see, e.g.*, Nw. Pulp & Paper Letter 71 (explaining the time and resources involved in obtaining permits). EPA dismissed future compliance costs as too “speculative” to evaluate, 87 Fed. Reg. at 69,195, but its failure to take regulated parties’ “serious reliance interests” into account is further reason to vacate the rule, *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020).

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EPA is free to change its policy through appropriate means so long as it displays awareness of the change, and the new policy is “reasonable and reasonably explained.” *Biden*, 142 S. Ct. at 2543. EPA violated the APA when it failed to do so here.

### **III. EPA Based Its Human Health Criterion for PCBs on Unreasonable Assumptions.**

“[T]he presumption of agency expertise may be rebutted if its decisions, even though based on scientific expertise, are not reasoned,” *Def. of Wildlife v. Babbitt*, 958 F. Supp. 670, 679

(D.D.C. 1997), and agency action cannot survive when its stated reasons are “[un]reasonable” or “internally inconsistent,” *ANR Storage Co. v. FERC*, 904 F.3d 1020, 1024 (D.C. Cir. 2018).

Here, EPA arrived at an unreasonable standard by engaging in an unreasonable analysis under the 2000 Methodology. EPA made unreasonable scientific assumptions that resulted in double- and triple-counting risk and refused to take into account more reliable methodologies and data. These unsupported assumptions led EPA to adopt an unreasonable FCR and CRL and, ultimately, an impossible-to-meet human health criterion for PCBs. For any and all of these reasons, the 2022 rule should be vacated.

1. EPA selected an unreasonably high FCR of 175 g/day based on a series of unjustifiable assumptions about the consumption habits of hypothetical subsistence fishers consuming contaminated fish at a counterfactual “unsuppressed” rate.

Under the 2000 Methodology, the FCR is the estimated amount of fish an 80-kilogram (176-pound) adult consumes every day from his or her twenty-first birthday until death. *See* 87 Fed. Reg. at 69,186 & nn.14–15. Since 2015, EPA has used a default national FCR of 22 g/day, a protective estimate that reflects the 90th percentile of fish consumption in the United States and that amounts to about two three-ounce filets of salmon per week. And since 2000, EPA has recommended a 142 g/day rate for subsistence fishers, *i.e.*, the 99th percentile of fish consumption. *See* 2000 Methodology at 1–5. But in the 2022 rule, EPA went further—adopting a 175 g/day rate that, quite literally, is off the charts of the agency’s longstanding guidance and amounts to about *fifteen* three-ounce filets of salmon per week. 87 Fed. Reg. at 69,189.

EPA’s choice of FCR is unjustified on the administrative record. EPA largely piggy-backed on the FCR selected by Washington, 87 Fed. Reg. at 69,188; EPA Response to Comments 51 (purporting to use the “FCR ... that Washington used in 2016”), and justified its own choice in

the 2022 rule by reference to “the same rationale” used “to support its use of those inputs in the 2016 Federal rule,” 87 Fed. Reg. at 69,189. EPA’s cross-references demonstrate that it arrived at its 175 g/day FCR not because the agency believes people in Washington actually eat that much fish every day for life, but rather as an approximation for the counterfactual “unsuppressed” rate of consumption by tribal subsistence fishers “prior to contact with European settlers.” 81 Fed. Reg. at 85,426 & n.53. And EPA arrived at that “unsuppressed” FCR using the 95th percentile rate from a cherry-picked 1994 survey of tribal members in the Columbia River Basin that asked about fish consumption at a time in the already distant past. *Id.* at 85,426 & n.54.

This rationale cobbled together from a 30-year-old study is too thin to render EPA’s choice of FCR reasonable. In EPA’s chosen study, “rates of consumption represent fish obtained *from all sources*,” including grocery stores—in other words, fish not even exposed to Washington waters. *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* 69 (Columbia River Inter-Tribal Fish Commission 1994), [tinyurl.com/53c9x9ar](https://tinyurl.com/53c9x9ar) (emphasis added). The study concedes that other studies “reporting estimates for tribal populations” reached “consistently lower” estimates of fish consumption. *Id.* at 60. And the study’s effort to determine a historical decrease in fish consumption was based on nothing more than a simple question to survey respondents over the age of 30 about whether their “current pattern of fish consumption differs from ... 20 years ago.” *Id.* at 20.

More fundamentally, however, EPA’s rationale fails as a matter of law. EPA based its use of an “unsuppressed” FCR on the assumption that tribal members would return to subsistence levels of fish consumption but for “suppression” of those resources. But EPA’s deployment of a counterfactual estimate of “unsuppressed” consumption—rather than real-world consumption data—contravenes the CWA’s statutory directive to States to promulgate standards that take into

account “their use and value for” certain current uses of waterbodies. 33 U.S.C. § 1313(c)(2)(A). At no point does the Act either compel States to consider historical, prior uses that may have been decades—if not centuries—in the past or direct States to prioritize historical uses over current or reasonably anticipated future uses. Likewise, the Act does not compel States to define reasonably anticipated future uses by employing estimates of historical or “heritage” use patterns. EPA cites no authority for its theory that States must “restore” all waters to century-old uses by setting criteria based on counterfactual assumptions.

What’s more, EPA’s consideration of what counts as “unsuppressed” consumption is so ill-defined as to be arbitrary. Only speculation supports EPA’s assumption that tribal members would return to a purported historical consumption rate from centuries ago absent “suppression” effects. And EPA fails to consider that tribal people with suburban or hybrid lifestyles and grocery-store diets consume fish largely from waters not covered by the 2022 rule, including the open ocean. It is arbitrary to base water quality criteria on conditions that are neither reflective of modern realities nor grounded in a fact-based forecast of the future.

In any event, as discussed, EPA’s reliance on a tribal rights theory to justify its selected FCR also renders that choice unlawful, because EPA has no authority to invoke tribal rights to expand its authority to set water quality standards under the CWA. *See supra* at 18–22.<sup>6</sup>

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<sup>6</sup> Nor can EPA justify its choice of FCR by pointing to Oregon’s approved rate of 175 g/day. *See* 87 Fed. Reg. at 69,189. EPA regulations do not require adopting equally stringent standards as downstream States, let alone using identical analytical inputs while doing so. *See* 40 C.F.R. § 131.10(b) (requiring States to “*take into consideration* the water quality standards of downstream waters” when setting designated uses (emphasis added)). A contrary conclusion would lead to absurd results—essentially allowing downstream States to dictate upstream standards—that cut against the CWA’s cooperative federalism scheme and treatment of States as equal sovereigns. In any event, if other States’ standards provide the relevant benchmark, then EPA faces another failure of explanation: In 2019, EPA approved Idaho water quality standards based on an FCR of 66.5

2. In picking its FCR, EPA also rejected a more reliable alternative method without adequate explanation—EPA’s in-house variant of the National Cancer Institute method, which adjusts risk to account for the reality that the general population does not eat the same amount of fish every day over a lifetime. *See National Health and Nutrition Examination Survey* 21–22 (Apr. 2014), <https://www.epa.gov/sites/default/files/2015-01/documents/fish-consumption-rates-2014.pdf>. Commentators pointed this out to EPA, but the agency offered no justification for rejecting this alternative. *Nw. Pulp & Paper Letter* 21–22; *EPA Response to Comments* 159–60.

3. Stacking flawed assumption on top of flawed assumption, EPA unreasonably assumed in setting its FCR that anadromous fish species that spend most of their lives in ocean waters far from the shore (*e.g.*, many species of salmon) have the same degree of exposure to pollutants in inland waters as fish and shellfish found exclusively inland and that the pollutant levels are the result of such exposure. *See* 87 Fed. Reg. at 69,190 (“The pollutant concentrations in anadromous fish are the same as those in inland and nearshore fish.”). Again, commenters pointed out this error in the agency’s reasoning to no avail. *See* *Nw. Pulp & Paper Letter* 185. This unsupported assumption is material because EPA relied on it to conclude that no adjustment to its chosen FCR was needed under the 2000 Methodology to account for relative source contributions to risk—*i.e.*, exposures to a chemical from sources other than drinking water and fish from inland and nearshore waters. *See* 87 Fed. Reg. at 69,190–91.

4. EPA compounded its error by combining an unjustifiably high FCR with an unjustifiably high CRL of  $1 \times 10^{-6}$  for PCBs based on a purported need to protect the general population at the level of tribal subsistence fishers. *See* 87 Fed. Reg. at 69,189. Under the 2000

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*g/day*, nearly three times lower than the input EPA used for Washington’s standards. EPA provided no explanation for its “dissimilar treatment” of these two States. *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1245 (D.C. Cir. 2023).

Methodology, these inputs together inform the criteria that are necessary to protect public health. *See, e.g.*, 2000 Methodology at 2–4. As explained, EPA failed to justify overriding Washington’s CRL of  $2.3 \times 10^{-5}$  for PCBs—and did not offer a good reason to abandon its longstanding policy authorizing a similar rate for the general population, including *in Washington*. *Supra* at 23–29. But even if good reasons supported a more protective CRL, there is no basis—and EPA offered none—for using the same tribal rights rationale to require *both* an inflated FCR *and* an inflated CRL. EPA did not justify deviating from longstanding policy in one instance, much less in two.

#### **IV. EPA’s Human Health Criterion for PCBs Is Arbitrary and Capricious Because It Is Neither Measurable Nor Achievable.**

“Impossible requirements imposed by an agency are perforce unreasonable.” *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 940 (D.C. Cir. 1991); *Hughey v. JMS Dev. Corp.*, 78 F.3d 1523, 1529 (11th Cir 1996) (“In interpreting the liability provisions of the CWA we realize that Congress is presumed not to have intended absurd (impossible) results.”). Thus, when a “contested regulation is unrealistic,” it cannot stand. *United States v. Cartwright*, 411 U.S. 546, 550 (1973). Indeed, EPA itself has acknowledged that it “cannot impose more protective measures than can be technically feasibly implemented, as the law cannot compel the impossible.” *Hazardous and Solid Waste Management System*, 84 Fed. Reg. 65,941, 65,945 (Dec. 2, 2019).

Here, EPA’s 7 ppq PCB criterion is so small that modern technology cannot even reliably detect or measure the pollutant at that concentration. A part per quadrillion is one part per 1,000,000,000,000,000 parts. Try to compare roughly seventeen minutes to the entire age of the Earth (4.5 billion years). That is 7 ppq. EPA has thus imposed a criterion that is unreasonable and unworkable. Yet EPA expects regulated parties to comply with this limit through as-yet-unknown technologies at enormous expense. That is arbitrary and capricious.

1. EPA does not dispute that its PCB criterion cannot be measured. As the agency explains, EPA’s most recently approved, state-of-the-art method for measuring PCBs to determine compliance with an NPDES permit “has an average analytical quantitation limit for each PCB congener of approximately 2,000 [ppq], which is a substantial improvement over the current regulatory method,” but “well above” EPA’s criterion. 87 Fed. Reg. at 69,195–96 (describing Method 1628). The “current regulatory method” can reliably quantify PCB concentrations only at 500,000 ppq and greater. See 40 C.F.R. § 136.3; *Puget Soundkeeper All. v. Wash. Dep’t of Ecology*, 424 P.3d 1173, 1176 (Wash. 2018). Even extremely sensitive analytical methods (which are not approved by EPA to measure NPDES compliance) come nowhere close to reliably measuring 7 ppq—at best, at 1,000 ppq (Method 8082A) or 100 ppq (Method 1668C).

2. EPA’s PCB criterion also cannot be attained with any existing technology even if analytical methods improve sufficiently to allow 7 ppq to be measured.

The administrative record is undisputed: 7 ppq is not achievable. As the City of Spokane explained, “[t]he City does not believe 7 ppq will ever be realistically achieved in the Spokane River or in other water bodies across the State” because “PCBs continue to be introduced into the environment under the Toxic Substances Control Act” at a concentration limit “7 billion times less restrictive than the proposed WQS.” Spokane Letter 2 (emphasis added). The City of Post Falls, Idaho—a small municipal discharger upstream of the Spokane River—similarly highlighted that “there is no existing technology that can be employed to meet these numeric values.” Post Falls Letter 1. And in a public presentation to stakeholders, Washington’s Department of Ecology has effectively recognized the same: no existing technology can achieve 7 ppq PCBs. Workshop on PCB Variances for Spokane River Dischargers 83 (Nov. 14, 2019), [https://www.ezview.wa.gov/Portals/\\_1962/Documents/SpokaneRiverCleanWater/VarianceWorkshop\\_All.pdf](https://www.ezview.wa.gov/Portals/_1962/Documents/SpokaneRiverCleanWater/VarianceWorkshop_All.pdf).



The available empirical evidence confirms the same conclusion. A 2013 study by the Association of Washington Business determined that the “best performing” municipal treatment facility in Washington using a microfiltration membrane could reduce PCBs to an approximate range of between 190 and 630 ppq. EPA-HQ-OW-2015-0174-0380, at 12. When AWB updated the study in 2022, it again concluded that “[t]he lowest levels achieved based on the literature review were ... two orders-of-magnitude greater than the proposed [criterion]” of 7 ppq. Nw. Pulp & Paper Letter, Attach. C at 36. EPA disputes none of this.

3. EPA’s unattainable PCB criterion has caused significant uncertainty among the regulated community and may, in the long run, undercut efforts to meet the standards.

“Setting a numeric value far below where it can be measured is misleading to the public” and “leaves the regulated community uncertain as to any foreseeable path to compliance and unable to plan for the consequences” that may follow from the standards. Post Falls Letter 2. In fact, the City of Spokane underscored the “uncertainty for the City and its ratepayers” *already* engendered by the 2022 rule. Spokane Letter 2. Washington regulators have developed a draft NPDES permit that proposes a compliance schedule for additional treatment to address PCBs. *Id.* The City has applied for a variance, but it has received no indication that it will be granted, and the City has thus been put to the dilemma of undertaking costly technological developments in a futile effort to comply, or else risking non-compliance while its variance request remains pending. *Id.* (“the City is left with few options”); *see also* National Mining Association Letter 2 (“unattainable standards ... inject significant legal and regulatory uncertainty into the process”).

The consequences of EPA’s criteria are also significant. When regulated entities attempt to achieve the impossible through “cost-prohibitive technology,” facility closures and job losses in Washington communities will follow. Nw. Pulp & Paper Letter 24. EPA’s fanciful criteria thus

may prove counterproductive, because “working toward unattainable water-quality standards diminishes” EPA’s and Washington’s “ability to achieve widespread buy-in on pollutant load controls.” K.H. Reckhow, *Unattainable Surface-Water Quality Standards May Diminish Widespread Public Support for Water Quality Improvements*, Cambridge University Press (2016).

4. EPA failed to adequately address these basic concerns. Indeed, its principal response epitomizes arbitrary and capricious decision-making: “[T]echnological feasibility,” EPA declared, *does not matter* in setting human health criteria. EPA 2022 Response to Comments 20.

That can’t be right. As explained above, water quality standards “set the permissible level of pollution in a specific body of water,” which, in turn, are translated into an NPDES permit “that app[lies] to individual polluters.” *City of Arcadia v. EPA*, 411 F.3d 1103, 1105 (9th Cir. 2005). Water quality standards thus “provide the basis for specific, enforceable requirements *designed to achieve them*,” as each permit “must include ... requirements sufficient to protect water quality standards.” *In re ACF Basin Water Litig.*, 467 F. Supp. 3d 1323, 1337 (N.D. Ga. 2020) (emphasis added). It is arbitrary to set standards that cannot *ever* be achieved or even measured when the very purpose of the standards is to provide a basis for requirements designed to achieve them.

EPA’s fallback response fares no better. EPA urged that potential “implementation concerns” could be addressed by applying for a variance or removal of a designated use for a waterbody. EPA 2022 Response to Comments 20. But these back-end remedies only amplify regulatory uncertainty, as parties are left in limbo while their applications are pending. *See* Spokane Letter 2. And neither option is realistic. Washington has *never* granted a variance, and even if granted, variances are vulnerable to challenge through citizen-suits under the CWA, 33 U.S.C. § 1365. An effort to remove a designated use is even less likely to succeed, since removing a use removes associated criteria for “all dischargers and all pollutants”—a less “targeted” solution

than a variance. *Upper Mo. Waterkeeper v. EPA*, 15 F.4th 966, 972 (9th Cir. 2021).

Thus, EPA’s unmeasurable and unachievable PCB criterion is arbitrary and capricious.

**V. The Rule Is Arbitrary and Capricious Because EPA Failed to Reasonably Consider Costs or, Alternatively, Conducted an Unreasonable Economic Analysis.**

EPA’s 2022 rule violates the APA and the CWA in two alternative respects. EPA erroneously concluded that “costs” cannot legally be “considered ... in development of water quality criteria,” EPA 2022 Response to Comments 109, or alternatively, that its impossible-to-meet PCB criterion imposes *no* “incremental costs” on regulated parties at all, 87 Fed. Reg. at 69,195. If EPA disclaimed authority to consider costs, EPA misconstrued the CWA and its implementing regulations. In the alternative, if EPA relied on a cost-benefit analysis, its analysis is unreasonable because it rested on the erroneous premise that the costs of its revised criteria are too “speculative” to evaluate before they are incurred. Either way, the rule should be vacated.

**A. EPA unreasonably failed to consider costs in setting water quality standards.**

EPA failed to meaningfully consider the large compliance costs the rule would impose. EPA’s response to comments proffered an erroneous reason as to why: EPA declared that it may *not* consider costs in establishing Washington’s revised criteria. *See* EPA 2022 Response to Comments at 109 & n.255. That is wrong as a matter of law, and agency action that disclaims discretion based “on a faulty legal premise” is *per se* arbitrary and capricious. *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985).

1. EPA has broad discretion to decide to weigh costs and benefits in implementing the CWA. As a general rule, agencies should consider costs unless the statute clearly precludes such consideration. *Michigan v. EPA*, 576 U.S. 743, 755 (2015); *see Michigan v. EPA*, 213 F.3d 663, 677–78 (D.C. Cir. 2000) (*per curiam*) (“[P]reclusion of cost consideration requires a rather express congressional direction”—a “clear congressional intent”).

Here, nothing in the CWA precludes consideration of costs in setting water quality criteria. The Act simply provides that the EPA Administrator must deem a new federal standard “necessary” to meet the requirements of the Clean Water Act. 33 U.S.C. § 1313(c)(4)(B). It further states that water quality standards must protect “the public ... welfare” and “serve the purposes of this chapter.” *Id.* § 1313(c)(2)(A). These open-ended mandates to make a necessity determination and to protect the “public ... welfare” do not express a “clear congressional intent” to preclude consideration of costs in setting criteria. *Michigan*, 213 F.3d at 678. If anything, they imply that consideration of costs is statutorily *required*.

The Supreme Court’s decision in *Michigan v. EPA* is illustrative. There, the Court considered whether EPA could find regulation of hazardous air pollutants from power plants “appropriate and necessary” under the Clean Air Act without considering costs. The Court held that the directive to regulate as “appropriate and necessary” compelled consideration of costs. 576 U.S. at 755–57. Open-ended terms like “appropriate and necessary,” the Court reasoned, incorporate cost as part of the relevant calculus both as a matter of common sense and longstanding practice. Regulation is neither necessary nor appropriate when it reflects “wasteful expenditure.” *Id.* at 753. And “[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate.” *Id.* at 752–53.

Similarly, here, the CWA commands the EPA to deem a new federal standard “necessary” to supersede the State’s criteria. 33 U.S.C. § 1313(c)(4)(B). The statute further provides that the standards should “protect the public health *or welfare*.” *Id.* § 1313(c)(2)(A) (emphasis added). Just like the phrase “appropriate and necessary” in *Michigan*, these open-ended terms—“necessary,” and “public ... welfare”—embrace economic considerations.

2. EPA justified its contrary view by citing a footnote from the Ninth Circuit’s decision in *Upper Missouri Waterkeeper v. EPA*, 15 F.4th 966 (9th Cir. 2021). There, the court construed EPA regulations in dicta to permit the agency to consider costs only in setting designated uses (the first component of a water quality standard), but not in setting criteria to protect those uses (the second component). *Id.* at 972 & n.1.

But *Upper Missouri Waterkeeper* misconstrued EPA’s regulations, and its reasoning is not persuasive. To be sure, the relevant regulation directs EPA to base criteria on a “sound scientific rationale.” 40 C.F.R. § 131.11(a)(1). But nothing in that directive *forecloses* consideration of costs. The Supreme Court has made clear that mere textual silence does not preclude such consideration. *See Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 222, 225–26 (2009) (concluding that consideration of costs is permissible even when the CWA “does not expressly authorize cost-benefit analysis,” and even when the CWA establishes a “best technology available” standard). Indeed, EPA itself has long understood that while the criteria are *partially* “grounded in science,” they also inescapably involve “risk management decisions.” 2000 Methodology at 2–4. Consideration of cost is a necessary element of risk management.

Moreover, EPA’s regulation must be “construed” “in light of the statutory mandat[e] under which [it] issue[d].” *Pac. Coast Med. Enters. v. Harris*, 633 F.2d 123, 131 (9th Cir. 1980). The Act draws no distinction between designated uses and water quality criteria for cost consideration purposes. After defining a “water quality standard” as consisting both “of the designated uses of the navigable waters involved and the water quality criteria for such waters based upon such uses,” Congress provided in the very next sentence that “[s]uch standards shall be such as to protect the public health or welfare.” 33 U.S.C. § 1313(c)(2)(A) (emphases added). The collective reference to the “standards” (and not merely the “uses”) suggests that *both* the uses and the criteria must

advance the “public ... welfare”—a capacious term that necessarily embraces economic considerations. *Cf. Michigan*, 576 U.S. at 755; *Michigan*, 213 F.3d at 677–78.

EPA thus erroneously disclaimed authority to consider costs and ignored an important aspect of the problem. That alone is reason to vacate and remand. *Prill*, 755 F.2d at 948.

**B. EPA’s economic analysis rests on unreasonable assumptions.**

Alternatively, to the extent EPA did rely on a cost-benefit analysis, its analysis was not reasonable. Whether or not an agency is “*require[d]*” to consider “economic effects,” when “EPA in fact consider[s] economic effects at length,” the Court “must review its economic reasoning” to determine “whether its overall decision was reasonable.” *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 525–26 (D.C. Cir. 1983); *see also Nat’l Ass’n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) (similar). Here, although EPA disclaimed authority to consider costs in setting the standard, the agency conducted an economic analysis of its rule. *See* 87 Fed. Reg. at 69,194–96; Economic Analysis for Restoring Protective Human Health Criteria in Washington (Nov. 2022), EPA-HQ-OW-2015-0174-1113 (“Economic Analysis”).

The APA does not require “rigorous exactitude,” but agencies must at least rationally weigh all relevant costs. *GTE Serv. Corp. v. FCC*, 782 F.2d 263, 273 (D.C. Cir. 1986). “The mere fact that the ... effec[t] [of a rule] is *uncertain* is no justification for *disregarding* the effect entirely.” *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004). Nor can an agency ignore economic impacts under the fiction that the impacts are “caused co-extensively by [another] agency action.” *N.M. Cattle Growers Ass’n v. U.S. Fish & Wildlife Serv.*, 248 F.3d 1277, 1283 (10th Cir. 2001). And an agency “may not minimize” evidence that undercuts its judgment “without adequate explanation.” *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018). By attributing *no* incremental costs to any major point sources, EPA’s economic analysis here flouts each of these principles.

1. The record shows that compliance costs will be significant. As the City of Spokane highlighted, Washington’s Department of Ecology has developed a draft NPDES permit based on the 2022 rule’s PCB criterion that would require the City to invest—by a highly conservative estimate—\$19 million per gram of additional PCB removal in the Spokane River. Spokane Letter

2. That draft NPDES permit suggests that almost every publicly owned wastewater treatment plant in Washington and other dischargers would need to adopt tertiary membrane filtration treatment or other prohibitively costly measures to address PCBs. As noted, commenters estimated that the incremental cost of such treatment, including construction costs and operation and maintenance costs, would be between \$53 and \$82 million for a plant that processes 500,000 gallons of wastewater per day, with a net present value unit cost of between \$106 and \$262 per gallon per day. Thus, “[i]f EPA follows the same approach on Puget Sound that it has on the Spokane River, this will amount to a range of compliance costs from nearly \$6 billion to over \$11 billion just for the ‘major’ permits” alone. *Nw. Pulp & Paper Letter 70*. And regulated parties would do all this not actually to attain the unmeasurable 7 ppq PCB criterion, but simply to bring themselves *within two orders of magnitude* of that criterion. *See supra* at 35–36.

Despite this record evidence, “EPA did not identify any incremental costs” from the rule. 87 Fed. Reg. at 69,195. The agency explained, however, that “[t]his does not mean that EPA anticipates there would” actually be “no costs” as regulated parties “implement controls or modify processes to meet future permit limits.” *Id.* Rather, according to EPA, “available data” made such costs too “speculative” to assess. *Id.* So the agency treated them as nonexistent.

EPA’s explanation repeats an error the D.C. Circuit has already condemned. In *Public Citizen v. Federal Motor Vehicle Safety Administration*, the D.C. Circuit confronted an agency rule that increased the maximum permissible daily driving time for truckers from ten to eleven

hours. 374 F.3d at 1218. The agency did so based on a cost-benefit analysis that assumed that “time spent driving is equally fatiguing as time spent resting”—thus zeroing out the marginal risk of accidents due to fatigue from “time on task.” *Id.* The agency did not deny that such time-on-task effects were real, but believed they were too “uncertain” to consider at all. *Id.* at 1219 (emphasis omitted). The D.C. Circuit was unpersuaded. The court vacated the rule, rejecting the agency’s “implausible” assumption that the “effects are nil” merely because they are “*uncertain.*” *Id.* Uncertainty, the court emphasized, “is no justification for *disregarding* the effect entirely.” *Id.* *Public Citizen* squarely compels vacatur here.

2. EPA’s finding of zero compliance costs was also based on unrealistic assumptions that offloaded the costs attributable to the rule to other past and future EPA actions.

a. *First*, EPA’s analysis assumed a baseline of “full compliance with existing (including not yet implemented) criteria,” and calculated marginal costs only above that baseline. EPA 2022 Response to Comments 139. EPA, in other words, ignored the real “status quo” in favor of its hypothetical baseline. *Id.* This unrealistic premise resulted in a vast understatement of the rule’s true costs. *See* *Nw. Pulp & Paper Letter 64* (EPA’s analysis “assumed” as part of its baseline “that a facility in Washington has an obligation to take additional actions to comply with the existing NTR arsenic criteria” and failed to treat those as incremental costs to the rule).

The Tenth Circuit confronted an analogous issue under the Endangered Species Act in *New Mexico Cattle Growers Ass’n*, 248 F.3d 1277. There, the court considered whether the Fish and Wildlife Service could adopt an approach to determining the “economic impacts” attributable to a critical habitat designation that included only those impacts that would not have occurred “but for” the designation. *Id.* at 1283. Under that approach, such designations were often deemed to have *zero* economic impact, because the effects of a critical habitat designation overlapped entirely with



a separate agency action, the listing of an endangered species. *Id.*

The Tenth Circuit held that this approach to economic analysis was impermissible. “[T]he fact that the FWS says that no real impact flows from the [critical habitat designation],” the court explained, “does not make it so.” *N.M. Cattle Growers Ass’n*, 248 F.3d at 1284. The court therefore held that “FWS must analyze all of the economic impacts of critical habitat designation (regardless of whether the impacts are co-extensive with other causes)” because FWS’s contrary method had rendered its economic analysis “virtually meaningless.” *Id.* at 1284–85.

So too here. Because EPA assumed an improper baseline, “the projected incremental costs in the economic impact analysis” do not track reality and are “vastly understated.” *Nw. Pulp & Paper Letter 65*. EPA’s failure to account for these costs is arbitrary and capricious.

**b.** *Second*, EPA discounted compliance costs by assuring regulated parties that *future* EPA action could alleviate them. Should “substantial costs arise in the future,” EPA stated, “alternative permit limits may be derived” and “EPA will provide guidance for applying alternative compliance mechanisms to minimize costs.” 87 Fed. Reg. at 69,195.

The APA, however, does not countenance this sort of “trust us” decision-making by federal agencies. *Am. Fed’n of Lab. & Cong. of Indus. Orgs. v. OSHA*, 965 F.2d 962, 980 & n.23 (11th Cir. 1992). As EPA acknowledges, advanced treatment technologies will almost certainly be necessary in the attempt to comply with NPDES permits as “analytical methods and quantitation limits” improve. 87 Fed. Reg. at 69,196. It is unreasonable to ignore such plainly foreseeable costs based on nothing more than EPA’s say-so that it will work with regulated parties to minimize them (which would reduce, but not eliminate, the costs to regulated parties).

**3.** EPA’s economic analysis is independently unreasonable because its “assumptio[n]” of zero compliance costs contradicts “data” and “information it had about” costs.

*Leather Indus. of Am., Inc. v. EPA*, 40 F.3d 392, 402–03 (D.C. Cir. 1994). The rule’s costs are not speculative: Washington “regulators have already” sought “to compel the City [of Spokane] to spend additional money to control PCBs” entering the Spokane River. Spokane Letter 2. And commenters provided specific estimates of the rule’s future costs.

EPA “minimize[d] [this] evidence without adequate explanation.” *Genuine Parts Co.*, 890 F.3d at 312. EPA addressed commenters’ cited studies and rejected their conclusions for (1) failing to “recognize baseline conditions” based on the hypothetical world of assumed compliance with current criteria; (2) “speculat[ing]” that new technologies would be required to comply with future NPDES permits; and (3) failing to “recognize the potential for WQS variances or other alternative compliance mechanisms.” EPA 2022 Response to Comments 140–41. Those responses simply recite the same baseless assumptions refuted above: EPA’s baseline approach misrepresents reality, and unfounded speculation regarding future technological developments or regulatory action cannot justify ignoring the real-world costs the rule would inflict on regulated parties. As EPA itself admits, its “assumption” of “[z]ero compliance costs” “[u]nderestimate[s]” “the total cost of compliance.” Economic Analysis 38.

Vacatur is required in light of the “substantial doubt that the administrative agency would have reached the result it did absent [the alleged error].” *Consol. Gas Supply Corp. v. FERC*, 606 F.2d 323, 329 (D.C. Cir. 1979).

## CONCLUSION

The administrative record conclusively establishes that EPA exceeded its authority under the CWA and violated the APA by reaching a result that is neither reasonable nor reasonably explained. This Court should enter summary judgment for Plaintiffs and vacate the 2022 rule.

Dated: May 13, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on May 13, 2024, I filed the foregoing document and all attachments with the Court's CM/ECF System, which will notify each attorney of record.

/s/ Helgi C. Walker  
Helgi C. Walker

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

ASSOCIATION OF WASHINGTON  
BUSINESS, et al.,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY, et al.,

Defendants.

Civil Action No. 23-cv-3605

**PLAINTIFFS' COMBINED REPLY MEMORANDUM IN SUPPORT OF  
MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO EPA'S AND  
INTERVENOR-DEFENDANTS' CROSS-MOTIONS FOR SUMMARY JUDGMENT**

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## INTRODUCTION

Defendants' cross-motions for summary judgment are a study in doublespeak. On one hand, EPA asserts that its new PCB criterion changes nothing because the "detection limit of 65,000 pg/L exceeds" both the existing and new criterion. On the other hand, EPA claims that its new criterion affords additional "protection," so vacating it would be seriously "disruptive." Dkt. 49-1 ("Opp.") 26, 44. EPA insists that "tribal treaty-reserved rights" were not a "basis" for the 2022 rule, but it also maintains that the rule is "protective of tribal members exercising" subsistence fishing rights. Opp. 26, 35. For their part, the Tribal Intervenors mistakenly defend EPA's choice of fish consumption rate ("FCR") as based on "suppressed," "*contemporary* fish consumption," but they cannot help adding that FCRs "should reflect consumption that is *not* suppressed by fish availability." Dkt. 52-1 ("Tribes Cross-Mot.") 20 & n.16. And Washington downplays EPA's disruption of the Clean Water Act's "cooperative federalism" scheme, while admitting that the State's "criteria have been in a state of flux since 2016" due to EPA's unwarranted interventions. Dkt. 54-1 ("Wash. Cross-Mot.") 20–21.

These inconsistencies reveal that Defendants lack a coherent theory to justify the 2022 rule. Their arguments fail across the board.

*First*, unable to defend the 2022 rule on the merits, EPA interposes standing as a hurdle. It beggars belief that businesses, the State of Washington, Tribes, and the federal government have spent nearly a decade litigating standards that might not "ever" matter. Wash. Cross-Mot. 13; *see* Opp. 21. EPA knows better. Plaintiffs' members must comply not only with permit monitoring conditions that require using EPA-approved method *detection* limits, but also with a host of *other* permit obligations arising from or intensified by EPA's new criteria. At minimum, the 2022 rule will force Plaintiffs' members to incur costs in reopening their existing NPDES permits to reflect

the new federal criteria. As regulated parties who are the object of the regulations on review, their standing to challenge this regulation should be beyond dispute.

*Second*, EPA cannot now disavow its tribal reserved-rights rationale. Plaintiffs have shown that on its face, EPA's final rule necessarily rests on that rationale, and EPA offers no persuasive showing to the contrary. On the merits, EPA does not even defend that rationale, and the Tribes' effort to do so in EPA's stead fails. The Tribes offer nothing remotely suggesting that any treaty imposes affirmative duties to promulgate specific criteria, for specific chemicals, based on specific inputs, under a regulatory scheme that does not require or authorize enforcing tribal rights.

*Third*, EPA fails to explain its numerous flip-flops. The 2022 rule departed from the 2000 Methodology's guidance that States may protect the general population using a cancer risk level ("CRL") of  $10^{-5}$  so long as highly exposed subpopulations are held to a CRL of  $10^{-4}$ ; reversed its position approving chemical-specific inputs in favor of lockstep CRLs for all pollutants; reversed course on EPA's rejection of a tribal-rights rationale in its 2019 approval of Washington's criteria; and abandoned its longstanding position that the CWA does not authorize EPA to reinterpret a State's designated uses. EPA insists that it has not changed position from its prior approval of Washington's criteria just three years earlier, but that stonewalling blinks reality.

*Fourth*, the 2022 rule is based on unreasonable inputs. EPA defends its decision to override Washington's chosen CRL by reciting the "sound science" refrain, but EPA apparently forgets that the "choice of an acceptable cancer risk level . . . is a risk management decision," not a scientific one. 2000 Methodology at 2–4. Washington's choice fell well within the limits of reasonable risk management allowed by EPA's 2000 Methodology. As to the FCR, EPA maintains that its hand-picked 1994 study of atypical populations accurately reflects contemporary fish consumption by the general population. But the record shows otherwise: "175 g/day is a *compromise* rate"—a

proxy for unsuppressed consumption in the absence of “sufficient data” of the *actual* unsuppressed rate. *Restoring Protective Human Health Criteria in Washington*, 87 Fed. Reg. 69,183, 69,188–89 & n.66 (Nov. 18, 2022) (emphasis added). That choice is arbitrary and unjustified.

*Fifth*, EPA does not dispute that its PCB criterion is neither achievable nor measurable. EPA’s suggestion that fallback measures—including variances, mixing zones, and removal of designated uses—could make the standard achievable some day in the unforeseeable future makes it no less irrational to impose an impossible standard *today*. In any event, neither EPA nor Washington can show that any of those fallback measures are realistic options.

*Sixth*, EPA cannot show that the Clean Water Act forecloses consideration of costs. EPA’s mistaken, contrary supposition alone mandates vacatur and remand. Alternatively, EPA at minimum acted unreasonably by attributing zero compliance costs to the 2022 rule. EPA’s repeated speculation that a projection of *zero* could be an “*overestimate*” is facially absurd, Opp. 41 (emphasis added), and EPA’s own economists disagree with the agency: EPA’s “assumption” of “[z]ero compliance costs” “[u]nderestimate[s]” “the total cost of compliance.” Economic Analysis 38 (emphasis added).

EPA’s glaring errors compel vacatur. The Court should enter summary judgment for Plaintiffs, deny the cross-motions for summary judgment, and vacate the 2022 rule.

## ARGUMENT

### **I. Plaintiffs Have Standing.**

As Plaintiffs have shown, they have standing to challenge the entirety of the 2022 rule because it imposes permitting and compliance costs on Plaintiffs’ members subject to NPDES permitting in Washington. *See* Dkt. 44-2, Declaration of Paul R. Noe (“AF&PA Decl.”) ¶ 9; Dkt. 44-3, Declaration of Christian M. McCabe (“NWPPA Decl.”) ¶ 8. Standing is “self-evident” when the plaintiff is “an object of the challenged government action,” *New Jersey v. EPA*, 989 F.3d

1038, 1045 (D.C. Cir. 2021), and where, as here, the challenged action “require[s] or forbid[s] some action by the plaintiff[s],” *FDA v. All. for Hippocratic Med.*, 144 S. Ct. 1540, 1556 (2024). EPA’s new criteria will lead to the reopening of existing permits, forcing Plaintiffs’ members to incur costs in modifying those permits. And EPA’s unattainable 7 ppq criterion for PCBs forces Plaintiffs’ members to expend significant resources to comply with criterion-based limits 24 times more stringent than limits based on Washington’s current, 170 ppq criterion.

EPA does not dispute Plaintiffs’ argument that if Plaintiffs’ members must bear these costs, Plaintiffs have associational standing. Mot. 17. Nor does EPA dispute the argument that the 2022 rule “subjects existing NPDES permits to modification.” *Id.* Because engaging in the permitting process and obtaining a modified permit cost both time and money, and because vacatur would avoid these injuries, those concessions alone suffice to establish standing.

EPA instead principally contends that Plaintiffs lack standing because its new PCB criterion will not change the compliance requirements of existing NPDES permits, which, according to EPA, turn *exclusively* on the detection limit of EPA-approved methods for measuring PCB concentrations. Opp. 21. That explanation, provided for the first time in EPA’s brief, is simply incorrect.<sup>1</sup> The CWA and EPA’s NPDES regulations tie compliance to water quality standards, not the detection limits of the EPA-approved method for measuring pollutant concentrations that is

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<sup>1</sup> The 2022 rule mentions detection limits only in its economic analysis section, in which EPA claims that “limits are subject to change over time” and that “it is important that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods.” 87 Fed. Reg. at 69,196. In responding to comments, EPA mentioned detection limits to refute “commenters asserting that dischargers are being pressured to use an unapproved PCB test method,” EPA Response to Public Comments 116, EPA-HQ-OW-2015-0174-1112 (“Final Rule RTC”), and to defend its economic analysis, *id.* at 139–40. But EPA never suggested (contrary to law) that non-detect results in monitoring are *sufficient* to comply with NPDES permit conditions and the requirements of the CWA.

applicable at the time to particular permit monitoring conditions. And the record shows that Washington’s permitting authority, the Department of Ecology (“Ecology”), has imposed additional permit conditions on Plaintiffs’ members that go beyond monitoring and require measurement techniques more sensitive than EPA’s asserted detection limit of 65,000 pg/L.

A. “[T]he outlay of funds necessary to secure” additional or modified permits “qualifies as a concrete and particularized, actual and imminent injury.” *Hydro Res., Inc. v. EPA*, 608 F.3d 1131, 1144–45 (10th Cir. 2010) (en banc) (Gorsuch, J.). Plaintiffs have standing because the 2022 rule triggers permit reopening and imposes additional out-of-pocket costs on their members.

Plaintiffs’ members hold NPDES permits issued by Ecology that are valid for five years so long as the holder remains in compliance with the conditions of the permit. AF&PA Decl. ¶ 9; NWPPA Decl. ¶ 8; Dkt. 49-2, NPDES WA0003697 at 1; Dkt. 49-3, NPDES WA0000124 at 1. Pursuant to EPA regulations, however, *see* 40 C.F.R. §§ 122.44(d)(1)(vi)(C)(4), 122.62(a)(3), (7), Ecology included a reopener clause in these permits that triggers “modification” upon the “[p]romulgation of new or amended standards or regulations having a direct bearing upon permit conditions,” NPDES WA0003697 at 31; NPDES WA0000124 at 84. For certain permits issued after EPA proposed the 2022 rule on April 1, 2022, Ecology included an express condition stating that “Ecology will reopen the permit should the Human Health Criteria for PCBs be revised.” *E.g.*, NPDES WA0000892 at 44 (issued Apr. 11, 2022); Supplemental Declaration of Christian M. McCabe (“Supp. McCabe Decl.”), Ex. 1, NPDES WA0000825 at 35 (issued June 30, 2022).

The 2022 rule forces Plaintiffs’ members to incur out-of-pocket expenses to engage in the permitting process and obtain a modified permit. *See* Supp. McCabe Decl. ¶¶ 5–8. Revising permits to reflect EPA’s criteria generally requires a drafting process and public-comment period, each of which requires both time and money from the permittee. *See id.* ¶ 8 (discussing “legal and



consulting support” and commitment of employee time to obtain permit modification); 40 C.F.R. §§ 124.5(c), 124.6(e). The 2022 rule also raises the costs of permit renewals by requiring applicants to collect additional data relevant to evaluating the more stringent federal criteria. *See* Supp. McCabe Decl. ¶ 9; 40 C.F.R. § 122.21(e)–(g). The “out-of-pocket costs” of “undergo[ing] the . . . permit process for a second time” are a classic injury-in-fact. *Hydro Res.*, 608 F.3d at 1144–45 (quotation omitted); *Iowa League of Cities v. EPA*, 711 F.3d 844, 870 (8th Cir. 2013) (finding standing where “[a]t least some [of plaintiffs’] members are currently operating under permits . . . inconsistent with the EPA [rule], which they must imminently rectify”); *see also City of Dover v. EPA*, 956 F. Supp. 2d 272, 277 (D.D.C. 2013) (finding standing where EPA “added restrictions to the [plaintiffs’] NPDES permits”). Indeed, even “[a] dollar of economic harm is . . . an injury-in-fact for standing purposes.” *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 5 (D.C. Cir. 2017).

These costs are traceable to the 2022 rule because Ecology is required to modify the permits to bring its NPDES program into compliance with EPA’s new criteria. *See* 33 U.S.C. § 1342(b); 40 C.F.R. §§ 122.43–44; *Me. Lobstermen’s Ass’n v. NMFS*, 70 F.4th 582, 593 (D.C. Cir. 2023) (finding standing to challenge biological opinion with “virtually determinative effect” on license conditions). EPA does not dispute the point, and Washington affirmatively concedes that permits must be reopened “to incorporate the 7 pg/L human health criteria for PCBs in the 2022 Final Rule,” Wash. Cross-Mot. 15. Ecology has given no indication that it intends to deviate from this practice here. These permit reopening costs alone establish standing.

**B.** EPA focuses its fire on the purported irrelevance of its own 7 ppq PCB criterion. Permit compliance, EPA asserts, is determined *entirely* by the applicable detection limit of 65,000 pg/L—not EPA’s new 7 ppq PCB criterion. Opp. 17, 42. That is an extraordinary claim. If it were right, EPA has wasted a decade attempting to override Washington’s 170 ppq standard for no reason at

all. *See* Opp. 21 (“the PCB criteria for Washington waters have never been measurable with EPA-approved methods”). EPA’s own persistent regulatory efforts reveal its claim as disingenuous—and wrong.

Contrary to EPA, NPDES compliance is tied *to water quality standards, not the detection limit* for monitoring. NPDES permits must include “any requirements . . . necessary to . . . [a]chieve *water quality standards established under section 303 of the CWA*,” including limits that “control all pollutants or pollutant parameters” that “may be discharged at a level which will cause, have the *reasonable potential* to cause, or contribute to an excursion above *any State water quality standard*.” 40 C.F.R. § 122.44(d)(1)(i) (emphases added). Ecology’s regulations are equally unambiguous: Permits “must be conditioned so the discharges authorized will meet *the water quality standards*,” and “[n]o waste discharge permit can be issued that causes or contributes to a violation of *water quality criteria*.” WAC 173-201A-510(1) (emphases added). When a permitting authority finds a “reasonable potential” that applicable standards or criteria will be exceeded, the permit “must” include conditions to address that potential. 40 C.F.R. § 122.44(d)(1)(iii)–(iv). For example, permits may require best management practices that impose additional obligations not tied to an EPA-approved detection limit, *id.* § 122.44(k), including by mandating technologies that reduce emissions before measurement, *id.* § 122.44(a)(1); *see* WAC 173-201A-020.

EPA’s discussion of monitoring is also incomplete. EPA claims that only the EPA-approved detection limit of 65,000 pg/L for PCBs matters for compliance purposes because States can only use methods that EPA has promulgated through notice-and-comment rulemaking for addition to 40 C.F.R. § 136.3. Opp. 21–22. But EPA’s own regulations say otherwise. States may require permit holders to use alternative methods with approval from the relevant EPA Regional

Office, 40 C.F.R. § 136.5, and approval is not required to use alternative methods for purposes other than standard monitoring requirements in permits, *id.* § 122.44(i)(1)(iv).

Here, Ecology has already imposed permit conditions on Plaintiffs' members untethered to EPA-approved methods, including a best-management-practices requirement that aims to reduce PCB emissions below 65,000 pg/L. *See* Supp. McCabe Decl., Ex.1, NPDES WA0000825 at 27–28. The cited permit uses the more sensitive Method 1668, which has a detection limit between 40 and 60 pg/L for PCBs, to require quarterly monitoring and develop additional permit conditions to avoid potential criteria violations. *See id.* at 28; Ecology Fact Sheet for NPDES Permit WA0000825, at 52–53 (“Ecology will also use data from Method 1668” to make reasonable-potential determinations, calculate effluent limits, impose technology-based requirements, and evaluate best-management practices). Tellingly, even Washington acknowledges that its Department of Ecology uses methods other than those codified in 40 C.F.R. § 136.3 to ensure compliance with pollution-minimization requirements and notes that variance determinations “could also be made based on data showing violations of the end-of-pipe effluent limit for PCBs collected using a . . . method that is *not approved* under 40 C.F.R. Part 136.” Wash. Cross-Mot. 15–16 (emphasis added). EPA mentions none of this, but it forecloses EPA’s assertion that the detection limit of its nationally approved method for PCB measurement, Method 608, sets the *sole* measure of NPDES permit compliance.

C. The implications of EPA’s position are also untenable. According to EPA, federally imposed water quality standards and criteria are not judicially reviewable unless EPA has already approved a method with a detection limit that is as sensitive or more sensitive than the criteria limit. So EPA’s PCB criterion may *never* be reviewable. *See* Opp. 41; Wash. Cross-Mot. 14 (“it is uncertain that there will ever be a detection method . . . sensitive enough to detect a violation of

the 7 pg/L standard”). Such a result cannot be squared with “the APA’s ‘basic presumption’” in favor of judicial review. *Corner Post, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 144 S. Ct. 2440, 2459 (2024).

Moreover, EPA’s theory means that any change in approved detection limits—whether through notice and comment or even Regional Office approval, which occurs entirely outside of the Federal Register—changes the effective *criteria* limit for States and permit holders. That would itself violate the CWA, which requires EPA to promulgate recommended criteria for States, impose federal criteria on noncompliant States, and promulgate criteria for federal permits through different, enumerated sets of procedures subject to different statutory standards. *See* 33 U.S.C. §§ 1314(a) (recommended criteria), 1313(c) (Administrator Determinations with respect to States), 1342 (federal permitting). EPA’s position requires accepting that when Congress required EPA to “promulgate *guidelines* establishing test procedures for the *analysis* of pollutants,” *id.* § 1314(h) (emphases added), it meant “promulgate guidelines establishing the compliance requirements for pollution control.” That position is not credible, and EPA does not even attempt to argue that its testing-guidelines authority empowers the agency to adjust substantive controls.

Consider, too, what EPA’s theory would mean when the agency proposes updated testing procedures. The stakes of such a proceeding would be a wholesale revision of nationally applicable effluent limits, applicable in one fell swoop to state permit holders, federal permit holders, and state standards—effectively obviating the CWA’s careful balance between state and federal authority and delineated procedures that apply separately to each category. Congress does not “hide elephants in mouseholes” in this manner. *Sackett v. EPA*, 598 U.S. 651, 677 (2023) (quoting *Whitman v. Am. Trucking Ass’n, Inc.*, 531 U.S. 457, 468 (2001)).

Even if the Court could accept EPA’s general theory that a party’s standing to challenge water quality criteria depends on the availability of a sufficiently sensitive EPA-approved test method, it would fail in this instance. EPA has already announced its intent to designate Method 1628—a more sensitive test method—as an approved test method. *See* EPA Agency Rule List – Spring 2024, [tinyurl.com/6wks95ws](https://tinyurl.com/6wks95ws) (projecting a proposed rule titled “Clean Water Act Methods Update Rule for the Analysis of Contaminants in Effluent” in 2025). So under EPA’s own theory, Plaintiffs’ harm is imminent.

In any event, EPA’s argument at best goes to the merits of the 2022 rule, not to standing. In assessing standing, “a federal court must assume *arguendo* the merits of [the plaintiff’s] legal claim.” *Tanner-Brown v. Haaland*, 105 F.4th 437, 445 (D.C. Cir. 2024); *NRDC v. EPA*, 755 F.3d 1010, 1018 (D.C. Cir. 2014) (similar). On the merits, Plaintiffs contend that the 2022 rule is unlawful because it imposed unreasonably stringent criteria and failed to account for reliance interests and compliance costs. Mot. 29–38. *Assuming* Plaintiffs are correct, Plaintiffs’ members are undoubtedly injured. Even EPA implicitly recognizes that its dispute goes to the merits (not standing) when it reiterates the same detection-limit theory to minimize the rule’s compliance costs in an effort to show that the 2022 rule is reasonable. Opp. 42; *accord* Wash. Cross-Mot. 13–16.

It should be no surprise that EPA’s standing arguments are misguided. Regulated parties, the State, the Tribes, and the federal government have not engaged in nearly a decade of litigation about criteria that might never matter. Plaintiffs have standing.

**D.** Finally, EPA is also incorrect that this Court “ha[s] jurisdiction to evaluate the reasonableness of *only* the Final Rule’s PCB criteri[on].” Opp. 20 (emphasis added). Plaintiffs argue that EPA arrived at the PCB criterion by reversing its 2019 approval of Washington’s criteria without adequate explanation, Mot. 23–29, and by adopting an unreasonable FCR for *all* federal

criteria imposed by the 2022 rule, Mot. 29–34. None of EPA’s reasoning was specific to a particular criterion. *See Restoring Protective Human Health Criteria in Washington*, 87 Fed. Reg. 19,046, 19,051 (Apr. 1, 2022) (reversing 2019 approval of all relevant Washington criteria); 87 Fed. Reg. at 69,188–89 (adopting 175 g/day FCR for all federal criteria); *accord* Opp. 13 (“EPA found that the 2019 approved 141 human health criteria did not protect Washington’s designated uses”). If the PCB criterion fails, so do the rest. *See Mozilla Corp. v. FCC*, 940 F.3d 1, 46–47 (D.C. Cir. 2019) (per curiam) (“When a party alleges concrete injury from promulgation of an agency rule, it has standing to challenge essential components of that rule . . . even if they are not directly linked to Petitioners’ injuries; if Petitioners’ objections carry the day, the rule will be struck down and their injury redressed.”); *see also Sierra Club v. FERC*, 867 F.3d 1357, 1366 (D.C. Cir. 2017) (“Because they allege concrete injury from FERC’s order certifying the pipeline project, and because that certification was based on an allegedly inadequate environmental impact statement, these Sierra Club members, and therefore Sierra Club itself, have standing to object to any deficiency in the environmental impact statement. The deficiency need not be directly tied to the members’ specific injuries.” (cleaned up)). Plaintiffs have standing to challenge the 2022 rule in its entirety.

## **II. EPA Exceeded Its Statutory Authority Under The CWA And Failed To Follow Its Own Regulations.**

In 2016, EPA aggressively defended a tribal-treaty rights rationale to adopt a PCB criterion of 7 ppq “based on harmonizing the requirements of the CWA with the terms of the treaty-reserved subsistence fishing right.” *Revision of Certain Federal Water Quality Criteria Applicable to Washington*, 81 Fed. Reg. 85,417, 85,423 n.39 (Nov. 28, 2016). EPA thus recognized that science alone could not support that impossible criterion. In 2022, EPA adopted the same criterion again, noting that it had “no new data,” 87 Fed. Reg. 69,190, was “applying the same rationale” as the

2016 rule in selecting the relevant inputs, *id.* at 69,189, and that its chosen criterion was necessary to protect “tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels,” *id.*

EPA now downplays those statements and insists that it arrived at the same 7 ppq criterion based on “sound science” alone. Opp. 23. The record shows otherwise. EPA’s statements in the 2022 rule themselves confirm that EPA relied on a tribal-treaty rights rationale, and EPA does not even try to defend that rationale on the merits. The Tribes’ effort to do so in EPA’s stead fails.

A. The final rule was unequivocal: “EPA is applying the same rationale here as the agency articulated to support its use of those inputs in the 2016 Federal rule.” 87 Fed. Reg. at 69,189. The 2022 rule adopted 2016 rule’s inputs wholesale, including by “using the same FCR of 175 g/day . . . that EPA used in its 2016 Federal rule,” *id.* at 69,188, and the same  $1 \times 10^{-6}$  CRL for PCBs, *id.* at 69,189. And the 2022 rule produced the same output. Indeed, the 2022 rule imposed the same criteria values for *all* pollutants that were also within the scope of the 2016 rule. *Compare* 81 Fed. Reg. at 85,430–31, *with* 87 Fed. Reg. at 69,192–93.

In so doing, EPA necessarily applied a tribal-treaty rights rationale. The 175 g/day FCR, for example, was a “compromise minimum consumption rate” advanced by the Tribes, which the Tribes accepted “so long as . . . coupled with a CRL of  $10^{-6}$ .” 87 Fed. Reg. at 69,189. According to EPA, the study that backed that consumption rate “provide[d] scientifically sound estimates of fish consumption . . . for the *tribal* target general population.” 81 Fed. Reg. at 85,426 (emphasis added). In turn, the selection of a *tribal* target population—rather than Washington’s general population—was based entirely on a tribal-treaty rights rationale. *Id.* at 85,424. Despite purporting to disavow any reliance on tribal rights in the 2022 rule, EPA incorporated the same inputs, based on the same study, and reached the same result. Without its tribal-treaty rights

rationale, there would be no support for EPA's decision to select the FCR or CRL that it did here.

EPA minimizes the “same rationale” statement in the 2022 rule, asserting that the rule “cited to narrow portions” of the 2016 rule discussing only its choice of FCR and “did not cite the portions of the 2016 rule” that concerned “tribal treaty-reserved rights.” Opp. 32. That is demonstrably wrong. In the 2022 rule, EPA “specifically cited” pages 85,426 to 85,428 of the 2016 rule, in which EPA adopted both an FCR and CRL *based on a tribal-treaty rights rationale*. Opp. 32; *see* 87 Fed. Reg. at 69,189 n.56 (citing 81 Fed. Reg. at 85,426–28). On those very pages, EPA explained that its chosen FCR was “scientifically sound . . . for the *tribal* target general population,” 81 Fed. Reg. at 85,426 (emphasis added), and that the CRL “ensures that the resulting human health criteria for carcinogens protect the *subsistence fishing* component of the designated use,” *id.* at 85,427 (emphasis added). Washington had no such designated use; EPA invented it using its tribal-treaty rights theory. *See* Mot. 20, 26–29. In incorporating the same inputs in the 2022 rule, EPA repeated the same mistakes: It chose inputs “protective of” tribal members’ right “to harvest and consume fish and shellfish at subsistence levels.” 87 Fed. Reg. at 69,189. The 2022 rule’s selected inputs and outputs are no mere coincidence. EPA cannot adopt the *results* of the 2016 rule’s rationale without backing the rationale itself—the 2022 rule “must be measured by what the [agency] did, not by what it might have done.” *SEC v. Chenery Corp.*, 318 U.S. 80, 93–94 (1943).

EPA’s other responses are makeweight. The agency asks the Court not to look behind its “sound science” rationale, Opp. 17; *see* Tribes Cross-Mot. 10, 12–13, but the tribal-treaty rights rationale is not lurking behind the curtain. It is plain on the face of the 2022 rule, which expressly incorporated it by reference. *Contra* Tribes Cross-Mot. 13 (characterizing tribal-treaty rights rationale as an “unstated” reason).



EPA also quibbles that the Tribal Reserved Rights Rule—which confirms EPA’s rationale in Washington and adopts that rationale nationwide—is outside the record. But EPA forfeited this argument when it failed to raise it in reply to Plaintiffs’ opposition to EPA’s transfer motion. *Cf.* Dkt. 25 at 5. And this Court already took judicial notice of the Tribal Reserved Rights Rule in denying EPA’s transfer motion. Dkt. 48 at 20 (citing Tribal Reserved Rights Rule and noting that “[t]he record supports the plaintiffs’ contention that the Agency intends to roll out the treaty-rights interpretation on a nationwide basis” (emphasis added)). That decision was correct: The Tribal Reserved Rights Rule is a public record of the *same agency* adopting *the same rationale* as the 2016 rule *at the same time* that the 2022 rule revived it. *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*, 87 Fed. Reg. 74,361, 74,365 (Dec. 5, 2022). The Court need not look beyond the record to find EPA’s tribal-treaty rights rationale, but in any event, it is “not required to exhibit a naiveté from which ordinary citizens are free.” *Dep’t of Com. v. New York*, 588 U.S. 752, 785 (2019); *see also Chenery*, 318 U.S. at 93–94.

**B.** On the merits, EPA does not even try to defend the tribal-treaty rights rationale. Even if EPA had defended it, EPA’s position would not be entitled even to “due respect” given the agency’s flip-flopping—embracing the tribal-treaty rights rationale in 2016, abandoning it in 2019, and reviving it in 2022. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2257–58 (2024) (courts owe “due respect to Executive Branch interpretations of federal statutes” only when “consistent over time”). The Tribes now take up the cause on EPA’s behalf, Tribes Cross-Mot. 23–26, but “[a]n intervening party may join issue only on a matter that has been brought before the court by another party,” *Ill. Bell. Tel. Co. v. FCC*, 911 F.2d 776, 786 (D.C. Cir. 1990); *see Grocery Mfrs. Ass’n v. EPA*, 693 F.3d 169, 185 n.5 (D.C. Cir. 2012) (Kavanaugh, J., dissenting) (“intervenors generally may not raise arguments not raised by the parties”). Because EPA has

abandoned its claimed statutory authority for the 2022 rule, the rule must be vacated. *See Johnson v. Copyright Royalty Bd.*, 969 F.3d 363, 389 (D.C. Cir. 2020); *Competitive Enter. Inst. v. Dep't of State*, 2022 WL 4547959, at \*1 (D.D.C. Aug. 10, 2022).

C. In any event, the Tribes' defense of the tribal-treaty rights rationale fails. As Plaintiffs have shown, EPA lacks authority to override state decisions by interpreting tribal treaties. *See* Mot. 6–9, 19–23. That asserted power lacks any basis in the Clean Water Act or its implementing regulations and falls far outside of the agency's expertise.

Moreover, the Stevens Treaties impose only *negative* duties—*limits* on the federal government's power. And nothing in any treaty creates affirmative authority for EPA to impose specific human health criteria on States under the CWA, much less to require *specific* inputs in calculating those criteria. Mot. 19–20.

Rather than refute these dispositive considerations, the Tribes essentially concede them. They principally contend that the Stevens Treaties imply a “duty” to “preserve” and “avoid interference” with tribal fishing rights. Tribes Cross-Mot. 23–24, 26. That is just another way of describing a negative duty, and it does not help EPA. Under a tribal-treaty rights theory, EPA must show that a treaty *affirmatively* compels *specific* water quality standards in Washington such that it has statutory authority to reject the State's standards and promulgate federal ones. The Tribes can point to no treaty text expressing any such obligation.

The Tribes' cases confirm that the Stevens Treaties impose only negative duties. *Northwest Sea Farms, Inc. v. U.S. Army Corps of Engineers*, 931 F. Supp. 1515, 1518 (W.D. Wash. 1996), involved a permit approval for a fish farm that “would deny members of the Lummi Nation access to the site.” *No Oilport! v. Carter*, 520 F. Supp. 334, 372 (W.D. Wash. 1981), concerned approval of a pipeline that would “degrade the fish habitat by destroying spawning grounds.” And

*Parravano v. Babbitt*, 70 F.3d 539, 546 (9th Cir. 1995), held only that the government may issue regulations to limit “overharvesting” of fish that “threatened the Tribes’ ability to harvest their share of the salmon.” The Tribes’ remaining cases fit the same pattern: a permit approval for “construction of a marina” that would occupy a fishing ground; a federal project that “would destroy salmon . . . nests”; and a federal dam that would “inundat[e] fishing grounds.” Tribes Cross-Mot. 26.

Plaintiffs do not dispute that States may not affirmatively destroy fishing grounds, bar fishers from accessing them, or obstruct fish passage. Mot. 20. But those direct interferences with fishing rights are far afield from the authority EPA has asserted here. EPA claims that “tribal treaty rights” somehow require Washington to promulgate specific human health criteria that are protective of tribal populations’ exercise of reserved rights; to rewrite the State’s Clean Water Act designated uses; to select an FCR appropriate for tribal subsistence fishers (not Washington’s general population); and to protect tribal subsistence fishers with a CRL of one case in a million persons. The Tribes do not seriously contend that any treaty affirmatively imposes such granular obligations, and their extended defense of a general duty of non-interference is irrelevant.

The Tribes likewise fail to refute *Arizona v. Navajo Nation*, 599 U.S. 555 (2023), and *Morong Band of Mission Indians v. FAA*, 161 F.3d 569 (9th Cir. 1998). The Tribes attempt to distinguish *Arizona* as a case involving “affirmative steps” to secure water, Tribes Cross-Mot. 27, but that is the key *similarity* here, not a difference: EPA must show that treaties require it to impose water quality standards with concomitant “affirmative” duties. And the Tribes miss *Morong Band’s holding* in distinguishing its *facts* as involving a “breach of [trust]”: Tribal treaties supply no affirmative obligations above generally applicable law unless they identify “a specific duty . . . with respect to Indians.” 161 F.3d at 574. The Tribes do not even attempt to

show that any such “specific duty” exists here that supports EPA’s power-grab.

Finally, the Court should greet with “skepticism” EPA’s newfound discovery that tribal treaty obligations supercharge its authority to override state water quality standards and change the federal-state balance struck by the Clean Water Act. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014); see *West Virginia v. EPA*, 597 U.S. 697, 725 (2022) (explaining that the “want of assertion of power by those who presumably would be alert to exercise it” is highly “significant in determining whether such power” exists). The Tribes suggest that harmonization of tribal-treaty rights tracks “decades of Executive Branch” practice, Tribes Cross-Mot. 28 n.20, but the cited practice involves the uncontroversial duty to avoid destroying or denying *access* to fishing grounds—not EPA’s authority to force States to adopt water quality standards to protect tribal populations at particular CRLs or FCRs. There is no such power, and not even EPA believed it existed for the first 45 years after the CWA’s enactment.

### **III. EPA’s Unjustified Changes In Position Violate The APA.**

EPA barely musters a defense of its unjustified changes of policy in the 2022 rule. Plaintiffs have shown that the 2022 rule abrogated longstanding policy by: (1) departing from the 2000 Methodology’s guidance that States may protect the general population using a CRL of  $10^{-5}$  so long as highly exposed subpopulations are held to a CRL of  $10^{-4}$ ; (2) reversing its position, expressed as recently as 2019, that States may use chemical-specific inputs and are not required to use blanket CRLs for all pollutants; (3) reversing the 2019 approval’s robust rejection of a tribal-rights rationale; and (4) abandoning its longstanding position that, consistent with the CWA, EPA lacks authority to reinterpret a State’s designated uses. Mot. 24–29. Instead of defending those decisions, EPA insists that the 2022 rule worked no change on the regulatory scheme at all. Opp. 33–35. So EPA fails even to acknowledge its changes, much less to “show that there are good reasons for the new policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

A. EPA counters that the 2022 rule did not reverse the agency's deferential approach to state selection of CRLs under the 2000 Methodology, or alternatively, that the agency adequately explained the change. Neither contention holds water.

In asserting that there was no change in position, EPA quibbles that Washington's  $2.3 \times 10^{-5}$  CRL for PCBs was "*less stringent*" than the  $1 \times 10^{-5}$  contemplated by the 2000 Methodology. Opp. 33–34. But the 2000 Methodology allowed any CRL at the " $10^{-5}$  risk level," 2000 Methodology at 2–6, and  $2.3 \times 10^{-5}$  falls along that level. That is why EPA's 2019 approval explained that "the chemical-specific [CRL] of  $2.3 \times 10^{-5}$  falls within the range of protective risk rates the EPA has recommended since it issued its 2000 Methodology and is protective of the State's designated uses." 2019 Approval at 19; *see also id.* at 23 (explaining that the 2000 Methodology authorizes states to protect "tribes" and "other highly exposed subpopulations" to  $1 \times 10^{-4}$ ). In 2019, EPA understood "that selecting an appropriate cancer risk level is a risk management decision." *Id.* at 10; 2000 Methodology at 2–6. In 2022, EPA did not.

Next, EPA changes tack to argue that the 2022 rule *did* include a reasoned explanation for the change by contending that the 2019 approval did not "engag[e] with Washington's lack of a scientific rationale for that value." Opp. 34 (citing 87 Fed. Reg. at 69,190). But the cited portion of the 2022 rule does not "acknowledge" any change in position, *Fox*, 556 U.S. at 515, much less fault the 2019 approval for failing to engage with Washington's rationale. And EPA mischaracterizes the 2019 approval. The agency there expressly found that Washington's criteria were "based on sound science" while, at the same time, acknowledging that the choice of CRL was ultimately a "risk management decision" involving non-scientific considerations. 2019 Approval at 10. EPA failed to address this rationale in the 2022 rule and simply declared the opposite conclusion. That is not reasoned decisionmaking. "EPA's final rule was not reasonably explained,"

and “it instead ignored an important aspect of the problem before it.” *Ohio v. EPA*, 144 S. Ct. 2040, 2054 (2024) (cleaned up).

**B.** EPA similarly contends that the 2022 rule is consistent with the agency’s prior policy that States may use chemical-specific CRLs, stating that the agency took issue *only* with Washington’s scientific basis for its PCB value. Opp. 33. Not so. The rule asserts that “*it is important* to keep these values consistent,” “because these values are associated with the population that the criteria are intended to protect and *are not pollutant-specific*.” 87 Fed. Reg. at 69,189 (emphases added). That was EPA’s sole affirmative justification for using  $1 \times 10^{-6}$ , rather than  $1 \times 10^{-5}$ , or any other value—and it is an unexplained departure from prior agency guidance leaving States discretion to manage risks on a chemical-by-chemical basis.

**C.** EPA’s attempt to disclaim any policy change on the appropriate role of tribal reserved rights fails for the same reason as its statutory-authority arguments: EPA necessarily relied on a tribal-treaty rights theory to reinstate the results of the 2015 disapproval and 2016 rule. *Supra*, at 12–14; *contra* Opp. 35. If EPA believes the 2019 approval was wrong in this respect, it must explain why and justify its new position.

**D.** Finally, as noted above, EPA’s only response on the rewriting of Washington’s designated uses is the *ipse dixit* that EPA “did not interpret” the State’s designated uses at all. Opp. 25 n.11. That is incorrect. EPA expressly reinterpreted Washington’s designated uses in the 2016 rule, and as explained above, it did the same thing in the 2022 rule by readopting the conclusions reached under that reinterpretation. *Supra*, at 13. Absent such reinterpretation, EPA’s decision here would lack any basis whatsoever.

#### **IV. EPA Based Its Human Health Criterion for PCBs on Unreasonable Assumptions.**

EPA fails to justify its unreasonable inputs—a 175 g/day FCR, and a  $1 \times 10^{-6}$  CRL.

**A. Fish Consumption Rate.** EPA's FCR was unjustifiably designed to approximate an unsuppressed tribal fish-consumption rate, and EPA fails to support the sole study on which that rate is based. EPA's responses do not track.

1. EPA contends that its FCR was rational because it would not have made sense to use "a different rate" for PCBs than other chemicals, and because EPA had no "new data" to justify a different rate from the 2016 rule. Opp. 28 (emphasis omitted). Neither explanation works. As to the first, EPA does not dispute that States are free to make "chemical-specific risk management decision[s]," Mot. 27, and "[t]he choice of default fish consumption rates for protection of a certain percentage . . . of the general population is clearly a risk management decision," 2000 Methodology at 1–9. Moreover, EPA cannot bootstrap the validity of its PCB criterion to its other criteria. The FCR is no more defensible for other chemicals, and EPA is wrong to assume otherwise. *See supra*, at 10–11.

EPA's no "new data" rationale also fails. It assumes that the "data" it used in the 2016 rule is supportable, but as Plaintiffs have shown, the 1994 CRITFC Study is not a valid source for extrapolating Washington's water quality standards and criteria. *See* Mot. 31.

EPA's efforts to rehabilitate the CRITFC Study's shortcomings fail. EPA resists Plaintiffs' characterization of the study as "cherry-picked," Opp. 30, but the agency fails to address the study's own statement that other studies "reporting estimates for tribal populations" reached "consistently lower" estimates of fish consumption, Mot. 31 (quoting *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* 60 (Columbia River Inter-Tribal Fish Commission 1994), [tinyurl.com/53c9x9ar](https://www.tinyurl.com/53c9x9ar)). EPA defends the study's inclusion of fish consumed from grocery stores by touting the importance of being able to "safely" consume fish from all potential sources, and the need to avoid producing "less stringent

water quality criteria.” Opp. 30. Put aside that this reflects precisely the sort of “outcome driven” reasoning for which EPA faults Washington. Opp. 26. More importantly, those considerations miss the point: Including fish consumed from grocery stores as part of the FCR makes no sense because grocery store fish are not necessarily ever *exposed* to Washington waters. *See* Mot. 31; *id.* at 9 n.1 (explaining that the logic for including FCR as an input is that fish are exposed to carcinogens in Washington waters). EPA offers no rational explanation.

The Tribes assert (at 29) that Plaintiffs wrongly characterize the CRITFC Study as investigating an “unsuppressed” FCR. Plaintiffs said no such thing. Rather, Plaintiffs contended that EPA used the study’s findings as “an approximation for the counterfactual ‘unsuppressed’ rate of consumption by tribal subsistence fishers.” Mot. 31. And that is indeed how the 2022 rule characterizes EPA’s selected rate: Absent “sufficient data regarding unsuppressed fish consumption”—which EPA said “could be necessary where tribal treaty or other reserved fishing rights apply”—EPA chose 175 g/day as a “compromise minimum consumption rate” with the Tribes—a proxy for unsuppressed consumption. 87 Fed. Reg. at 69,186, 69,189 n.66. Despite EPA’s efforts to disclaim what it plainly did, even the Tribes acknowledge that “EPA explains that FCRs generally *should* reflect consumption that is not suppressed by fish availability or concerns about the safety of available fish.” Tribes Cross-Mot. 20 n.16 (citing 87 Fed. Reg. at 19,049) (emphasis added). But Plaintiffs have already explained why attempting to track “‘unsuppressed’ consumption” is contrary to the Clean Water Act’s design and reflects arbitrary decisionmaking, Mot. 31-32—and again, EPA’s and the Tribes’ only answer is silence.<sup>2</sup>

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<sup>2</sup> EPA errs again in asserting that the “CRITFC Survey focused on *contemporary* consumption of aquatic species,” Opp. 29 (emphasis added). As Plaintiffs explained, that study attempted to discern a historical decrease in fish consumption by asking survey respondents over the age of 30



EPA’s “no new data” rationale is especially arbitrary because the 2016 rule reasoned only that the CRITFC Study supplied an appropriate benchmark “for the *tribal* target general population.” 81 Fed. Reg. at 85,426 (emphasis added). As EPA admits, “the survey was specific to tribal members consuming fish in the Columbia River Basin.” Opp. 29. Having purportedly disavowed a tribal-treaty rights rationale, EPA could no longer blindly rely on the same study to reach the same result. Doing so was arbitrary and capricious.

2. EPA and the Tribes’ remaining arguments fare no better. They suggest that EPA’s choice is defensible because it mirrored Washington’s own choice. But that is not a justification; it only pushes the arbitrariness of EPA’s choice back a step. And it underscores that EPA did not actually conduct a scientifically sound inquiry, simply piggybacking off Washington’s unrealistic FCR.

The Tribes also point to Oregon’s and Maine’s FCR inputs as comparators. Tribes Cross-Mot. 20. Plaintiffs already explained that Oregon is an inappropriate comparison, and the Tribes offer no response. *See* Mot. 32 n.6. Maine only reinforces EPA’s error: Maine has adopted an FCR of 200 g/day because it (not EPA) has designated a “*sustenance* fishing use” for its waters. Tribes Cross-Mot. 20 (emphasis added). Washington has no such use; EPA invented such a use for Washington only by invoking a tribal right to subsistence fishing. *See supra*, at 13. Comparing Washington to Maine thus highlights EPA’s error—its invocation of a tribal-treaty rights theory to rewrite Washington’s designated uses.

**B. *Cancer Risk Level.*** EPA’s efforts to justify its CRL also lack merit.

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about whether their “current pattern of fish consumption differs *from . . . 20 years ago.*” Mot. 31 (emphasis added) (quoting A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin 20 (Columbia River Inter-Tribal Fish Commission 1994), [tinyurl.com/53c9x9ar](https://tinyurl.com/53c9x9ar)).

1. As EPA's 2000 Methodology explained, a State complies with the Clean Water Act in selecting a CRL "if the State . . . has identified the most highly exposed subpopulation, has demonstrated that the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation." 2000 Methodology at 2–6. EPA concedes that States may select a CRL at the level of  $10^{-5}$  or lower so long as highly exposed subpopulations are protected at the  $10^{-4}$  level. Opp. 5. Washington indisputably complied with these requirements. That should have been the end of the inquiry.

2. Nonetheless, EPA contends that it had authority to override Washington's "risk assessment" because the State's CRL "was not supported by sound scientific reasoning." Opp. 33. But that commits a category error. CRLs are not principally science-based. As EPA has explained, the "choice of an acceptable cancer risk level" is a "risk management decision," involving "social, economic, and political concerns." 2000 Methodology at 2–3 to 2–4 (comparing science, which "refer[s] to the extraction of data from toxicological or exposure studies," with risk management, which is a normative endeavor). Whether PCBs are a carcinogen is a scientific question; the acceptable population-level risk of cancer from PCB exposure is not. EPA's mistake is predictable, but it is one the 2000 Methodology warned against—failing "to separate scientific analysis from . . . risk management decisions." *Id.*

EPA derides Washington's selected  $2.3 \times 10^{-5}$  CRL as "outcome driven," Opp. 26, but that similarly reflects the agency's misunderstanding of the purpose of a CRL. That choice of CRL necessarily turns on the State's view of acceptable outcomes—the amount of risk it is willing to tolerate from PCBs, subject to federal minimum requirements.

In any event, EPA offers no reason for *replacing* that CRL with its choice of  $1 \times 10^{-6}$ . It is EPA's burden to justify that choice, and EPA has not done so. The 2022 rule attempts to justify

picking a  $1 \times 10^{-6}$  value over a  $1 \times 10^{-5}$  risk level, or any other risk level, by invoking a categorical preference for lockstep CRLs for all chemicals. *See supra*, at 19. EPA now apparently concedes that “States may use chemical-specific cancer risk levels,” Opp. 33, but that concession leaves it with no affirmative rationale for its choice. In the end, therefore, EPA’s chosen input reflects only arbitrary decisionmaking.<sup>3</sup>

**V. EPA’s PCB Criterion Is Arbitrary and Capricious Because It Is Neither Measurable Nor Attainable.**

EPA does not dispute that impossible requirements are per se unreasonable, or that EPA cannot impose technically infeasible measures. *See Mot.* 34 (collecting authorities). Moreover, EPA does not dispute that a 7 ppq PCB criterion may *never* be achievable. And EPA does not dispute that this concentration is so small that currently available technology *cannot even reliably detect it*. *Id.*; Wash. Cross-Mot. 14 (agreeing that it is “uncertain” whether there will “ever” be a detection method “sensitive enough to detect a violation of the 7 pg/L standard”). Those concessions alone end this case in Plaintiffs’ favor. EPA’s responses fall flat.

A. EPA first seeks to usher its new PCB criterion off-stage by repeating its refrain that only EPA’s 65,000 pg/L detection limit matters. To begin, EPA did not even *mention* the detection limit in seeking to minimize attainability concerns during the rulemaking, or in any way suggest that non-detects in monitoring are sufficient for NPDES and CWA compliance. *See generally* Final Rule RTC; *supra*, at 4 & n.1. It cannot raise the argument for the first time in litigation. *See*

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<sup>3</sup> EPA accuses Plaintiffs of “mistakenly contend[ing]” that Washington used a  $1 \times 10^{-5}$  CRL. Opp. 32. That is incorrect; one searches Plaintiffs’ brief in vain for any such reference. Plaintiffs simply explained that EPA had authorized CRLs *at the  $10^{-5}$  risk level*—and  $2.3 \times 10^{-5}$  certainly falls along that order of magnitude. *See Mot.* 9, 10, 12, 13, 14, 25, 33, 34 (repeatedly characterizing Washington’s CRL as “ $2.3 \times 10^{-5}$ ”). It is EPA’s brief that muddies the waters on this issue, not Plaintiffs’. EPA declares that  $1 \times 10^{-6}$  “cancer risk level is a scientifically sound, risk-management decision *made by Washington*,” Opp. 33 (emphasis added), but it was EPA that made that choice, not Washington.

*DHS v. Regents of Univ. of Cal.*, 591 U.S. 1, 20 (2020) (“review of agency action is limited to the grounds that the agency invoked when it took the action” (quotation omitted)). Regardless, as explained, EPA is incorrect: Other EPA and Ecology regulations leave room for requiring the use of more sensitive analytical tools. *See supra*, at 7–8. Some regulated permitholders must undertake quarterly monitoring obligations that require measurement of PCB concentrations using a method that can detect concentrations as low as 40 ppq. *Supra*, at 8. That falls far below the current 170 ppq standard (while still exceeding EPA’s impossible-to-achieve 7 ppq standard). And EPA itself is preparing to approve the more sensitive Method 1628. *See supra*, at 10.

**B.** EPA next suggests that human health criteria are merely aspirational goals, and that any noncompliance will be mitigated by variances, removal of designated uses, and mixing zones. But the criteria are not mere ideals. They “provide the basis for *specific, enforceable* requirements designed to achieve them.” *In re ACF Basin Water Litig.*, 467 F. Supp. 3d 1323, 1337 (N.D. Ga. 2020) (emphasis added); *see* 33 U.S.C. § 1365(a) (authorizing citizen suits to enforce “a permit or condition of a permit issued under section 1342,” *i.e.*, an NPDES permit). Washington’s current PCB criterion is 170 pg/L, and it is no coincidence that NPDES permits impose “an end-of-pipe effluent limit of 170 pg/L.” Wash. Cross-Mot. 15. When criteria change, permit limits change, too. *See supra*, at 7.

Regardless, neither EPA nor Washington claims that the State has actually adopted any of these fallback measures. *See* Opp. 44; Wash. Cross-Mot. 15–16 nn.5–6. Washington suggests that it diligently processed variance applications after 2016, but the Spokane River dischargers’ variance applications have remained in limbo for nearly a decade. Wash. Cross-Mot. 15–16 nn.5–6. The State’s cited source (*id.* at 16 n.6) tells the true story: “This rulemaking is permanently on hold.” Wash. Dep’t of Ecology, Ch. 173-201A WAC (Variances), [tinyurl.com/ycy7u8sm](https://www.tinyurl.com/ycy7u8sm).

EPA's other proposed mechanisms lend the government no additional support. Implicitly conceding that "removing designated uses is unrealistic," Opp. 44, EPA suggests that "mixing zones" would offer a more targeted solution, *id.* But a mixing zone permits a discharger "to exceed applicable water quality criteria within a defined area or volume of water around the discharge *as long as the WQS is met at the edge of the mixing zone.*" Final Rule RTC 20 (emphasis added). EPA offers no reason to believe that this edge-of-the-zone requirement could ever be met, because its PCB criterion is *impossible* to meet.

In short, EPA demonstrates a clear lack of concern for the plight of permit holders who will be out of compliance indefinitely, and EPA's nonchalant reliance on the notion that supposed regulatory "tools" may solve the problem is misplaced.

C. Finally, EPA's rulemaking never addressed the significant uncertainty and downstream regulatory consequences the rule engenders while its proposed fixes go through the required process. *See* Mot. 36–37. Nor does the rule address the implications of EPA's new argument that the detection limit is in fact the compliance expectation, which would mean NPDES permit holders must constantly be on the lookout for detection-limit developments and EPA's review of the same in administrative proceedings that have nothing to do with substantive water quality standards and criteria. *Supra*, at 8–9. EPA's opposition again offers only silence. That is a significant aspect of the problem EPA has failed to consider, and sufficient reason to vacate and remand.

**VI. The 2022 Rule Is Arbitrary And Capricious Because EPA Failed To Reasonably Consider Costs Or, Alternatively, Conducted An Unreasonable Economic Analysis.**

EPA either erroneously concluded that costs cannot be considered at all in setting criteria, Final Rule RTC 109, or else unreasonably relied on an analysis showing that the 2022 rule imposes *no* compliance costs at all, 87 Fed. Reg. at 69,195. Either way, the rule cannot stand.

**A. EPA Cannot Show That The Clean Water Act Authorizes It To Ignore Costs.**

EPA purports to prove that the Clean Water Act *forecloses* consideration of costs in setting water quality criteria, but EPA largely ignores the interpretive arguments Plaintiffs have advanced. And EPA’s proof fails.

1. **Text.** EPA does not dispute that “preclusion of cost consideration requires” a “clear” statement of congressional intent. *Michigan v. EPA*, 213 F.3d 663, 677–78 (D.C. Cir. 2000) (per curiam); Mot. 38. But EPA does not even try to point to any such clear statement, and none exists.

a. As Plaintiffs explained, the Clean Water Act’s text *at least* permits consideration of costs in setting human health criteria. *See* Mot. 40. The Act provides that the Administrator must promulgate new criteria if “necessary” to meet the Act’s requirements, 33 U.S.C. § 1313(c)(4)(B), and that water quality standards—both designated uses *and* corresponding criteria—must protect “the public . . . welfare” and “serve the purposes of this chapter,” *id.* § 1313(c)(2)(A). EPA does not dispute that the Act’s purposes include attainability, *id.* § 1251(a)(2), or that terms as capacious as “necessary” and “public welfare” embrace cost considerations, *see* Mot. 39–40. Indeed, EPA does not discuss these textual phrases at all.

Instead, EPA principally misdirects the Court to its own *regulations*. *Opp.* 36 (citing 40 C.F.R. §§ 131.10, 131.11(a)). But EPA fails to show that anything in its regulations forecloses cost consideration, and nothing in the statutory text prohibits setting human health criteria based on economic considerations. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024) (“Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority.”); Mot. 40.

b. When EPA finally turns to the statute, the best it can muster (in a “*see also*” signal) is that considering costs somehow contravenes the requirement that human health criteria be “based

upon” designated uses, 33 U.S.C. § 1313(c)(2)(A). Opp. 36; *see also* Opp. 38. But EPA does not explain how considering costs contravenes that provision. It does not. The “based on designated uses” provision defines *the purposes* the criteria serve (to protect, say, fish harvesting), not *the inputs* for calculating them. And there is no contradiction in saying that human health criteria must reflect technologically feasible and cost-attainable limits in supporting a designated use. *See* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 57 (2012) (no statute pursues a single “purpose at all costs”); Mot. 37 (citing authority for the proposition that “unattainable” standards backfire in achieving their purposes because they undercut community buy-in). In fact, if EPA were right today, its 2000 Methodology would be wrong: Setting human health criteria is an irreducibly normative task, requiring consideration not only of scientific data and the designated uses, but also of “social, economic, and political concerns.” 2000 Methodology at 2–4.<sup>4</sup>

Finding no support in Section 1313, EPA pivots to an entirely different statutory section—33 U.S.C. § 1314(a). But that section concerns the EPA Administrator’s promulgation of criteria *recommendations* to assist States in setting their own criteria. It is unsurprising that those non-binding recommendations must “accurately refle[t] the latest scientific knowledge,” *id.*, because they impose no duties and involve no risk assessment or cost-balancing. But the standards that States must actually promulgate and enforce are different—and governed by different text and purposes, *see id.* § 1313(c). In the statutory provision that matters, EPA finds nothing to back its view that Congress intended to foreclose cost consideration.

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<sup>4</sup> Moreover, the concept of a “designated use” can embrace economic considerations. Such uses can include not only environmental purposes (like “propagation of fish and wildlife”) but also “industrial, and other purposes.” 33 U.S.C. § 1313(c)(2)(A).

In a last gasp, EPA perplexingly suggests that Plaintiffs have “forfeited” their statutory interpretation arguments by “ma[king] no statutory-interpretation argument regarding EPA’s consideration of cost” in their opening brief. Opp. 38 n.15. EPA apparently missed multiple pages in Plaintiffs’ brief in support of summary judgment. *See* Mot. 38–40 (arguing that “consideration of costs is statutorily required” under the Act (emphasis altered)).

**2. Precedent.** Controlling Supreme Court precedent confirms that EPA’s interpretation is wrong. EPA points to purportedly contrary cases, but its cases are wrong, irrelevant, or both.

**a.** EPA offers no persuasive answer to *Michigan v. EPA*, 576 U.S. 743 (2015). It says that the phrase “appropriate and necessary” in *Michigan* permitted cost consideration because the statute concerned a decision “whether to regulate,” and regulation necessarily involves balancing costs. Opp. 39. But imposing more stringent human health criteria is also a decision “whether to regulate.” Water quality standards “provide the basis for specific, enforceable requirements designed to achieve them.” *In re ACF Basin Water Litig.*, 467 F. Supp. 3d at 1337; *see supra*, at 25. The fact that *other* mechanisms may mitigate a new criterion’s burdens renders the decision initially to impose those burdens no less “regulatory.”

EPA also cavils (at 39) that the agency was required “to study” costs in the provision at issue in *Michigan*. But that was only “further indication” of Congress’s intent there. 576 U.S. at 753. EPA misses *Michigan*’s key takeaway: When Congress uses capacious language in authorizing regulation—“appropriate and necessary” in *Michigan*, “necessary” and “public . . . welfare” here—EPA errs when it disclaims authority to consider costs.

**b.** EPA’s own cases lend it little support. Its principal authority—the Fifth Circuit’s decision in *Mississippi Commission on Natural Resources v. Costle*—rested on the mistaken premise that Congress must “explicitly requir[e]” consideration of “economics and cost.” 625 F.2d 1269,



1276 (5th Cir. 1980). That flips the D.C. Circuit’s clear-statement rule on its head. *See supra*, at 27. *Costle* also arose in a pre-*Loper Bright* world: The Fifth Circuit undertook no serious analysis of the Act’s text, and it analyzed statutory questions by asking whether it was “not unreasonable for the EPA Administrator to interpret the Act” as he did, 625 F.2d at 1276 (discussing another aspect of Act).

The Ninth Circuit’s decision in *Upper Missouri Waterkeeper v. EPA*, 15 F.4th 966 (9th Cir. 2021), undercuts EPA’s statutory construction. The court reasoned that the Act “*does not speak at all* to whether EPA may consider compliance costs when approving a State’s proposed water quality standards,” and held only that it was reasonable at *Chevron* step two for EPA to construe the Act to require States to consider costs in setting designated uses, but not in setting human health criteria. *Id.* at 973 (emphasis added). That conclusion conflicts with EPA’s view that the CWA *does* speak to the issue by foreclosing consideration of costs in setting criteria. Regardless, the Ninth Circuit’s reasoning—bottomed on *Chevron*’s obsolete method—should not persuade. And EPA offers no response to Plaintiffs’ showing (Mot. 40–41) that *Upper Missouri Waterkeeper* misconstrued EPA’s regulations even if it lawfully interpreted the statute.<sup>5</sup>

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<sup>5</sup> EPA’s remaining cases add nothing. *Grand Portage Band v. EPA*, 2024 WL 1345202, at \*10 (D. Minn. Mar. 29, 2024), merely cited *Costle* without analysis. And *Grand Portage*, if anything, undermines EPA’s position. The court upheld EPA’s decision to *approve* Minnesota’s removal of certain criteria because of “[c]oncerns about convenience and costs,” noting that these were appropriate for at least the State to consider in setting criteria. *Id.* EPA’s other two cases—*NRDC v. EPA*, 16 F.3d 1395 (4th Cir. 1993), and *El Dorado Chemical Co. v. EPA*, 763 F.3d 950 (8th Cir. 2014)—did not even present the issue whether EPA may consider costs in setting human health criteria. *See NRDC*, 16 F.3d at 1402 (refusing to review “every bit of technical evidence,” and simply holding that EPA “applied the correct legal standard” in reviewing state criteria); *El Dorado*, 763 F.3d at 960 (noting that state challenged only “the scientific evidence in the record”).

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When a statute permits cost consideration, it is arbitrary and capricious for agencies not to consider the costs its desired regulation would impose on the public. *Michigan*, 576 U.S. at 753; *see Loper Bright*, 144 S. Ct. at 2263. And at minimum, EPA has acted under the mistaken legal premise that it may *not* consider cost considerations. Vacatur and remand are thus required. *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985).

**B. Alternatively, EPA Unreasonably Zeroed Out Compliance Costs.**

EPA fares no better in defending the economic analysis that it actually performed. Its responses only underscore why vacatur is required.

1. EPA first asserts that its economic analysis is “outside the scope” of APA review because an economic analysis was not “require[d]” and thus is not a “basis” for the rule. Opp. 39–40. But EPA’s economic analysis is plainly in the “existing administrative record” and part of EPA’s “contemporaneous explanation,” *Dep’t of Com.*, 588 U.S. at 780; EPA points to its economic analysis *by citing the record*, Opp. 40–41 (citing Final Rule RTC 139). And EPA offers no answer to the rule that when “EPA *in fact* consider[s] economic effects at length,” the Court “must review its economic reasoning” to determine “whether its overall decision was reasonable”—regardless of whether EPA was “require[d]” to consider “economic effects.” *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 525–26 (D.C. Cir. 1983) (emphasis added); *see* Mot. 41. EPA cannot insulate its unreasonable economic analysis from review.

2. EPA defends its erroneous baseline for analyzing costs—a hypothetical world of full compliance with existing standards—on the ground that it prevents “double count[ing]” costs attributable to existing standards. Opp. 40. On its own terms, that rationale makes little sense. When EPA replaces current standards with new ones, it wipes the existing standards from the

books; there is nothing left to “double count.” And regulated parties inhabit the real world, not EPA’s counterfactual one. They must incur *all* incremental costs to comply with the new standard.

EPA does not dispute that the Tenth Circuit rejected a similar approach to agency economic analysis in *New Mexico Cattle Growers Association v. Fish & Wildlife Service*, 248 F.3d 1277 (10th Cir. 2001). *See* Mot. 43–44. The agency’s analysis there was “virtually meaningless,” EPA agrees, but EPA greenlights its own meaningless analysis here because “the [Clean Water] Act and EPA’s regulations do not even require an economic analysis.” Opp. 40. But EPA overlooks that the Administrative Procedure Act always demands reasonableness. *See Loper Bright*, 144 S. Ct. at 2263 (courts must “ensur[e] the agency has engaged in ‘reasoned decisionmaking’” (quoting *Michigan*, 576 U.S. at 750)). When EPA prepares a 98-page analysis and touts the benefits of public “transparency,” Opp. 14, it cannot deflect scrutiny by dismissing its own analysis as an empty ritual, *cf. Small Refiner*, 705 F.2d at 525–26. Rather, when EPA undertakes such an analysis, EPA “must analyze all of the economic impacts” of its actions, “regardless of whether the impacts are co-extensive with” other agency actions. *N.M. Cattle Growers*, 248 F.3d at 1284–85.

3. EPA also fails to show that its estimate of zero compliance costs was “reasonable and reasonably explained.” *Ohio*, 144 S. Ct. at 2053. EPA asserts that it made “conservative assumptions to err on the side of overestimating costs,” Opp. 41 (citing Final Rule RTC 139), but the notion that *zero* compliance costs is an “overestimat[e]” is hard to take seriously. Even EPA’s economists say the opposite: EPA’s “assumption” of “[z]ero compliance costs” “[u]nderestimate[s]” “the total cost of compliance.” Economic Analysis 38; *see* Mot. 45.

And EPA’s assertion that zero is an overestimate reflects an obvious fallacy. Because “improve[d] . . . treatment technologies” could “reduce compliance costs” from the rule, the argument seems to run, compliance costs could someday be lower than they are today—and the rule,

EPA thus concludes, could impose *negative* compliance costs. Final Rule RTC 139. That is a *non sequitur*. Regulated parties' ability to reduce compliance costs through *other means* does not reduce the costs *imposed by the rule*, any more than a tenant's new income reduces the rent he owes his landlord. It simply makes the regulated industry (or the tenant) better equipped to pay. Anyway, there is no evidence in the record that an improved treatment technology that would lower compliance costs is forthcoming. And even if such a hypothetical treatment system were eventually developed, it would not offset costs incurred until such time. EPA's conclusion of negative compliance costs has no basis in reality, much less the record.

Moreover, EPA's uncertainty about the magnitude of the compliance costs did not justify zero-ing them out. EPA cannot distinguish *Public Citizen v. Federal Motor Vehicle Safety Administration*, 374 F.3d 1209, 1218–19 (D.C. Cir. 2004), which condemned this exact error. EPA asserts that in *Public Citizen* it was “implausible” and “dubious” that the cost effects there were “nil,” *id.*, but it is equally implausible here. Commenters offered “a range of compliance costs from nearly \$6 billion to over \$11 billion just for the ‘major’ permits” alone. Nw. Pulp & Paper Letter 70. EPA's speculation that improvements in technology could reduce these costs did not justify discounting them altogether. *See Interstate Nat. Gas Ass'n of Am. v. Pipeline & Hazardous Materials Safety Admin.*, 2024 WL 3837458, at \*7 (D.C. Cir. Aug. 16, 2024) (explaining that an agency “fails to meet the requirement of a reasoned cost-benefit analysis” when it “contradicts itself” by asserting both that the rule will “impose no costs at all” and that it will “impose some costs that cannot be calculated”). And EPA's last resort—that nothing will change because permit holders need satisfy only the EPA-approved detection limit of 65,000 pg/L—simply reruns its meritless standing arguments. *See supra*, at 6–10.

At the very least, EPA’s explanation for its economic analysis was inadequate. Commenters apprised the agency of significant compliance costs, Mot. 42, yet EPA “elected not to speculate on future analytical capability.” Final Rule RTC 141. That was especially unjustifiable given EPA’s recent push to approve a more sensitive test method—Method 1628, which EPA could easily have considered in modeling the 2022 rule’s potential costs. See EPA Agency Rule List – Spring 2024, [tinyurl.com/6wks95ws](https://www.tinyurl.com/6wks95ws). “EPA’s own statements and actions confirm the agency appreciated” cost concerns, but “it failed to address the concern adequately.” *Ohio*, 144 S. Ct. at 2055–56.

## VII. The Court Should Vacate The 2022 Rule.

EPA ends with a plea for remand without vacatur. Given that remedy’s hotly “disputed legality,” *In re Core Commc’ns, Inc.*, 531 F.3d 849, 862 (D.C. Cir. 2008) (Griffith, J., concurring), courts reserve it only for “exceptional” circumstances, *Am. Great Lakes Ports Ass’n v. Schultz*, 962 F.3d 510, 519 (D.C. Cir. 2020); see *Corner Post*, 144 S. Ct. at 2463 (Kavanaugh, J., concurring) (“[T]he D.C. Circuit . . . [has] long recognized vacatur as the usual relief when a court holds that agency rules are unlawful.”)<sup>6</sup> Courts assess (1) “the seriousness of the [rule’s] deficiencies,” and (2) “the disruptive consequences of vacating the [r]ule.” *Humane Soc’y of U.S. v. Zinke*, 865 F.3d 585, 614 (D.C. Cir. 2017) (cleaned up). “The burden to demonstrate such

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<sup>6</sup> As several judges on the D.C. Circuit have explained, remand without vacatur “rests on thin air. No statute governing judicial review of agency action permits such a disposition and the controlling statute—5 U.S.C. § 706(2)(A)—flatly prohibits it.” *Checkosky v. SEC*, 23 F.3d 452, 490 (D.C. Cir. 1994) (separate opinion of Randolph, J.); see also *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 757 (D.C. Cir. 2002) (Sentelle, J., dissenting) (similar); cf. *In re Core Commc’ns*, 531 F.3d at 862 (Griffith, J., concurring). Scholars have backed the same view, e.g., Ronald M. Levin, “*Vacation*” at Sea: *Judicial Remedies and Equitable Discretion in Administrative Law*, 53 *Duke L.J.* 291, 378–80 (2003), as have other circuits, e.g., *Nat’l Ass’n of Priv. Fund Managers v. SEC*, 103 F.4th 1097, 1114 (5th Cir. 2024) (“Under section 706 of the APA, when a court holds that an agency rule violates the APA, it ‘shall’—not may—‘hold unlawful and set aside’ [the] agency action.” (citation omitted)).

extraordinary circumstances lies with the government.” *Cigar Ass’n of Am. v. FDA*, 2023 WL 5094869, at \*3 (D.D.C. Aug. 9, 2023).

EPA does not come close to such a demonstration. As to the “seriousness” of the rule’s defects, EPA contends that it faces at most “record-based deficiencies.” Opp. 45. That’s wrong. Because EPA lacks statutory *authority* to harmonize state standards with tribal rights, the rule is *ultra vires*, full stop. And while EPA seemingly believes that its errors are cosmetic, they cut to the heart of the rule. EPA failed to consider compliance costs or the effects of regulatory uncertainty; attempted to revive an unlawful tribal-rights rationale; and wrongly second-guessed the State’s risk-management decisions. *See SecurityPoint Holdings, Inc. v. TSA*, 867 F.3d 180, 185 (D.C. Cir. 2017) (“the court *must* vacate a decision that ‘entirely failed to consider an important aspect of the problem’” (emphasis added)); *Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009) (vacatur is appropriate “when the agency has not responded to empirical data or to an argument inconsistent with its conclusion”). Remand without vacatur would only reinforce EPA’s apparent “indifference.” *In re Core Commc’ns*, 531 F.3d at 862 (Griffith, J., concurring).

As to disruptive consequences, EPA unironically asserts that vacatur would “frustrate Washington’s ability to implement CWA programs.” Opp. 45. But any such frustration is of EPA’s own making—its repeated override of the State’s standards and risk-management decisions, dating back to 2016. More to the point, if the challenged rule is vacated, existing permits will continue to enforce the prior water quality standards. It is EPA’s new standards themselves, not vacatur of those standards, that would disrupt the status quo.

### CONCLUSION

The Court should enter summary judgment for Plaintiffs and vacate the 2022 rule.

Dated: September 24, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on September 24, 2024, I filed the foregoing document and all attachments with the Court's CM/ECF System, which will notify each attorney of record.

/s/ Helgi C. Walker  
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