

ORAL ARGUMENT NOT YET SCHEDULED**Case No. 24-1188 (and consolidated cases)**

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

AMERICAN WATER WORKS ASSOCIATION, et al.,
Petitioners

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

On Petition for Review of Final Action of the
United States Environmental Protection Agency

**AMICUS CURIAE BRIEF FOR CONNECTICUT, CALIFORNIA,
NEW JERSEY, ARIZONA, COLORADO, DELAWARE, DISTRICT OF
COLUMBIA, HAWAII, ILLINOIS, MARYLAND, MASSACHUSETTS,
MICHIGAN, MINNESOTA, NEW YORK, NORTH CAROLINA, OREGON,
RHODE ISLAND, AND WISCONSIN IN SUPPORT OF RESPONDENT**

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**CERTIFICATE AS TO PARTIES, RULINGS,
AND RELATED CASES**

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel of record certifies as follows:

A. Parties and Amici

Except for the following, all parties, intervenors, and amici appearing in this Court are listed in the Brief of American Water Works Association and Association of Metropolitan Water Agencies (ECF 2078734) at page i; and in the Brief of National Association of Manufacturers, American Chemistry Council, and the Chemours Company FC, LLC (ECF 2078734) at page iii.

Amicus curiae in support of Petitioners is the Chamber of Commerce of the United States of America.

Amici curiae in support of Respondents are States of New Jersey, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maryland, Michigan, Minnesota, New Jersey, New York, North Carolina, Oregon, Rhode Island, and Wisconsin, Commonwealth of Massachusetts, District of Columbia, Center for Environmental Health, Cape Fear River Watch, Toxic Free North Carolina, Harper Peterson, Michael Watters, and an unidentified “group of interested scientists.”

B. Rulings Under Review

The agency action under review is a rule entitled “PFAS National Primary Drinking Water Regulation,” 89 Fed. Reg. 32,532 (April 26, 2024).

C. Related Cases

The above-captioned case (No. 24-1188) has been consolidated with two additional petitions for review, *National Ass’n of Manufacturers, et al. v. EPA, et al.* (No. 24-1191) and *The Chemours Co. FC, LLC v. EPA, et al.* (No. 24-1192). The rule at issue has not been previously reviewed in this or any other court and there are no related cases within the meaning of Circuit Rule 28(a)(1)(C).

/s/ Christopher Patrick Kelly
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GLOSSARY

EPA	United States Environmental Protection Agency
Goal	Maximum Contaminant Level Goal
HBWC	Health-Based Water Concentration
HFPO-DA	Hexafluoropropylene Oxide Dimer Acid
Index PFAS	HFPO-DA, PFBS, PFHxS, and PFNA
PFAS	Per- and Polyfluoroalkyl Substances
PFBS	Perfluorobutane Sulfonic Acid
PFHxS	Perfluorohexane Sulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonic Acid
Rule	PFAS National Primary Drinking Water Regulation
SDWA	Safe Drinking Water Act
Standard	Maximum Contaminant Level
UCMR	Unregulated Contaminant Monitoring Rule

INTERESTS OF *AMICI CURIAE*

State Amici—Connecticut, California, New Jersey, Arizona, Colorado, Delaware, District of Columbia, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Minnesota, New York, North Carolina, Oregon, Rhode Island, and Wisconsin—submit this brief in support of Respondent the U.S. Environmental Protection Agency (“EPA”) and its rule establishing nationwide drinking water standards for certain per- and polyfluoroalkyl substances (“PFAS”) under Section 1412 of the Safe Drinking Water Act, 42 U.S.C. § 300g-1 (“SDWA” or the “Act”). *See* 89 Fed. Reg. 32,532 (Apr. 26, 2024) (the “Rule”).¹

State Amici have powerful interests in protecting their residents from the harms of PFAS exposure through drinking water. The presence of PFAS in drinking water is an established threat to public health and safety. A growing body of research shows that most, if not all, PFAS are highly toxic to humans and animals, with even minimal exposures over time associated with deleterious effects to human health.² They also resist degradation in the environment and are accordingly known as “forever chemicals.” These toxins were used for decades in myriad industrial and military settings, along with airports and fire departments,

¹ The PFAS included in the Rule are Perfluorooctanoic Acid (“PFOA”), Perfluorooctane Sulfonic Acid (“PFOS”), Hexafluoropropylene Oxide Dimer Acid (“HFPO-DA”), Perfluorobutane Sulfonic Acid (“PFBS”), Perfluorohexane Sulfonic Acid (“PFHxS”), and Perfluorononanoic Acid (“PFNA”).

² *See, e.g.*, Pelch, K. et al., *PFAS-Tox Database* (last visited Jan. 16, 2025), <https://pfastoxdatabase.org> (“Health Outcomes” tab).

and remain in countless consumer products, from infant car seats and strollers to non-stick cookware and food packaging. As a result, dangerous and highly mobile PFAS have contaminated numerous drinking water sources throughout the State Amici jurisdictions and the bodies of our residents—where they accumulate and persist. Several State Amici have repeatedly urged Congress and EPA to take prompt and aggressive actions to respond to the national PFAS crisis.³ Finally, EPA has acted by issuing this Rule.

The Rule supports those compelling state interests.⁴ While some State Amici already regulate some PFAS contaminants in drinking water under state law, the Rule establishes a federal baseline. This is a particularly important public health measure for jurisdictions without existing regulations, as it will mark the first set of legal protections their residents receive from the harms of particular PFAS present in drinking water. For those States that already regulate PFAS in drinking water, EPA's rule broadly complements and reinforces the various approaches taken by these States and establishes the federal floor above which States may choose to regulate. *Cf. New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932).

In addition, State Amici have a strong interest in seeing the Rule upheld in light of States' significant involvement in the enforcement of the Act and the

³ See, e.g., Comment Letter from State Attorneys General (May 30, 2023), <https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1687>.

⁴ State Amici emphasize that no State has challenged the Rule as a petitioner, intervenor, or amicus curiae.

operation of public drinking water systems. Most, but not all, of the State Amici are authorized by EPA to exercise primary enforcement authority over drinking water in their respective jurisdictions, pursuant to 42 U.S.C. § 300g-2(a), and thus have an interest in the law that they enforce. In addition, some State Amici own and operate public water systems that will be subject to the requirements of the Rule. *See* 89 Fed. Reg. 32,535. According to federal data, the State Amici collectively own and operate 2,482 public water systems, of which 353 are subject to the Rule.⁵ Moreover, State Amici provide financial assistance to operators of public water systems which are subject to the Rule to treat PFAS in the water they serve to the public.

As to the statutory and procedural challenges to the Rule in this case, the petitions brought by both the Utility Petitioners and Industry Petitioners should be denied. *See* ECF 2091318 (“EPA Br.”) at i (identifying both sets of petitioners); ECF 2078734 (“Utility Br.”); ECF 2078731 (“Industry Br.”). The Rule is consistent with the purposes of the Act and protects the public from contaminants of concern affecting multiple jurisdictions. Under the Rule, EPA correctly determined, based on the best available science and information, to regulate emerging contaminants across multiple States that qualify as contaminants of public health concern. The Rule also acknowledges the overlapping health

⁵ EPA, *SDWIS Federal Reports Search*, https://sdwis.epa.gov/ords/sfdw_pub/r/sfdw/sdwis_fed_reports_public/200.

concerns presented by these contaminants and implements a hazard index approach to comply with the requirements of the Act. Finally, the Rule complies with the Act's unique procedural requirements for the issuance of nationwide drinking water regulations, including those pertaining to the sequencing of regulatory action as well as the Act's feasibility analysis.

STATUTES AND REGULATIONS

Relevant statutory and regulatory provisions not included with EPA's addendum are contained in the addendum filed with this brief.

STATEMENT OF THE CASE

The statutory and regulatory background is set forth in EPA's Statement of the Case.

SUMMARY OF THE ARGUMENT

I. The Rule serves the public health mandate of the Act by regulating contaminants of concern with substantial evidence of toxicity, which benefits and empowers States to protect drinking water. *See* 42 U.S.C. § 300g-2.

II. EPA's determination that the Index PFAS are substantially likely to occur in public water systems with a frequency and at levels of public health concern is supported by the contemporaneous efforts of state regulators to address the risks from these chemicals. *Id.* § 300g-1(b)(1)(A).

III. The hazard index approach adopted under the Rule has long been used by state and federal environmental regulators to recognize and mitigate the harms of co-occurring contaminants across a variety of environmental media, including to PFAS in drinking water. Petitioners present arguments against the hazard index that are factually inaccurate and contravene the Act's mandate to avoid known or anticipated harm to human health as much as is feasible. *Id.* § 300g-1(b)(4)(A); *Id.* § 300g-1(b)(4)(B).

IV. Petitioners present an interpretation of the Act that hamstring public health regulation with a narrow, less-informed public process and confuses the feasibility analysis required under the Act with a cost-benefit analysis. *Id.* § 300g-1(b)(4). EPA complied with the plain language procedural requirements of the Act.

ARGUMENT

I. The Rule Advances the Act's Public Health Mandate and its Cooperative Federalism Framework.

Drinking water comes from public water systems and private wells, which are fed by surface waters and underground reservoirs that are vulnerable to various contaminants, including PFAS.⁶ PFAS are a class of synthetic organic chemicals that have been used in numerous consumer and industrial products since the

⁶ NJDEP, Drinking Water Quality Institute, *Appendix A: Health-Based Maximum Contaminant Level Support Document: Perfluorooctane Sulfonate (PFOS) ES-3* (June 2018), <https://www.nj.gov/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf>.

1940s.⁷ PFAS are characterized in part by their strong carbon-fluoride bonds, which allow many PFAS to persist in the environment for years, decades, or longer.⁸

Research over the past two decades clearly demonstrates PFAS toxicity, and that even miniscule exposures over time are associated with a range of adverse human health effects, including various cancers, liver disease and damage, developmental issues such as low birth weight, hormonal changes, weakened immune system, diabetes, and fertility issues.⁹ Furthermore, oral exposure to certain PFAS are associated with several harmful health effects, including impacts on the liver, thyroid, immune system, pregnancy and fetal development, and cancer.¹⁰ While some types of PFAS (such as PFOA and PFOS) have been phased out of production domestically, they remain in circulation via existing products and newly imported products. *See* EPA Br. 12. Meanwhile, other types of PFAS

⁷ ECOS, Sarah Grace Hughes, *Processes & Considerations for Setting State PFAS Standards* 6 (last updated March 2023), <https://www.ecos.org/wp-content/uploads/2023/03/2023-ECOS-PFAS-Standards-Paper-Update.pdf>; NJDOH, *Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (last updated Apr. 2024), https://www.nj.gov/health/ceohs/documents/pfas_drinking%20water.pdf.

⁸ EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* 9 (Feb. 2019) https://www.epa.gov/sites/default/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.

⁹ *See* Pelch et al., *supra* note 2.; *see also* NJDEP, Drinking Water Quality Institute, *Review of Interim USEPA Health Advisories for PFOA and PFOS and Other Relevant Information* (June 12, 2023), <https://www.nj.gov/dep/watersupply/pdf/dwqi-health-effects-pfas-report.pdf>.

¹⁰ EPA, *supra* note 8 at 13.

continue to be manufactured, and human exposure to those PFAS is expected to increase over time.¹¹ Currently, PFAS are detectable in the blood of nearly all people in the United States.¹²

The Act governs EPA's process for regulating contaminants of concern in approximately 150,000 public water systems, which supply drinking water to a majority of Americans.¹³ To begin, the Act provides a data-based framework through which EPA can determine to regulate new contaminants. *See* EPA Br. 5. Every five years, EPA must publish a Contaminant Candidate List and must determine whether to regulate no fewer than five listed contaminants. 42 U.S.C. §§ 300g-1(b)(1)(B)(i), (b)(1)(B)(ii)(I). A determination to regulate requires a notice-and-comment rulemaking process and considers public health-focused criteria geared toward seizing “meaningful opportunity for health risk reduction” through regulation. *Id.* § 300g-1(b)(1)(A); *see id.* § 300g-1(b)(1)(B)(ii)(II); EPA Br. 5. The determination to regulate does not consider costs, but rather, the “best available public health information” and EPA's database of occurrences in public

¹¹ *Id.*

¹² Agency for Toxic Substances and Disease Registry, *Fast Facts: PFAS in the U.S. Population* (Nov. 12, 2024), <https://www.atsdr.cdc.gov/pfas/data-research/facts-stats/index.html>; NJDEP, Sandra Goodrow and Gloria B. Post, *Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (Aug. 16, 2021), <https://dep.nj.gov/wp-content/uploads/dsr/private-well-consortium-pfas-2021.pdf>.

¹³ EPA, *Basic Information about Your Drinking Water* (last updated Nov. 7, 2024), <https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-your-drinking-water>.

water systems. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II). As this Court recently explained, the “Act frontloads EPA’s discretion” when determining whether to regulate contaminants. *NRDC v. Regan*, 67 F.4th 397, 399 (D.C. Cir. 2023).

After EPA determines to regulate, it must then, with limited exceptions, establish both Maximum Contaminant Level Goals (“Goals”) and Maximum Contaminant Levels (“Standards”). 42 U.S.C. § 300g-1(b)(4). The former must be “set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.” *Id.* § 300g-1(b)(4)(A). The Standards—which are the enforceable drinking water standards—must be set as close to the Goals “as is feasible.” *Id.* § 300g-1(b)(4)(B). While cost considerations factor into the feasibility analysis, the Act does not mandate that a Standard’s benefits outweigh its costs. *See infra* Part IV.B; EPA Br. Part IV.A. In setting those standards, EPA is required to use the “best available, peer-reviewed science” and data collected using the “best available methods.” 42 U.S.C. § 300g-1(b)(3)(A). Certain statutory deadlines also apply to this phase. *See infra* Part IV.A; EPA Br. Part I.B.

Consistent with the Act’s requirements, the Rule advances regulation of multiple PFAS in a number of ways. The Rule finalized drinking water standards for PFOA and PFOS by setting Goals of zero and Standards of 4.0 parts per trillion (“ppt”). 89 Fed. Reg. 32,535. For HFPO-DA, PFHxS, and PFNA, the Rule both

finalized determinations to regulate and established Goals and Standards for each of those contaminants individually. *Id.* Finally, as to HFPO-DA, PFHxS, PFNA, and PFBS (collectively “Index PFAS”), the Rule both finalized a determination to regulate these substances *as a mixture*—where two or more of those contaminants co-occur—and established a Goal and Standard for those mixtures as a hazard index level of 1 (unitless). *Id.*¹⁴

The Rule will protect drinking water in Amici States, which have an integral role under the Act’s cooperative federalist model to ensure safe drinking water for their residents.¹⁵ The landscape of state-level PFAS regulation varies significantly across the country. Laws in some states adopt, but go no further than, federal drinking water regulations for regulated contaminants, leaving PFAS unregulated until EPA acts. Other jurisdictions, such as Wyoming and the District of Columbia, do not have primary enforcement authority under the Act and are directly regulated by the federal government. For residents of those jurisdictions, the Rule is an essential protection from contaminated drinking water. Even States that have adopted monitoring and reporting requirements stand to benefit because the Rule can ease the administrative burden for States that would otherwise set their own

¹⁴ Each aspect of the Rule is severable from the others, and the remainder of the Rule should remain in effect if Petitioners succeed in challenging any portion of it. *See* 89 Fed. Reg. 32,731.

¹⁵ *See, e.g.*, Cal. Water Code, § 106.3 (“[I]t is hereby declared to be the established policy of the state that every human being has the right to safe, clean, affordable, and accessible water.”).

regulations. In California, drinking water regulators have taken concrete steps to quantify PFAS contamination in the state, starting in 2019 with drinking water general monitoring orders, as well as setting nonregulatory notification and response levels for certain PFAS starting in 2020.¹⁶ State regulators may rely on EPA's scientific justification, saving agency resources and easing the burden on state regulators to accomplish this goal when compared to a state-initiated regulation.

The Rule will provide important complementary benefits even for those States that already limit PFAS in drinking water. For instance, New Jersey has maximum contaminant levels for PFOS, PFOA, and PFNA,¹⁷ but not for the other contaminants included in the Rule. New Jersey regulates the former set of compounds because those compounds were disproportionately detected during New Jersey's rulemaking compared to EPA's nationwide occurrence levels.¹⁸ The Rule enhances New Jersey's drinking water protections with the benefit of more

¹⁶ California State Water Resources Control Board, *PFAS: Per- and Polyfluoroalkyl Substances* (last updated Oct. 9, 2024), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/pfas.html.

¹⁷ See NJDEP, *Per- and PolyFluoroalkyl Substances (PFAS)* (last updated Apr. 16, 2024), <https://dep.nj.gov/pfas/drinking-water/>.

¹⁸ NJDEP, Division of Science and Research, *Per- and Polyfluoroalkyl Substances (PFAS) Research* (last updated Dec. 18, 2024), <https://dep.nj.gov/dsr/pfas/#first>; see 49 N.J.R. 2361(a) (Aug. 7, 2017); 50 N.J.R. 1939(a) (Sept. 4, 2018); 51 N.J.R. 437(a) (Apr. 1, 2019); 54 N.J.R. 1165(b) (June 1, 2020).

recent and comprehensive data.¹⁹ The Rule also establishes more stringent standards for the contaminants New Jersey already regulates, which New Jersey has begun seeking to adopt as its own pursuant to both the Act and state law. The State thus stands to benefit from the Rule’s robust protections, as do other States that already regulate PFAS in drinking water.²⁰

II. The Index PFAS, Individually and as Mixtures, are Contaminants of Public Health Concern.

Contrary to Petitioners’ arguments, state and federal occurrence data unequivocally demonstrate that the Index PFAS are contaminants of “public health concern” within the meaning of 42 U.S.C. § 300g-1(b)(1)(A).²¹ Consequently, EPA has appropriately determined to regulate them, both individually and as mixtures, and has properly issued national primary drinking water regulations to address them.²²

To make an initial determination on whether to regulate contaminants, EPA is required to consider, among other things, whether those contaminants “occur in

¹⁹ See EPA, *Per- and Polyfluoroalkyl Substances (PFAS) Occurrence and Contaminant Background Support Document for the Final PFAS National Primary Drinking Water Regulation 25-29* (Apr. 2024), EPA-HQ-OW-2022-0114-3086.

²⁰ Some States have regulated some PFAS at concentrations lower than those implemented by the Rule. See, e.g., Mich. Admin. Code R. 325.10604g (setting a maximum contaminant level for PFNA at 6 ppt).

²¹ Petitioners do not contest EPA’s threshold determination to regulate PFOA and PFOS in the first instance, which was not part of this Rule. See *infra* Part IV.A (discussing this element of the Act’s scheme).

²² The Rule does not regulate PFBS individually, but it is included as part of a mixture under the Hazard Index.

public water systems with a frequency and at levels of public health concern.” *Id.* § 300g-1(b)(1)(A)(ii). Whether a contaminant’s occurrence is “of public health concern” is not defined by the Act, nor has a court defined a standard for meeting that criterion; rather, Congress explicitly authorized the Agency to apply its expertise to protect public health. *See NRDC*, 67 F.4th at 399 (“The Act frontloads EPA’s discretion, allowing the agency to . . . select which of those listed contaminants to consider for regulation, and determine whether the selected contaminants meet the statutory criteria for regulating.”).

Petitioners contest EPA’s determination that the Index PFAS—specifically HFPO-DA, PFNA, and the Index PFAS when co-occurring—occur with a frequency and at levels of public health concern. Utility Br. Part III; Industry Br. Part II.C.1, III.A (asserting specifically that HFPO-DA does not qualify as a public health concern). Most of Petitioners’ arguments fault EPA for using allegedly flawed state monitoring data and for not awaiting additional occurrence data from the Fifth Unregulated Contaminant Monitoring Rule (“UCMR 5”). Utility Br. 42-43; *see, e.g.*, Industry Br. 47.

Both of Petitioners’ criticisms misconstrue EPA’s duty under the Act. First, the Act requires the “best available” data and does not require—or expect—statistical perfection. *See* 42 U.S.C. § 300g-1(b)(1)(B)(ii) (determinations “shall be based on the best *available* public health information” (emphasis added)). Second,

the Act does not require EPA to await future data before regulating. *See Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000) (“EPA cannot reject the ‘best available’ evidence simply because of the possibility of contradiction in the future by evidence unavailable at the time of action—a possibility that will always be present.”).

EPA reasonably exercised its discretion when assessing occurrence data for the Index PFAS and identifying them as contaminants of public health concern. *See* 89 Fed. Reg. 32,555 (“[T]he agency emphasizes that occurrence and co-occurrence of these PFAS is not only at a regional or local level, rather it covers many states throughout the country; therefore, a national level regulation is necessary to ensure all Americans served by PWSs are equally protected.”). EPA’s brief explains in detail how the Agency evaluated the available data and considered the occurrence of HFPO-DA, PFNA, and the Index PFAS. *See* EPA Br. 39-40 (outlining the six factors EPA used when evaluating the available occurrence data). Furthermore, EPA explains that Petitioners have misstated the occurrence data and that the state-provided occurrence data demonstrated frequent co-occurrences of the Index PFAS. *Compare* Industry Br. 40 (“Co-occurrence of even three of the Index [PFAS] is extremely rare”), *with* EPA Br. 59-60 (identifying 1% of sampled water systems with all four Index PFAS and 25.9% of water systems with three Index PFAS).

State Amici concur that these contaminants appear with a frequency, and at levels, that create a public health concern. Occurrence of the Index PFAS is national in scope and each of these contaminants appears within numerous states, including in transboundary waterways. *See, e.g.*, 89 Fed. Reg. 32,557 (noting that available state data showed HFPO-DA detections in 75 systems across 13 states); *see also* Utility Br. 46 (attributing potential HFPO-DA detections to the Ohio River). Many of the State Amici have demonstrated their concern about these contaminants by issuing drinking water testing orders, regulations, and health advisories. For example, the Connecticut Department of Public Health issued advisory health-based “Action Levels” in June 2022 and June 2023 for a total of ten PFAS, including HFPO-DA, PFNA, PFHxS, and PFBS.²³

Since 2019, California has issued several general orders to public water systems to monitor PFAS. The orders have expanded from a focus on at-risk systems to a broader range of systems and require responsive action from systems that exceed the state-set PFAS response levels.²⁴ California established nonregulatory, health-based notification and response levels for PFHxS and PFBS,

²³ Connecticut Department of Public Health, *Per- and Polyfluoroalkyl Substances (PFAS) – Information for Public Water Systems* (last visited Jan. 17, 2025), <https://portal.ct.gov/dph/drinking-water/dws/per--and-polyfluoroalkyl-substances>.

²⁴ *See* California State Water Resources Control Board, *PFAS DDW General Orders* (last updated Mar. 11, 2024), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/pfas_ddw_general_order/.

which are represented in the Hazard Index. The human health risk assessment, on which the notification and response levels are based, determined that children were the most vulnerable population.²⁵

III. The Hazard Index is an Appropriate and Reasonable Tool that is Necessary Under the Safe Drinking Water Act.

Petitioners erroneously assert that the Rule's hazard index is an unreasonable and illegal form of Standard.²⁶ To the contrary, hazard indices are established and prevalent tools in environmental regulation. Moreover, because EPA identified dose-additive harms from co-occurring contaminants, EPA was obligated to use a hazard index in the Rule.

A. The Hazard Index is an Established and Practical Means to Evaluate Contaminant Levels and Risk.

The Rule establishes a Goal and a Standard for mixtures of the Index PFAS using a hazard index, which creates a level that reflects the measured amount of any of the four Index PFAS in a mixture and the individual toxicity of each. 89 Fed. Reg. 32,568. To calculate the index value of the contaminants, EPA set a "health-based water concentration" ("HBWC") for each of the Index PFAS, which is a ratio value "set at the level below which adverse effects are not likely to occur and allows for an adequate margin of safety." 89 Fed. Reg. 32,567-32,568; *see also*

²⁵ California State Water Resources Control Board, *supra* note 17.

²⁶ State Amici concur with EPA's argument that the Standards for PFOA and PFOS are feasible and lawful. EPA Br. Part III.A.

42 U.S.C. § 300g-1(b)(4)(A). The Goal and the Standard are both set at a unitless value of 1 on the hazard index. 89 Fed Reg. 32,532. The hazard index value is calculated by, first, dividing the measured concentration of each of the Index PFAS by its HBWC, which yields the “hazard quotient” for each PFAS in the sample, and then adding the hazard quotients together to determine whether they exceed the unitless value of 1. 89 Fed. Reg. 32,568.

Hazard indices are frequently used in environmental and public health contexts when contaminants that can produce similar “dose addition” effects, or similar health effects, are mixed.²⁷ The intention of the hazard index approach is to ensure that, “if the sum of the [hazard quotients] for an individual is kept below [1], then adverse [noncancer human health] effects are no more likely to occur than if each chemical’s exposure occurred separately.”²⁸ A hazard index can provide greater health protectiveness than individual limits that do not account for the additive and synergistic effects of commingled pollutants, and helps to manage the unique toxicological questions that such pollutants raise.

EPA has most notably used hazard indices in the Superfund program since 1982, evaluating sites under the “Hazard Ranking System” to determine the “potential hazard presented by releases or threatened releases of hazardous

²⁷ See, e.g., Price, P.S. *The Hazard index at thirty-seven: New science new insights*, 34 *Toxicology* 100388 (June 2023),

<https://www.sciencedirect.com/science/article/abs/pii/S2468202023000037>.

²⁸ *Id.*

substances.”²⁹ EPA’s Science Advisory Board considers the longstanding hazard index approach to be “validated” and “a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media.”³⁰

State-level environmental regulators have also adopted hazard indices where authorities must evaluate the human health risk from mixed or potentially mixed contaminants with additive adverse health effects. For example, California uses this approach with respect to remediation of hazardous substances to reduce noncancer risks for future users of contaminated sites.³¹ California also uses a method similar to a hazard index, called an “MCL-equivalent,” to set treatment goals for the direct domestic use of extremely impaired water sources.³² Likewise, Minnesota applies a hazard index approach to remediation of numerous

²⁹ National Oil and Hazardous Substances Contingency Plan, 47 Fed. Reg. 31,180, 31,187 (Jul. 16, 1982); see EPA, *Hazard Ranking System (HRS)* (last updated Oct. 9, 2024), <https://www.epa.gov/superfund/hazard-ranking-system-hrs>.

³⁰ EPA, Science Advisory Board, *Review of EPA’s Analyses to Support EPA’s National Primary Drinking Water Rulemaking for PFAS, Final Report* at 91 (2022), EPA-HQ-OW-2022-0114-3107.

³¹ 22 Cal. Code Regs. 68400.5; see also California Department of Toxic Substances Control, *DTSC Toxicity Criteria Rule for Human Health Risk Assessments* (last visited Jan. 17, 2025), <https://dtsc.ca.gov/toxicity-criteria-rule-for-human-health-risk-assessments-faq/>.

³² See California State Water Resources Control Board, Division of Drinking Water, Process Memo 97-005-R2020, *Revised Guidance for Direct Domestic Use of Extremely Impaired Sources* (1997), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/docs/process_memo_97-005-r2020_v7.pdf.

contaminants in groundwater.³³ States also frequently use hazard indices to assess risks in air quality and air quality monitoring from industrial facilities burning hazardous waste, such as in Oregon and Colorado.³⁴

Many states have arrived at the same conclusion as EPA that the health risks of PFAS cannot be addressed in isolation, and accordingly now regulate PFAS in drinking water and other media under a hazard index or in summation.³⁵ For example, Wisconsin has developed a health-based hazard index level of one for seventeen types of PFAS, which is used in various regulatory programs that impact groundwater. Maine, Massachusetts, and Vermont have established drinking water standards for sums of PFAS, which include some of those regulated under the Rule: PFOA, PFOS, PFNA, and PFHxS.³⁶ Minnesota has set enforceable Health Risk Limits for individual PFAS contaminants in drinking water and uses a hazard index for mixtures of those contaminants.³⁷

³³ Minn. Admin. R. 4717.7810 to 4717.7900.

³⁴ Or. Rev. Stat. 468A.335, 468A.337, and Or. Admin. R. ch. 340, div. 245; 6 Colo. Code Regs. 1007-3, sec. 264.342.

³⁵ See ECOS, *supra* note 7.

³⁶ (Maine) Resolves 2021, ch. 82; The Massachusetts Drinking Water Regulations, 310 CMR, § 22.00; Water Supply Rule, 12 Code Vt. R. § 12-030-003.

³⁷ Minnesota Department of Health, *Evaluating Concurrent Exposures to Multiple Chemicals* (Oct. 3, 2022), <https://www.health.state.mn.us/communities/environment/risk/guidance/gw/additivity.html>.

B. The Hazard Index Is the Most Practical Means to Prevent Dose-Additive Harms from PFAS Mixtures.

State Amici agree with EPA's sound conclusion that the Hazard Index "is the most practical approach for establishing [a Goal] for PFAS mixtures that meets the statutory requirements outlined in section 1412(b)(1)(A) of SDWA." 89 Fed. Reg. 32,568; *see* 42 U.S.C. § 300g-1(b)(1)(A). Because EPA has identified dose-additive health effects when the Index PFAS are found in combination, EPA *had* to use a hazard index to protect public health to the greatest extent feasible.

EPA's evaluation of the "best available public health information" determined that, not only do the Index PFAS each have an adverse effect on human health, but they also have dose-additive effects that can result in the same adverse health outcomes in combination. 89 Fed. Reg. 32,543; EPA Br. 62 ("[E]xposure to each of the four PFAS leads to endocrine, liver, and kidney toxicity."). The Science Advisory Board supported that conclusion by agreeing with EPA's evaluation of contaminants based upon similar health outcomes and noted that "many PFAS, including the four used in the examples in the draft EPA mixtures document and others, elicit effects on multiple biological pathways that have common adverse outcomes in several biological systems." 89 Fed. Reg. 32,569.³⁸

EPA recognized that promulgating Goals and Standards for individual contaminants would not address the dose-additive effects that may occur when

³⁸ EPA, Science Advisory Board, *supra* note 31 at 91.

those contaminants co-occur at concentrations below their respective Standards. 89 Fed. Reg. 32,543. Having concluded that the Index PFAS have dose-additive effects when in combination, EPA therefore cannot promulgate a Goal to avoid adverse human health effects and allow a margin of safety without the hazard index because promulgating individual Goals for the Index PFAS alone would be insufficient to meet the requirements of the Act. *See* 42 U.S.C. § 300g-1(b)(4)(A). EPA had to use the hazard index to address the relative toxicity and common health risks of these PFAS in order to comply with the plain language and proactive purposes of the Act.

Petitioners object to the hazard index on various grounds. However, Petitioners are incorrect as to each, as explained below.

First, Industry Petitioners object to the hazard index because the Act allegedly only permits regulation of single contaminants in isolation. Industry Br. 31-33. But as explained in EPA's brief, that interpretation contradicts the broad language chosen by Congress, as well as the longstanding interpretation that the Act permits EPA to regulate multiple contaminants together. EPA Br. 28-29 (citing past EPA rulemakings to regulate as groups disinfection byproducts, radionuclides, polychlorinated biphenyls, and asbestos). Furthermore, EPA cannot set appropriate Goals if it may only consider contaminants in isolation and must ignore threats to public health arising from mixtures of contaminants with dose-additive effects. *See*

42 U.S.C. § 300g-1(b)(4)(A). That deleterious outcome would be inconsistent with the requirements of the Act.

Second, Petitioners criticize EPA for using a mathematical equation as a Standard and erroneously characterize all drinking water Standards as “a fixed number” that are “expressed and described as a concentration level.” Utility Br. 34-35. Nothing in the Act supports Petitioners’ arbitrary limitations on Standards. In fact, the use of the hazard index is entirely consistent with the diversity of Standards that EPA has promulgated over decades. Curiously, Utility Petitioners provide their own exception to their mathematical equation argument: EPA regulates sums of radionuclides under the Act, requiring water systems to add together the measured values of individual contaminants. *Id.* at 34; *see also City of Waukesha v. EPA*, 320 F.3d 228, 232 (D.C. Cir. 2003). The 1991 radionuclides regulations address the isotopes radium-226 and radium-228 by combined picocuries/liter, all beta/photon emitters by combined millirems effective dose equivalent, and naturally occurring uranium by micrograms per liter. *City of Waukesha*, 320 F.3d at 231-32. Picocuries measure the rate at which radioactive compounds disintegrate and millirems measure “the dose of radiation an individual receives from a certain type of exposure.” *Id.* at 232, n. 1 and 2. EPA thus has long employed a diversity of Standards that are no less complex than the hazard index.

Third, Petitioners assert that a hazard index approach is only suitable for “screening.” Utility Br. 36-40; Industry Br. 41. But any review of the Act should make clear that “screening”—however Petitioners choose to define it—is exactly what Congress commands the Agency to do. Consider the mandate for Goals, which must be set at the level at which “no known or anticipated adverse effects on [human health] occur *and which allows an adequate margin of safety.*” 42 U.S.C. § 300g-1(b)(4)(A) (emphasis added). Standards are then set as close to that precautionary value as possible. *Id.* § 300g-1(b)(4)(B). The Act is designed to eliminate, to the extent appropriate according to the information available to EPA at that time, any risk to human health. To the extent that Petitioners cite commentary that hazard index screening can identify what contaminants should be further investigated, that commentary serves as no limitation on the ability of EPA to set regulations at this time with the information available to it.

IV. EPA Complied with the Procedural Requirements of the Act.

Under the plain language of the Act, EPA complied with the procedural requirements to issue the Rule. Petitioners misconstrue the statutory language’s procedural requirements with respect to sequencing and incorrectly conflate the Act’s feasibility analysis with a cost-benefit analysis.³⁹

³⁹ State Amici concur with EPA that Petitioners’ other procedural objections to the Rule fail. *See, e.g.,* EPA Br. 72 (explaining that EPA adequately considered

A. EPA Can Propose National Primary Drinking Water Regulations in Parallel with Determinations to Regulate.

Petitioners argue that the Act mandates a strictly sequential process that EPA violated by proposing regulations for the Index PFAS alongside the proposed determination to regulate them. Utility Br. Part I; Industry Br. Part II.B.1. This argument reads new requirements into the Act that are not in the Act's plain language. While the Act establishes a deadline to propose regulations—no later than 24 months after the final determination to regulate—it does not foreclose EPA proposing regulations sooner, including at the same time it renders a preliminary determination to regulate. *See* 42 U.S.C. § 300g-1(b)(1)(E). Petitioners' cramped reading would hamper EPA's ability to implement the Act.

The plain language of the provision at issue permits EPA to propose determinations and regulations in parallel. The provision instructs that EPA “shall propose [Goals and Standards] . . . not later than 24 months after the determination to regulate under subparagraph (B), and *may publish such proposed regulation concurrent with the determination to regulate.*” *Id.* § 300g-1(b)(1)(E) (emphasis added). This provision itself is silent as to whether “determination” means only the *final* determination, as Petitioners claim, or affords EPA latitude to propose standards at the same time *as either the proposed or final* determination, as EPA

alternative standards that were appropriate under the Act); *id.* at 92 (explaining that EPA adequately consulted the Science Advisory Board as required by the Act).

argues. Interpreting this language against the backdrop of the Act’s scheme as a whole readily shows that EPA’s reading is superior. *See United States Sugar Corp. v. EPA*, 113 F.4th 984, 993 (D.C. Cir. 2024).

The phrase “determination to regulate” does not uniquely refer to the *final* determination. The Act uses “determination to regulate” inconsistently across different provisions, and its meaning in a particular provision must therefore be gleaned from the surrounding words and context of that provision. *Cf. Catskill Mountains Chapter of Trout Unlimited, Inc. v. Env’t Prot. Agency*, 846 F.3d 492, 532 (2d Cir. 2017) (“[T]here is no requirement that the same term used in different provisions of the same statute be interpreted identically.”) (citing *Envtl. Def. v. Duke Energy Corp.*, 549 U.S. 561, 574–76 (2007)). For instance, in 42 U.S.C. § 300g-1(b)(1)(B)(iii), the very same phrase can only be read to refer to the *preliminary* determination. *See id.* (“Each document setting forth the determination for a contaminant ... *shall be available for public comment.*”). In contrast to subsection (b)(1)(B)(iii), nothing in subsection (b)(1)(E) tethers the option of “propos[ing] regulation concurrent with the determination to regulate” exclusively to the preliminary or final determination.

Unlike the Petitioners’ confused assertion, EPA’s reading provides a coherent meaning to subsection (b)(1)(E) as a whole. Interpreting “determination” in subsection (b)(1)(E) to mean “final determination” only, as Petitioners do,

renders the third clause of the paragraph mere surplusage. By expressly adding the option of proposing regulations “concurrent with the determination,” Congress makes clear that EPA need not move in a strict sequence and can instead elect to bundle a preliminary determination together with a proposed standard. *See* EPA Br. 33. If Congress wanted to specify a *single* starting point, as well as an endpoint, for the period in which EPA must propose regulations, it certainly could have as it did elsewhere in the Act. *See* 42 U.S.C. § 300j-7(a) (“shall be filed *within* the 45-day period beginning *on the date of the promulgation* of the regulation . . .”) (emphases added).

Finally, interpreting the Act to permit parallel publishing is consistent with the Act’s purposes. Parallel publishing enables EPA to advance to final rulemaking more quickly and better respond to emerging contaminants of concern that threaten human health. In addition, parallel publishing can yield a greater breadth of public comment at the determination stage than if EPA were to proceed in the four-step sequence Petitioners demand. *See* 89 Fed. Reg. 32,541-32,542. EPA’s process likely yielded a greater amount of public input and data to consider before issuing “final determinations” than if it followed a sequential process. *See id.* Petitioners claim they were entitled to two notice and comment periods instead of one, but do not argue their comments would have materially differed with an additional comment period. Indeed, all Petitioners commented on the combined proposal;

some of them more than once.⁴⁰ This practical reality only further weakens Petitioners' textual argument, and bolsters EPA's.

Petitioners' extratextual limitations undermine the public health goals of the Act. The correct reading of the Act does not insert sequential limitations that are absent from the statutory language. Under the correct reading, a proposed regulation may be issued concurrently with the preliminary determination to regulate, and no later than 24 months after a final determination to regulate. *See* 42 U.S.C. § 300g-1(b)(1)(E).

B. EPA's Economic Analysis and Determination Complied with the Requirements of the Act

Petitioners erroneously contend that the Rule must be vacated due to alleged flaws in EPA's economic analysis. Utility Br. Part IV; Industry Br. 14-23.

Petitioners misunderstand the role of the economic analysis required by 42 U.S.C. § 300g-1(b)(3)(C) specifically and the Act generally. The Act does not permit cost to be a consideration when determining to regulate, *id.* § 300g-1(b)(1)(A), or when establishing Goals. *id.* § 300g-1(b)(4)(A). EPA must *consider* costs as part of the feasibility analysis when setting Standards, but mere consideration of costs is different from the kind of cost-benefit analysis Petitioners demand. *Id.* § 300g-1(b)(4)(D); *see City of Portland v. EPA*, 507 F.3d 706, 712

⁴⁰ *See, e.g.*, Comment Submitted by American Water Works Association (Apr. 5, 2023), EPA-HQ-OW-2022-0114-1465; Comment Submitted by American Water Works Association (June 2, 2023), EPA-HQ-OW-2022-0114-1759.

(D.C. Cir. 2007) (rejecting the conflation of cost-benefit analysis with the Act’s feasibility analysis).

Petitioners appear to argue that any regulation must produce net positive quantifiable benefits over costs. *See, e.g.*, Industry Br. 18 (“EPA’s analysis does not reveal the expected quantifiable net benefit for any one substance taken alone”). On the contrary, the Act does not require benefits to exceed the quantified costs of rules. Instead, Standards are set “as close to the [Goal] as is feasible.” 42 U.S.C. § 300g-1(b)(4)(B).

This Court has already rejected any interpretation that conflates cost with feasibility. *See City of Portland*, 507 F.3d at 712 (“But if ‘feasible’ meant that the technique’s benefits justified its costs, section 300g-1(b)(6)(A) . . . would be surplusage.”). This interpretation of the Act is further evidenced by subsection (b)(6)(A), which gives EPA discretion to set a less stringent Standard than feasible when the benefits of a regulation “would not justify the costs”—but does not require it to do so. 42 U.S.C. § 300g-1(b)(6)(A).

Finally, Petitioners’ substantive criticisms of EPA’s economic analysis do not establish the Agency acted unreasonably. For example, Petitioners allege the Black & Veatch study that American Water Works Association submitted during the comment period demonstrates EPA underestimated costs. Utility Br. 54. But EPA thoroughly engaged with this study in its response to comments and included

three tables critiquing the assumptions made in the study. 89 Fed. Reg. 32,640-32,647. As extensively explained in the Rule, EPA found that numerous faulty assumptions led the study to overestimate the costs of the Rule. *Id.* EPA reasonably considered the study as a submitted comment but was not obligated to adopt its conclusions.

Given their policy interest in ensuring the provision of safe drinking water, and their role in operating their own water systems, Amici States appreciate the practical importance of affordability. Indeed, California already serves as the administrator for numerous financially struggling third-party water utilities and is keenly familiar with the fiscal challenges regulations can impose on such utilities.⁴¹ Although the Act limits cost considerations when promulgating national regulations, it includes tools to mitigate disparate impacts on water systems.⁴² EPA itself has already taken steps to lessen the burden of the Rule by extending the compliance deadline to the maximum allowable five years. *See* 42 U.S.C. § 300g-1(b)(10).

CONCLUSION

For the reasons set forth above, this Court should deny the Petitions.

⁴¹ California State Water Resources Control Board, *Water System Administrators: Community and Program Info* (last updated July 16, 2024), https://www.waterboards.ca.gov/water_issues/programs/hr2w/.

⁴² *See* 42 U.S.C. § 300g-4(e) (providing States with discretion to grant variances to small water systems); 42 U.S.C. § 300g-5 (providing States with discretion to grant water systems additional time to achieve compliance).

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I hereby certify that, on January 17, 2025, I electronically filed the foregoing Amicus Brief of the State Amici with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit via the CM/ECF system. Participants in the case who are registered CM/ECF users will be served electronically by that system.

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