ORAL ARGUMENT NOT YET SCHEDULED

Nos. 24-1188 (lead), 24-1191, 24-1192

United States Court of Appeals
District of Columbia Circuit

NATIONAL ASSOCIATION OF MANUFACTURERS & AMERICAN CHEMISTRY COUNCIL, *petitioners*,

– v. –

U.S. ENVIRONMENTAL PROTECTION AGENCY *and* MICHAEL S. REGAN, *in his official capacity as EPA Administrator*, *respondents.*

THE CHEMOURS COMPANY FC, LLC, *petitioner*,

– v. –

U.S. ENVIRONMENTAL PROTECTION AGENCY *and* MICHAEL S. REGAN, *in his official capacity as EPA Administrator*, *respondents.*

On Petition for Review of a Final Rule of the Environmental Protection Agency, 89 Fed. Reg. 32,532 (Apr. 26, 2024)

BRIEF FOR PETITIONERS NATIONAL ASSOCIATION OF MANUFACTURERS, AMERICAN CHEMISTRY COUNCIL, AND THE CHEMOURS COMPANY FC, LLC

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CERTIFICATE AS TO THE PARTIES, RULINGS, AND RELATED CASES

1. Petitioners are American Water Works Association and Association of Metropolitan Water Agencies (No. 24-1188); National Association of Manufacturers and American Chemistry Council (No. 24-1191); and The Chemours Company FC, LLC (No. 24-1192). Respondents are the United States Environmental Protection Agency and Michael S. Regan. Intervenors are the Natural Resources Defense Council, the Buxmont Coalition for Safe Water, Clean Cape Fear, Clean Haw River, Concerned Citizens of WMEL Water Authority Grassroots, Environmental Justice Task Force, Fight for Zero, Merrimack Citizens for Clean Water, and Newburgh Clean Water Project.

2. The consolidated petitions for review challenge the Environmental Protection Agency's final rule titled *PFAS National Primary Drinking Water Regulation*, 89-FR-32,532 (April 26, 2024).

3. The case was not previously before this or any other Court.

CORPORATE DISCLOSURE STATEMENT

The National Association of Manufacturers and American Chemistry Council both are nonprofit, tax-exempt advocacy and public policy organizations. Neither has a parent corporation or issues stock. The Chemours Company FC is a Delaware limited liability company wholly owned by The Chemours Company, a publicly traded corporation.

TABLE OF AUTHORITIES*

Cases

* Authorities upon which we chiefly rely are marked with asterisks.

Statutes and Regulations

42 U.S.C.

Other authorities

GLOSSARY OF ABBREVIATIONS

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
EPA (the agency)	Environmental Protection Agency
HFPO-DA	hexafluoropropylene oxide dimer acid
Index Substances	PFHxS, PFBA, PFNA, and HFPO-DA
MCL (a Level)	maximum contaminant level
MCLG (a Goal)	maximum contaminant level goal
NPDWR (a Regulation)	national public drinking water regulation
PFAS	per- and polyfluoroalkyl substances
PFBS	perfluorobutanosulfonic acid
PFHxS	perfluorohexanesulfonic acid
PFNA	perfluorononanoic acid
PFOA	perfluorooctanoic acid
PFOS	perfluorooctanesulfonic acid
ppt	parts per trillion & the equivalent of ng/L
SAB	Science Advisory Board
SDWA (the Act)	Safe Drinking Water Act
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 5	Fifth Unregulated Contaminant Monitoring Rule

INTRODUCTION

This case concerns new drinking water standards promulgated by the Environmental Protection Agency (EPA) under the Safe Drinking Water Act (the SDWA or Act). The final Rule establishes maximum contaminant level goals (MCLGs, or Goals) and maximum contaminant levels (MCLs, or Levels) for six substances within a broad family of chemicals known as PFAS. These are substances at the center of modern innovation and sustain many common technologies including semiconductors, telecommunications, defense systems, life-saving therapeutics, and renewable energy sources.

Petitioners support rational regulation of PFAS that allows manufacturers to continue supporting critical industries, while developing new chemistries and minimizing any potential environmental impacts. But that requires a measured and evidence-based approach that the Rule lacks.

Congress required as much when it enacted the SDWA. The Act requires EPA to follow strict, multi-step procedures and undertake detailed, multi-step analyses to justify regulation of any given substance. Recognizing that marginal benefits may impose prohibitive burdens for the public, the Act expressly requires the agency to weigh a proposed Level's foreseeable costs against its benefits. The Act also directs EPA to consider the feasibility of achieving any Level in light of costs and the limits of existing technologies, using the best available science. Here, EPA obscured the costs and benefits of each Level it

proposed by lumping them together, allowing the net positives of some to compensate for the net negatives of others. Beyond that, the agency failed to consider meaningful regulatory alternatives and refused to consider or respond to public comments that undercut its judgment.

Key aspects of the Rule exceed also EPA's statutory authority and flout the Act's express procedural requirements. The Rule purports to regulate undifferentiated *mixtures* of substances, using a "hazard index" approach that EPA has never before used in the Act's 50-year history and is not permitted by the statute's text. EPA also unlawfully collapsed two distinct rulemaking steps into a single step, forgoing Science Advisory Board review along the way. Congress baked those procedural safeguards into the Act not as mere formalities, but to discourage poor decision-making. This case proves the dangers of discarding them.

Finally, EPA's determination to regulate HFPO-DA was unsupported, as was the Level the agency selected for that substance. EPA lacked sufficient data to regulate HFPO-DA in the first place, and the Level it finalized was arbitrary and capricious several times over.

JURISDICTION

EPA promulgated the Rule under the Act. 42 U.S.C. § 300g-1. This Court has jurisdiction to review EPA's final rule under 5 U.S.C. § 702 and 42 U.S.C. § 300j-7(a)(1). Petitioners filed timely petitions for review on June

10, 2024, which is within 45 days of the final Rule's April 26, 2024, publication date. *See* 45 U.S.C. § 300j-7(a)(2).

ISSUES PRESENTED

1. Whether the Rule is unlawful or arbitrary and capricious for: (a) impermissibly combining multiple cost-benefit analyses into a single analysis; (b) failing to explain with evidence how the Rule's benefits justify its costs; (c) failing adequately to consider important factors bearing on the Rule's costs and feasibility; or (d) failing to consider reasonable regulatory alternatives and meaningfully respond to related comments.

2. Whether EPA's hazard index and Levels for three substances were statutorily authorized, procedurally unlawful, or arbitrary and capricious.

3. Whether EPA adequately supported its determination to regulate HFPO-DA at the selected Level.

STATUTES AND REGULATIONS

Relevant provisions are set out in an addendum to this brief.

STATEMENT

A. Legal background

1. The Act requires EPA to undertake a multi-step process for regulating previously unregulated contaminants. Every five years, EPA must publish a list of contaminants "which may require regulation." 42 U.S.C. § 300g-1(b)(1)(B)(i)(I). Listed contaminants are subject to reporting requirements

under the Unregulated Contaminant Monitoring Rule (UCMR), 40 C.F.R. §§ 141.35, 141.40(a). UCMR data must be maintained in a publicly available contaminant occurrence database. 42 U.S.C. § 300j-4(g)(1), (g)(5). The UCMR database must contain "monitoring information collected by [all] public water systems that serve a population of more than 10,000," as well as "from a representative sampling of public water systems that serve a population of 10,000 or fewer." *Id.* § 300j-4(g)(7)(A)-(B).

Every five years, EPA must evaluate whether to regulate at least five contaminants on the UCMR list. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I). Before EPA may regulate any substance, it must first make a determination to regulate. "[A]fter consultation with the scientific community, including [EPA's] Science Advisory Board, after notice and opportunity for public comment, and after considering the occurrence data base," it must "publish a list of contaminants which . . . *may* require regulation." 42 U.S.C. § 300g-1(b)(1)(B)(i)(I) (emphasis added). The statute refers to this notice of intent to make a determination as a "preliminary determination." *Id.* § 300g-1(b)(1)(B)(ii)(I).

The Act requires the agency next to issue a final "determination to regulate," which is necessary for further regulatory steps. *Id.* § 300g-1(b)(1)(B)(ii)(I). The agency may regulate only where a contaminant 1) "may have an adverse effect on the health of persons," 2) "is known to occur or there is a substantial likelihood that the contaminant will occur in public

water systems with a frequency and at levels of public health concern," and 3) where regulation "presents a meaningful opportunity for health risk reduction." *Id.* § 300g–1(b)(1)(A)(ii). These findings "shall be based on the best available public health information, including the occurrence data base established under section 300j-4(g) of this title." *Id.* § 300g–1(b)(1)(B)(ii)(II).

The final determination to regulate must follow a separate "notice of the preliminary determination and opportunity for public comment" upon it. *Id.* § 300g-1(b)(1)(B)-(ii)(I). Only after (or with) a final determination to regulate may EPA proceed to propose regulatory standards for the identified contaminants. *Id.* § 300g-1(b)(1)(E).

For each contaminant EPA decides to regulate, the Act next requires it to set a "maximum contaminant level *goal*," or Goal, "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) (emphasis added). EPA then must promulgate a National Primary Drinking Water Regulation (Regulation) that, among other options, sets a "maximum contaminant *level*," or Level, "as close to the [Goal] as is feasible." *Id.* § 300g-1(b)(4)(B) (emphasis added).

2. The Act requires EPA to make two additional findings before finalizing any Regulation of a contaminant: that each proposed Level is justified by its benefits relative to its costs, and that the Level is feasible. The Act thus

requires EPA to analyze, publish, and seek comment on the "[q]uantifiable and nonquantifiable health risk reduction *benefits*" likely to result from compliance with a proposed Level, along with the "[q]uantifiable and nonquantifiable *costs*" of complying with the Level, "including monitoring, treatment, and other costs." *Id.* § 300g-1(b)(3)(C)(i)(I)-(III) (emphasis added). EPA also must address "[t]he incremental costs and benefits associated with each alternative [Level] considered." *Id.* § 300g-1(b)(3)(C)(i)(IV).

EPA must determine "whether the benefits of the [Level] justify, or do not justify, the costs" based on the analysis above. *Id.* § 300g-1(b)(4)(C). If anticipated costs *do* outweigh the benefits, "the Administrator may, after notice and opportunity for public comment, promulgate" an alternative Level "for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits" (*id.* § 300g-1(b)(6)(A)) or elect not to promulgate a regulation. The Act requires that EPA use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" when making any decisions regarding establishing Regulations. *Id.* § 300g-1(b)(3)(A).

The Act requires EPA to set a Level as close to the corresponding Goal "as is *feasible*." *Id.* § 300g-1(b)(4)(B) (emphasis added). Feasible is defined to mean "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy

under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)." *Id.* § 300g-1(b)(4)(D).

EPA must "list the technology, treatment techniques, and other means" it "finds to be feasible" for achieving the Level. *Id.* § 300g-1(b)(4)(E)(i). And it must separately "list any technology, treatment technique, or other means that is affordable, as determined by the Administrator in consultation with the States, for small public water systems." *Id.* § 300g-1(b)(4)(E)(ii).

B. Factual and rulemaking background

1. PFAS are a class of synthetic compounds commonly used in consumer, commercial, and industrial products for their resistance to heat, water, and stains. There are thousands of different kinds of PFAS. For the present rulemaking, EPA first published a preliminary determination to regulate two PFAS substances: PFOA and PFOS. *See* 85-FR-14098, 14120 (Mar. 10, 2020). But it did not issue a preliminary determination to regulate any other PFAS substance at that time, stating it "plan[ned] to consider available human health toxicity and occurrence information for other PFAS as they become available." *Id.*

2. EPA issued a final determination to regulate PFOA and PFOS. *See* 86-FR-12272, 12276 (Mar. 3, 2021). It also confirmed its intent to "make regulatory determinations for additional PFAS" in the near term, for any compound "where sufficient information is available." 86-FR-12279.

EPA submitted its final determination to regulate PFOA and PFOS to its Science Advisory Board (SAB), which includes independent experts in the field. The SAB raised serious concerns with EPA's scientific analysis and conclusions. It "identified multiple inconsistencies and deficiencies in both the description and execution of the systematic review process utilized in the evaluation of both PFOA and PFOS" and raised "significant concerns that the reviews for PFOA and PFOS do not appear to have established a predefined protocol." SAB.Report 3 (JA__). It also took issue with the agency's substantive scientific analysis, calling it "unclear," "inconsistent," "confus[ing]," and in critical respects "unjustified," ultimately "recommend[ing] several changes" to the agency's work. SAB.Report 3-5 (JA__-__).

3. EPA issued a notice of proposed rulemaking for PFOA and PFOS two years after the final determination to regulate and approximately one year after the SAB's report was finalized. *See* 88-FR-18638 (Mar. 29, 2023). It did not meaningfully alter its analysis and proposed setting a Goal for both compounds at zero. It proposed setting Levels for both at 4.0 parts per trillion (ppt) as the lowest feasible level, considering costs. 88-FR-18638.

In the same regulatory action, EPA issued a "preliminary regulatory determination" to regulate four additional PFAS molecules: PFHxS, HFPO-DA, PFNA, and PFBS. *Id.* For simplicity's sake, we refer to these collectively as the Index Substances.

Simultaneously with this "preliminary determination," EPA proposed a Goal and Level for mixtures of these four substances. But it did not propose Goals or Levels for any of the Index Substances *individually*. Unlike its approach to PFOA and PFOS—or, for that matter, to any other compound it has regulated under the Act—EPA instead proposed a combined Goal and Level "expressed as" a *hazard index*, with a unitless value of 1.0 for any mixture of two or more of the Index Substances. 88-FR-18668.

EPA has defined a hazard index as "the sum of [hazard quotients]" for a mixture of substances. *Id.* A hazard quotient is "the ratio of potential exposure to a substance and the level at which no health effects are expected." *Id.* In other words, a hazard index purports to define when a substance may be harmful only insofar as it appears with other substances. 88-FR-18639. EPA has used a hazard index approach in other contexts, including under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)—which, unlike the Act, expressly provides for regulation of mixtures. But it has never before used a hazard index for a Regulation under the Act.

EPA requested comments on whether to promulgate individual Goals and Levels for the four PFAS covered by the hazard index. *See* 88-FR-18671.

4. One year later, EPA published a final Rule, finding that the Rule's benefits justify its costs. 89-FR-32532 (Apr. 26, 2024). The agency finalized the proposed Goals and Levels for PFOA and PFOS without change. *Id.* at

32532. It also finalized a 1.0 hazard index for mixtures of two or more of the four Index Substances. And EPA both proposed and finalized Goals and Levels for three of the Index Substances (PFHxS, PFNA, and HFPO-DA) taken individually. *Id.*

SUMMARY OF ARGUMENT

I. EPA's cost-benefit analysis was unlawful. The Act does not permit EPA to combine cost-benefit analyses for individual Levels into a group determination; to do so allows it to hide unjustified Levels behind other, more easily justified ones. Plus, EPA's cost-benefit analysis failed to account for a number of costs brought to the agency's attention, including costs of the hazard index and Levels for individual Index Substances. EPA's review of nonquantifiable benefits could not make up the difference. A nonquantifiable benefit is a qualitative one that can't be measured. EPA relies on quantifiable benefits lacking evidence; but these are not "nonquantifiable"—they are just unsupported.

EPA next failed adequately to consider important aspects of the Rule's feasibility. For instance, the agency ignored that there is insufficient laboratory capacity for all water systems to measure Rule compliance. Water systems also lack sufficient staff and facilities. Overcoming these problems is prohibitively expensive, but EPA did not consider them. It also declined to respond to public comments bearing on more reasonable Levels.

II. The hazard index and individual Levels for the Index Substances are unlawful. To start, the Act does not authorize EPA to regulate mixtures through a "hazard index," which is a break from 50 years of practice. The Act requires regulation of substances one at a time.

The hazard index and individual Levels for the Index Substances are also procedurally defective. EPA may not announce a preliminary determination to regulate at the same time it proposes Goals and Levels, and EPA did not consult the SAB, which the statute requires it to do. These procedural checks are not mere niceties, and EPA's failure to follow them dooms the Rule.

The hazard index is not supported by substantial evidence, either. EPA did not demonstrate a substantial likelihood of co-occurrence among the Index Substances, nor did it prove that combinations of Index Substances below the Levels adversely affect human health.

III. EPA's regulation of HFPO-DA, in particular, was unlawful. EPA first erred in concluding that HFPO-DA occurs in public water systems with a frequency and at levels of public health concern. The evidence does not bear out that finding, and EPA ignored UCMR data undermining its conclusions—despite two separate congressional instructions to consider such data. No alternative federal or state data sources support EPA's determination to regulate HFPO-DA. Beyond that, the Level for HFPO-DA is arbitrary and capricious because EPA relied on uncertainty factors that deviate from its own

standard methods and ignored relevant evidence. The HFPO-DA Level also relies on a flawed exposure assumption, toxicological effects on rodent livers that are irrelevant to humans, and a novel toxicological endpoint to generate an artificially low reference dose.

STANDING

An association must demonstrate that its members would have standing to sue in their own right, that the interests advanced in the suit are germane to the organization's purpose, and the participation of individual members is not necessary. *Sierra Club v. FERC*, 827 F.3d 59, 65 (D.C. Cir. 2016).

Petitioners in No. 24-1191—the National Association of Manufacturers and American Chemistry Council—are trade associations that regularly represent the interests of their members in litigation challenging agency rulemakings. Their members manufacture PFAS, and use PFAS in manufacturing other substances and products, and face imminent risk of harm from the Rule. *See* Addendum B2-12.

Petitioner in No. 24-1192 is The Chemours Company, a chemical manufacturer and member of ACC. It manufactures and uses HFPO-DA, one of the PFAS at issue here. *See* Addendum B13-16.

The Rule causes concrete and immediate harm to current and former manufacturers and industrial users of the regulated PFAS.

First, state-court plaintiffs have relied on the Levels and Goals established by the Rule as a benchmark for liability under state law. *See* Addendum B4-5, 10. The Rule is already having an immediate impact on defendants in state-law suits, including petitioners' members, who face heightened risk of liability and greater financial exposure.

Second, the Rule bears on liability under CERCLA. *See* 89-FR-39124 (May 8, 2024) (designating PFOA and PFOS as "hazardous substance[s]" under CERCLA). Levels established by regulation under the Act generally provide "a relevant and appropriate standard" for determining liability for remedial action under CERCLA. 42 U.S.C. § 9621(d)(2)(A). Industrial users of PFOA and PFOS may face CERCLA liability where they have released or disposed of those substances. This Court has long recognized that exposure to CERCLA liability satisfies the injury-in-fact requirement to confer standing to challenge Regulations under the Act. *See Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1289-1290 (D.C. Cir. 2000); *International Fabricare Institute v. EPA*, 972 F.2d 384, 390 (D.C. Cir. 1992).

STANDARD OF REVIEW

This Court must set aside agency regulations that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or that are "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706. An action is arbitrary or capricious "if it is not 'reasonable and

reasonably explained.'" *Ohio v. EPA*, 144 S.Ct. 2040, 2053 (2024) (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). The Court "must ensure, among other things, that the agency has offered 'a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made,'" and that it did not "ignore 'an important aspect of the problem.'" *Id.* (quoting *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance*, 463 U.S. 29, 43 (1983)).

On questions of statutory interpretation, the Court "must apply what [it] regard[s] as the statute's 'best' reading" without affording the agency's interpretation any special deference." *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 991 (D.C. Cir. 2024) (citing *Loper Bright Enterprises v. Raimondo,* 144 S.Ct. 2244, 2266 (2024)).

ARGUMENT

I. EPA DID NOT ADEQUATELY SUPPORT THE LEVELS SELECTED

A. The agency's cost-benefit determination is substantively unlawful and disregards important factors.

The Act specifies that EPA must determine "whether the benefits of" a proposed Level "justify, or do not justify, the costs" of compliance with the Level. 42 U.S.C. § 300g-1(b)(4)(C). In this case, EPA's reported cost-benefit analysis favored the Rule by an economic hair—just $760,000 annually, or about $2,080 daily. 89-FR-32709, Table 68. For a sector of the economy that

moves hundreds of *billions* of gallons of water each day at a daily cost of more than *$1 billion*, a $2,080 daily national benefit is less than a rounding error; it's essentially zero. And with a margin that thin, virtually any cost that EPA failed to consider is likely to tip the scale against the Rule. There were many such costs. In fact, the agency's cost-benefit analysis is pervaded by legal errors and shoddy empirical work. That alone calls for vacatur of the entire Rule.

1. The Act does not permit EPA to combine the cost-benefit analyses for individual Levels into a group determination

a. EPA first departed from the statutory text by lumping substances together into a single cost-benefit analysis. The Act directs EPA to consider each proposed Level taken alone and thus calls for individual, substance-by-substance analyses.

The text makes this clear. Paragraph (b)(4)(C) uses the singular when directing EPA to conduct an analysis of "whether the benefits of *the* maximum contaminant level justify, or do not justify, the costs" of *the* Level. 42 U.S.C. § 300g-1(b)(4)(C) (emphasis added). Likewise using the singular, the statute directs that "[f]or *each* contaminant that [EPA] determines to regulate," it "shall publish *a* maximum contaminant level goal and promulgate *a* national primary drinking water regulation." *Id.* § 300g-1(b)(1)(E). And it specifies further that, "[w]hen proposing any national primary drinking water regulation that includes *a* maximum contaminant level, the Administrator shall, with

respect to *a* maximum contaminant level that is being considered," address certain factors. 42 U.S.C. § 300g-1(b)(3)(C) (emphasis added). The word "each" means "every (one) of two or more considered individually." *Collins English Dictionary* 621 (14th ed. 2023) (hereinafter, *Collins*); *accord Websters Third New International Dictionary* 713 (2002) (hereinafter, *Websters*) ("one of two or more distinct individuals having a similar relation" and "considered one by one").

Use of the singular, together with the word "each," indicates that EPA must conduct a cost-benefit analysis for every Level it proposes, taken alone. The language does not permit the agency to combine the costs and benefits of Levels for multiple substances into a single analysis, allowing the net positive effect of some to offset the net negative effects of others.

b. EPA undertook no such substance-by-substance analysis here. Instead, the agency "determined" with respect to the proposed Levels as an undifferentiated group that "the benefits justify the costs for [Levels] set as close as feasible to the [Goals]." 89-FR-32651. Throughout its cost-benefit analysis, it thus combined the costs and benefits for all five individually regulated substances and the hazard index, taken together. *E.g.*, 89-FR-32691 (Table 58); 32709 (Table 68); EA Appendices Table C-5 (JA__). Elsewhere, it provided cost and benefit estimates for PFOA and PFOS taken together, while omitting the hazard index and Index Substances. *E.g.*, 89-FR-32707, 32710;

EA Appendices Table C-6 (JA__). But nowhere in either the notice or the preamble to the final Rule did the agency undertake cost-benefit analyses individually for each substance.

This case readily demonstrates the problem with that approach. The preamble shows that the expected total net benefits from just the "PFOA and PFOS MCLs," taken together, was $5.67 million annually. 89-FR-32710 (Table 69). But it also shows that adding the hazard index and individual Index Substance Levels *reduces* the total net benefits from $5.67 million to just $760,000. 89-FR-32709 (Table 68). By implication, the net benefit from regulating the Index Substances is *negative* $4.9 million annually—meaning that they are not justified, even as a group.

Along similar lines, analyzing PFOA and PFOS together overstates the benefits of regulating PFOS. For example, a major element of EPA's benefit analysis for PFOA and PFOS is alleged cardiovascular disease reduction. Cardiovascular disease reduction depends on EPA's calculation of the impact of reduction of total cholesterol. Even assuming EPA's analysis on this score is accurate, which petitioners dispute, the impact on total cholesterol from reducing PFOS is nearly two orders of magnitude *less* than the same reduction EPA calculated for PFOA. *See* 89-FR-32683. By considering the cost-benefit of PFOA and PFOS together rather than individually, EPA obscures these variable costs and benefits of regulating individual substances.

At bottom, EPA's analysis does not reveal the expected quantifiable net benefit for any one substance taken alone. It is commonsense that each Level for each substance will have its own cost-benefit profile. That is why Section 300g-1(b) expressly requires EPA to undertake individual cost-benefit analyses for "each" Level, in the singular. Combining analyses (as EPA has done here) is too simple an expedient to promulgate a manifestly unjustified Level, obscuring net negative effects using the net positive effects of the other Levels proposed in the same rule.

2. EPA's cost-benefit analysis failed to account for a number of costs brought to the agency's attention

Even supposing the Act permits EPA to combine its cost-benefit analyses (it does not), its analyses are arbitrary and capricious on their own terms.

a. Treatment costs for HFPO-DA, PFNA, and PFBS. EPA calculated yet expressly omitted treatment costs for PFNA, HFPO-DA, and PFBS. When these costs are properly considered, the Rule's net benefits no longer exceed its costs, as the agency reported. *See* 89-FR-32709 (Table 68).

EPA employed a different method to calculate treatment costs for HFPO-DA, PFNA, and PFBS than for the other substances. It asserted that it "had insufficient nationally representative data to precisely characterize [their] occurrence," so it instead conducted a "sensitivity analysis" to approximate treatment costs for those three substances and the hazard index. 89-FR-

32533; *see also* EA App. N-4 thru N-5 (JA__-__). Based on that analysis, EPA concluded that treatment costs for these compounds would likely enlarge the Rule's annually recurring costs by around $82 million. *See* 89-FR-32650, 32713; EA App. N-5 thru N-6 (JA__-__).

EPA omitted these results from the Rule's total quantified cost calculation. Its only explanation was to insist that its calculations omitting them were only "marginally underestimated," and if the added costs were considered, it would not change the cost-benefit outcome. *See* 89-FR-32650; EA Appendices N-6 (JA__). That makes no sense. An $82 million cost, compared with a $760,000 benefit, can hardly be dismissed as marginal. Including that cost made the Rule's overall net benefit substantially negative. That is arbitrary and capricious decision-making in its clearest form.

b. Underinclusive data. EPA's "primary dataset" to estimate the number of systems that will be affected by the Rule (and thus incur compliance costs) was collected through the agency's Third Unregulated Contaminant Monitoring Rule (UCMR 3). *See* EA 4-25 (JA__). "The UCMR is a national drinking water monitoring program administered by the EPA." *Id.* at 4-21. Many PFAS are subject to UCMR reporting requirements. 40 C.F.R. §§ 141.35, 141.40(a).

Based primarily on the data water systems reported through UCMR 3, EPA estimated that approximately 7.7% of water systems would incur

compliance costs under the Rule. *Id.* But UCMR 3's reporting thresholds (between 20 and 90 ppt) are far higher than the compliance levels in the Rule. *See* 77-FR-26072, 26099 (Table 1) (May 2, 2012). UCMR 3 would not have captured water systems with PFAS occurrences below the higher UCMR 3 levels, leading EPA to underestimate the number of systems impacted by the Rule within the range with the least benefits and highest costs.

The monitoring levels for the Fifth UCMR (UCMR 5), which has a study period of 2023-2025, more closely match the Rule's Levels. *See* 86-FR-73131, 73156 Table 1 (Dec. 27, 2021). EPA analyzed the UCMR 5 data available to date, which confirms that the number of systems that will incur major costs is higher than the number that EPA took into account in its economic analysis. Indeed, sample-level analysis of UCMR 5 data suggested that 15.8% of systems saw PFAS at levels between UCMR 3 and the Rule—the range in which costs of compliance are greatest and benefits are least. 89-FR-32601. EPA was obligated to use "the best available evidence at the time of the rulemaking" (*Chlorine Chemical Council*, 206 F.3d at 1291), but it did not do so.

3. EPA's consideration of "nonquantifiable" benefits spurned the statute's text and was arbitrary and capricious

EPA will say that our challenge to its cost-benefit analysis disregards the Rule's nonquantifiable benefits. And true, the Act directs EPA to consider both "[q]uantifiable and nonquantifiable health risk reduction benefits." 42

U.S.C. § 300g-1(b)(2)(C)(i). But EPA has misconstrued what Congress meant by "nonquantifiable" benefits. The term means benefits that by their nature cannot be measured. It does not mean benefits that *can* be measured but as to which the agency lacks sufficient evidence or data to make an adequately supported measurement.

a. The dictionary definition of "nonquantifiable" bears this out. *See Taniguchi v. Kan Pacific Saipan, Ltd.*, 566 U.S. 560, 566 (2012) ("When a term goes undefined in a statute, we give the term its ordinary meaning," principally by reference to "dictionaries."). Something is nonquantifiable when it is "not capable of being quantified." *Collins* 1353.

A factor incapable of being measured turns on behaviors and lived experience, not numeric measurement. These factors are addressed by qualitative research, which is common in the healthcare context and "involves broadly stated questions about human experiences and realities" using "descriptive data [to] help . . . understand those individual[s'] experiences." Vishnu Renjith, et al., *Qualitative Methods in Health Care Research*, 12 International Journal of Preventive Medicine 1, 1 (2021). It "is widely used to understand patterns of health behaviors, describe lived experiences, develop behavioral theories, explore healthcare needs, and design interventions." *Id.*

The beneficial role of qualitative research in a cost-benefit analysis under the Act is easy to see. Using qualitative data, EPA might give greater

weight in its cost-benefit analysis to avoiding incidents of Effect 1 rather than Effect 2 if the evidence shows that living with Effect 1 is painful or uncomfortable, whereas living with Effect 2 is not. Reducing the risk of Effect 1 thus would produce greater *nonquantifiable* benefits than reducing the risk of Effect 2, even if it would not also increase the *quantifiable* economic benefits. EPA might therefore use this nonquantifiable benefit to justify incurring greater costs to avoid Effect 1 rather than Effect 2.

b. In EPA's view, a benefit is "nonquantifiable" when it *is* capable of being quantified, but the agency "lack[s] the economic or other information needed for a quantitative analysis." EA 1-3 (JA__). It thus purported here to "evaluat[e] nonquantifiable costs" by engaging in a supposedly "qualitative discussion" of factors for which its data did not allow for reliable quantification. 89-FR-32649-32650.

There are two problems with this approach. First, a factor is not "unquantifiable" simply because the agency lacks the empirical evidence needed to make a reliable measurement. A quantifiable factor as to which there is "inadequate data" (89-FR-32638) is simply *unsupported*—meaning that to rely on it would be arbitrary and capricious. The solution is simply to get adequate data.

That leads to the second problem: EPA took Congress's direction to consider "nonquantifiable" benefits as an invitation to engage in pure guesswork.

It was candid about this: Throughout its "nonquantifiable" effects analysis—which lacked any discussion of qualitative effects—EPA explained that the studies it reviewed concerned "nonquantifiable" effects *because* the evidence painted an "inconsistent," "limited," "mixed," and "indeterminate" picture of any correlations between PFAS exposure and the effects hypothesized. *See* 89-FR-32697-32698, 32700.

On the back of that equivocal and unreliable evidence, the agency then engaged in admitted speculation. It simply assumed that the benefits the agency *could* support with evidence are "likely" understated in light of the benefits it could *not* support with evidence. 89-FR-32651.

Neither the Act nor the APA permits "it must be so" reasoning like this. Agencies must base their rulemaking decisions on "logic and evidence, not sheer speculation." *Sorenson Communications Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014). And a reviewing court may not "defer to the agency's conclusory or unsupported suppositions." *United Technicians v. U.S. Department of Defense*, 601 F.3d 557, 562 (D.C. Cir. 2010)). That is all EPA offers with its "nonquantifiable" factors analysis.

B. EPA failed adequately to consider important aspects of the Rule's feasibility

EPA's assessment of the Rule's feasibility also was woefully incomplete. Feasibility here is a defined term: It "means feasible with the use of the

best technology, treatment techniques and other means" that are actually "available (taking cost into consideration)." 42 U.S.C. § 300g-1(b)(4)(D). As a matter of both plain text and common usage, the feasibility analysis requires the agency to consider all factors affecting water systems' practical ability to implement a Regulation.

EPA acknowledged as much. It expressly recognized in the preamble that its statutory obligation is "to ensure that any public water system nationwide can monitor, determine compliance, and deliver water that does not exceed the maximum permissible level of a contaminant in water to any of its consumers." 89-FR-32573.

But the agency artificially limited its feasibility inquiry to two sub-issues only. It addressed, first, whether "analytical methods" are available "to reliably quantify levels of the contaminants in drinking water" with sufficient "precision and accuracy" to reach compliance with the new Levels. *Id*. It addressed, second, whether the "costs of treatment technologies that have been demonstrated under field conditions to be effective at removing PFOA and PFOS and determined that the costs of complying with" the Levels "are reasonable for large metropolitan water systems." *Id*.

The question whether "public water system[s] nationwide can monitor, determine compliance, and deliver water" in compliance with the Rule (89-FR-32573) turns on far more than that. Feasibility is an inquiry about practical

realities—about the rubber hitting the road. For instance, it includes whether there is sufficient laboratory and supply-chain capacity *in the real world* to measure and treat the regulated PFAS at the Levels set by the Rule, and whether there are sufficient field facilities and water-system personnel *in the real world* to implement cleanup technologies. These are "important aspect[s] of the problem before [EPA]." *Ohio*, 144 S.Ct. at 2054.

A Level is not "feasible" if only a small subset of water systems can actually access the technologies and facilities necessary for compliance. And if compliance requires opening new laboratories and building new on-site facilities, those (enormous) added costs must be factored into the agency's determination of whether the new Levels are "feasible . . . *taking cost into consideration*." 42 U.S.C. § 300g-1(b)(4)(D) (emphasis added).

Commenters raised these issues with respect to the Levels set for PFOA and PFOS. Several expressed concerns that the materials and skilled personnel required to build and operate treatment technologies will be in short supply. *E.g.*, SBA.Comment (JA__); NRWA.Comment (JA__). Others stressed that existing laboratory capacity is insufficient to ensure that all water systems are able to comply. *E.g.*, 3M.Comment (JA__); TCEQ.Comment (JA__-__); A.O. Smith.Comment (JA__-__). Specifically, commenters expressed concern that few laboratories nationwide are approved to analyze systems for PFAS to the level the Rule requires. *See* 3M.Comment (JA__-__).

EPA did not substantively address these issues. It simply assumed without explanation that these problems would simply resolve themselves at no cost to anyone. For instance, with respect to testing technology and personnel, the agency speculated that "structural demand increase is expected to lead to supply increases as well as innovation such as proposed technologies which were not designated as [best available technologies]." 89-FR-32624. Shortfalls in testing materials and personnel, EPA surmised, will work themselves out at some point in the future, ensuring the Rule's *present* feasibility.

The agency took the same approach to laboratory capacity. It assumed without meaningful support that "the 53 laboratories for PFAS methods" participating in EPA's UCMR 5 monitoring program will have sufficient capacity to handle the Rule's implementation. 89-FR-32575. But that was a bare assertion at odds with evidence-based comments to the contrary. In fact, UCMR 5 requires monitoring of large systems and only a sample of 800 small water systems. *Id.* EPA did not explain how existing testing capacity—even if sufficient for limited monitoring requirements—will necessarily offer adequate support for the thousands of additional water systems, which will require more extensive and frequent testing under the Rule. *See* EA Appendices 4-28.

Nor did EPA respond to specific concerns about laboratory testing for *commercial* water samples. Accreditation data narrows that number even further, to 38 that are certified to perform approved EPA methods of PFAS

testing. 3M.Comment (JA__-__). Although the "53 labs" currently testing for PFAS have "demonstrated sufficient capacity for current UCMR 5 monitoring" (89-FR-32575), that is a non sequitur with respect to the objections raised concerning capacity to meet Rule compliance.

Congress's requirement to ensure that Levels under the Act are *feasible* requires the agency to stick to what is possible in the real world. By failing to analyze or reasonably respond to key problems bearing on the Rule's feasibility, EPA made unsupported assumptions and unlawfully "ignore[d] 'an important aspect of the problem.'" *Ohio*, 144 S.Ct. at 2053.

C. EPA failed to respond to significant public comments on regulatory alternatives

"[A]n agency must 'respond to relevant and significant public comments'" when those comments "disclose the factual or policy basis on which they rest." *American Waterways Operators v. Wheeler*, 507 F. Supp. 3d 47, 68 (D.D.C. 2020). Critically, it is not enough for an agency to demonstrate "awareness" of an objection and then "sidestep it." *Ohio*, 144 S.Ct. at 2054-2055. It must engage the substance of the comment. *Id*. But here, EPA simply declined to consider alternative Levels commenters proposed.

The Act expressly envisions that EPA will consider alternative Levels at the same time it evaluates the justification and feasibility of its main proposal. *See* 42 U.S.C. § 300g-1(b)(3)(C)(i)(III)-(IV). Beyond that specific require-

ment, an agency's obligation to make rational choices requires it to identify and consider "alternative way[s] of achieving the objectives" it pursues and provide "adequate reasons" for rejecting those alternatives. *State Farm*, 463 U.S. at 48-49. An agency need not anticipate every possible policy choice, but it must consider "significant and viable" or "obvious" alternatives, including those identified in comments. *National Shooting Sports Foundation v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013).

Commenters identified reasonable, alternative Levels of 20 ppt and 40 ppt, but EPA refused without response to consider them. *See* ACC.Comment 53 & n.203 (JA__-__); Chamber.Comment 43 (JA__). EPA's own scientific guidance supported including an obvious alternative no less than 40 ppt, an order of magnitude more than 4.0 ppt. *See* U.S. EPA, *Health Effects Test Guidelines OPPTS 870.3050 Repeated Dose 28–Day Oral Toxicity Study in Rodents* 1, 5 (2000), https://perma.cc/77JA-TR5W (describing dosing guidance). Presented with reasonable alternatives to its Rule, EPA had the burden to reasonably explain why it declined to adopt them—a burden it did not satisfy here.

EPA asserted that considering higher alternatives would be contrary to its mandate "to establish MCLs as close to the MCLGs as feasible, taking cost into consideration." EPA Response 13-524 (JA___). But as EPA's response acknowledges, feasibility is, by statute, a function of cost. It is required to set

the Level as close to the Goal (here, 0) as feasible *taking cost into consideration*. 42 U.S.C. § 300g-1(b)(4)(D). And when EPA takes the costs of a particular Level into consideration, it must "use" its determination of the "incremental costs . . . associated with each alternative [Level]." *Id.* § 300g-1(b)(3)(C)(i)(IV). It did not do so.

It is no answer that EPA considered alternatives of 5.0 ppt and 10 ppt. The difference between 4.0 ppt and 5.0 ppt is within the margin of measurement error, meaning there is no appreciable toxicological difference between those two Levels—and EPA has explained none. *See* EPA Response at 5-193 (JA__). For context, 4.0 ppt is about the equivalent of one drop in five Olympic-sized swimming pools. *See* GAO, *Persistent Chemicals* 4 n.12, GAO-22-105135 (Sept. 2022). EPA cannot seriously mean that 1.25 drops (5.0 ppt) is a meaningful alternative to 1.0 drop (4.0 ppt)—or, at least, if that is its position, it must explain why. The same is true for 10 ppt, which offers no more meaningful a variation.

EPA provided no real explanation for its choice of 5.0 ppt. EPA stated that it chose this option only because 5.0 is "25 percent above" 4.0. 88-FR-18670. That purely arithmetic observation fails to "examine the relevant data and articulate a satisfactory explanation," (*State Farm*, 463 U.S. at 43), of how the differences between 4.0 and 5.0 were meaningful and why it would not have been more appropriate to consider 20 or 40. This response, if that is

what it is, "did not address the [stated] concern so much as sidestep it." *Ohio*, 144 S.Ct. at 2055.

The same goes for the 10 ppt alternative, as to which the agency's reasoning was self-contradictory. EPA noted that New York had already adopted a threshold of 10 ppt "for certain PFAS." 88-FR-18670. That ignores that every other state had selected a higher threshold for PFOS. *See* EA 4-26 (JA__). And at any rate, EPA elsewhere rejected the suggestion that state standards should influence its evaluation. *See* 89-FR-32577. The agency also asserted that raising the threshold to 10 ppt would reduce the number of utilities required to take remedial actions. 88-FR-18670. But EPA acknowledged that it lacked reliable data on how many utilities currently exceed the 10 ppt threshold, so the number of affected water systems did not provide "a basis for informing the agency's decisions." 89-FR-32601.

Commenters explained the scientific and economic problems with selecting 5.0 ppt and 10 ppt as alternatives, rather than more meaningful upper bounds. *See* 3M.Comment 62-68 (JA__-__); ACC.Comment 52 (JA__). EPA again failed to provide a reasoned response.

II. THE HAZARD INDEX AND INDIVIDUAL LEVELS FOR THE INDEX SUBSTANCES ARE UNLAWFUL

The opening brief for petitioners in No. 24-1188, at pages 21-46, explains well the legal deficiencies inherent in EPA's use of a hazard index and

its promulgation of individual Levels for three of the Index Substances. Petitioners in Nos. 24-1191 and 24-1192 incorporate and adopt that reasoning in full and offer the following additional explanation.

A. The Act does not authorize EPA to regulate mixtures through a "hazard index," which is a break from 50 years of practice

1. The Rule's hazard index purports to regulate the Index Substances as mixtures "where they co-occur in drinking water." 89-FR-32535. But the Act authorizes EPA to regulate levels of individual contaminants only, not mixtures of them.

The Act states that a Goal and Level may regulate only one "contaminant" at a time. It refers to "a" or "the" contaminant in the singular throughout. *See* 42 U.S.C. §§ 300g-1(b)(1)(A), (B)(ii)(II)-(III). And it requires EPA to publish a Goal and Level "[f]or *each* contaminant" that it decides to regulate. *Id.* § 300g-1(b)(1)(E) (emphasis added). With these words, there is no avoiding the call for singular, contaminant-by-contaminant regulation. Again, the word "each" means "every (one) of two or more considered individually." *Collins* 621. And use of the singular "tells us that each [contaminant] requires a separate assessment." *Cf. United States v. Randall*, 34 F.4th 867, 876 (9th Cir. 2022) (the "phrasing 'an offense'" using the singular "tells us that each 'offense' requires a separate assessment").

EPA does not directly disagree. Instead, it takes the position that a single "contaminant" is best read to include "mixtures" of contaminants. *See* 89-FR-32542. But Congress defined "contaminant" in the Act, again using the singular, as "any physical chemical, biological, or radiological substance or matter in water." 42 U.S.C. § 300f(6). Meanwhile, the dictionary defines a "mixture" as "matter consisting of two or more components" or "a product of mixing." *Websters* 1449; *accord Collins* 1263 ("two or more substances mixed together"). These definitions suggest that a mixture is *multiple* substances combined together, distinct from a single chemical taken alone.

EPA focused in the preamble on the word "matter" rather than "substance," insisting that "matter, . . . by definition, is comprised of either pure substances or mixtures of substances." 89-FR-32542. But "matter," taken literally in that way, means anything with a physical manifestation, as distinct from something that is only "mental, spiritual, etc." *Collins* 1213. Such a broad reading would make the rest of the clause superfluous—Congress could just as well have authorized EPA to regulate "any matter in water."

That is not what Congress said, and under the doctrine of *noscitur a sociis*, "a word is given more precise content by the neighboring words with which it is associated." *United States v. Hillie*, 39 F.4th 674, 685 (D.C. Cir. 2022) (quoting *United States v. Williams*, 553 U.S. 285, 294 (2008)). Here, that suggests that Congress had in mind for EPA to regulate *singular* chemical

substances, and not open-ended mixtures or combinations of them. EPA's contrary reading is owed no deference.

2. Other factors confirm this conclusion. First, when Congress means to authorize EPA to regulate mixtures, it says so expressly. In CERCLA, for example, Congress authorized regulation of a "pollutant or contaminant," which it expressly defined to include "any element, substance, compound, *or mixture*." 42 U.S.C. § 9601(33) (emphasis added). If the word "contaminant" already included "mixture" by definition, Congress would have had no need to state so expressly. Moreover, if Congress had intended the word contaminant in the SDWA to include mixtures, "it knew how to say so." *See Wallaesa v. FAA*, 824 F.3d 1071, 1083 (D.C. Cir. 2016). It did not.

Second, the legislative history suggests the same. Although the House committee responsible for the Act "anticipat[ed] that the Administrator will establish primary drinking water regulations for some groups of contaminants" in a single Regulation, it also was clear that a Level must be "specifie[d] for *each* such contaminant," not for the group as an indeterminate mixture. *See* H.R. Rep. 93-1185, 1974 U.S.C.C.A.N. at 6463-6464; *see also id.* ("Once the Administrator specifies contaminants, including groups and subgroups thereof . . . he must prescribe for each contaminant a maximum contaminant level."). The Hazard Index is thus unlawful.

B. The Hazard Index and individual Levels for Index Substances are procedurally defective

The Hazard Index suffers from procedural defects, as well. First, in promulgating the Rule, EPA disregarded the Act's multistep process for issuing a Regulation. Second, it failed to consult its Science Advisory Board before proposing drinking water standards for the Index Substances.

1. EPA may not announce a preliminary determination to regulate at the same time it proposes Goals and Levels

a. EPA did not follow the Act's express procedure for proposing to regulate the Index Substances. EPA announced its preliminary determination to regulate these substances simultaneously with issuing the proposed hazard index itself, against the statute's mandate.

The Act provides for a multistep rulemaking process between EPA's decision to regulate a substance, on the one hand; and its decision to set a Goal and Level, on the other hand. Section 300g-1(b)(1)(B) is unequivocal: EPA must issue a "preliminary determination" to regulate a substance. 42 U.S.C. § 300g-1(b)(1)(B)(i)(I). This determination must follow "consultation with the scientific community, including the Science Advisory Board," "notice and opportunity for public comment," and "consider[ation of] the occurrence data base." *Id.* "*After* notice of the preliminary determination and opportunity for public comment," the agency may issue a final determination "of whether or not to regulate such contaminants." *Id.* § 300g-1(b)(1)(B)(ii)(I) (emphasis

added). And after "determin[ing] to regulate [a contaminant]" or concurrently with its determination, EPA must publish a Goal and Level. *Id.* § 300g-1(b)(1)(E). EPA may, however, publish its proposed Goals and Levels "concurrent with the determination to regulate." *Id.*

Despite the Act's clear regulatory sequence, EPA published a proposed hazard index for mixtures of the Index Substances concurrently with its *preliminary* determination to regulate them. In the notice of proposed rulemaking, EPA stated that it was "requesting comment on a preliminary determination to regulate additional PFAS" and "[c]oncurrent[ly] . . . proposing an HI of 1.0 as the [Goal] and enforceable [Level]." 88-FR-18641. This was a clear-cut procedural error.

b. EPA's contrary position requires giving the phrase "determination to regulate" varied meanings across different paragraphs of the same statutory provision. *See* 89-FR-32541 (asserting that "Congress did not use the term 'determination to regulate' consistently"). That is not defensible.

Paragraph (b)(1)(E) permits EPA to propose Goals and Levels simultaneously only with a "determination to regulate under subparagraph (B)." As EPA sees it, this provision authorizes it to propose Goals and Levels alongside *either* a final determination *or* a preliminary determination—both, in its view, are "determinations to regulate." But EPA fails to account for the fact that paragraph (b)(1)(B) expressly defines "determination to regulate" as the

decision made "*after* the preliminary determination and opportunity for public comment." 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I) (emphasis added). Congress's choice to distinguish the "preliminary determination" from "the determination to regulate" thus indicates that "the determination to regulate" is the *final* determination following the preliminary one.

From that angle, EPA's argument fails. EPA would give "determination to regulate" one meaning in paragraph (b)(1)(B) (a final determination only) and a different meaning a few lines down the page, in paragraph (b)(1)(E) (a final or preliminary determination). That flouts the "well-established rule of statutory construction, that a word is presumed to have the same meaning in all subsections of the same statute." *SW General, Inc. v. NLRB*, 796 F.3d 67, 75 (D.C. Cir. 2015). Even that aside, paragraph (b)(1)(E) refers not to just any "determination to regulate," but specifically to a "determination to regulate *under subparagraph (B).*" 42 U.S.C. § 300g-1(b)(1)(E) (emphasis added). There is no plausible basis for concluding that Congress meant in paragraph (b)(1)(E) something different from what it meant in (b)(1)(B).

EPA invokes notions of congressional purpose and the importance of expeditious decision-making. *See* 89-FR-32541-32542. But Congress allowed EPA to shortcut the normal process when "urgent threats to public health" justify doing so (42 U.S.C. § 300g-1(b)(1)(D)), and it has not asserted such urgency here. Courts may not "disregard the plain terms of a valid

congressional enactment based on surmise about unenacted legislative intentions." *Students for Fair Admissions, Inc. v. President & Fellows of Harvard College*, 600 U.S. 181, 309 (2023) (Gorsuch, J., concurring).

c. There is also good reason that Congress would not have intended to collapse the preliminary determination to regulate with a proposed Regulation establishing drinking water Goals and Levels for that contaminant.

As the Rule here demonstrates, the factual considerations underpinning *both* the decision to regulate *and* the appropriate regulatory standard are complex and highly technical. Bifurcated rulemaking allows the interested public an opportunity to meaningfully comment on each proposal. Congress reasonably determined that EPA would be more likely to give genuine consideration to alternative ideas (*e.g.*, that it should *not* regulate a contaminant), before it has already devoted considerable resources to determining what Goals and Levels would be appropriate.

EPA complains that bifurcated rulemaking would be inefficient and unnecessary here. *See* 89-FR-32542. But that view "is irrelevant, for '[w]hen a statute commands an agency without qualification to carry out a particular program in a particular way, the agency's duty is clear; if it believes the statute untoward in some respect, then it should take its concerns to Congress, for in the meantime it must obey [the statute] as written.'" *Friends of Blackwater v. Salazar*, 691 F.3d 428, 447 (D.C. Cir. 2012).

2. EPA unlawfully failed to consult the Science Advisory Board

EPA also violated the requirement that it "shall request comments from the Science Advisory Board . . . prior to proposal of a maximum contaminant level goal and national primary drinking water regulation." 42 U.S.C. § 300g-1(e). EPA sought comments from the SAB only with respect to Levels for PFOA and PFOS. It did not consult the SAB on Goals or Levels for the individual Index Substances or the hazard index itself. EPA acknowledged as much in the NPRM. *See* 88-FR-18736. It developed the hazard index—and the individual Goals and Levels for PFHxS, PFNA, and HFPO-DA—only after SAB's review was complete.

The agency submitted detailed proposals for deriving Goals for PFOA and PFOS, with targeted charge questions related to "developing Goals based on the best available health effects information for PFOA and PFOS." 88-FR-18736; *see* EPA 2021e (JA__); EPA 2021f (JA__). For the hazard index, it consulted SAB only as to whether an index is an appropriate tool for regulating PFAS mixtures in the abstract. *See* 88-FR-18736. EPA's failure to adequately consult the SAB on the hazard index is all the more concerning given the Board's sharp criticisms of the agency's PFOA and PFOS proposals. *See* SAB.Report 3-5 (JA__-__).

EPA argues it had no obligation to consult the SAB on anything other than PFOA and PFOS, contending it satisfied its obligation by submitting "a

question specifically focused on the utility and scientific defensibility of the Hazard Index approach in the context of mixtures risk assessment in drinking water." 89-FR-32568. But that inquiry, as EPA's phrasing suggests, focused on the propriety of the hazard index *methodology*—not a proposal for Goals or Levels for an actual group of PFAS substances.

Confronted on this point, EPA simply "disagree[d] with commenters who contend[ed] that [it] must seek advice from the SAB on all aspects of the [Regulation]." 89-FR-32569. In its view, the Act "does not dictate on which scientific issues the EPA must request comment from the SAB." *Id.* That is wrong. The statute is clear that EPA "shall request comments from the Science Advisory Board prior to proposal of *a* [Goal] and [Level]." 42 U.S.C. § 300g-1(e). There, again, Congress used the singular, suggesting that Congress wanted SAB review for each Goal and each Level. It hardly could be otherwise—paragraph (e) would mean next to nothing if all the agency had to do is promulgate multiple Goals and Levels at once and seek SAB review only on one of them. EPA's failure to consult the SAB is another basis for vacating the Rule.

C. The hazard index is not supported by substantial evidence

Even supposing EPA could regulate mixtures using a "hazard index" rather than setting an actual level—and it assuredly cannot—the hazard index must be vacated because it is not supported by substantial evidence. EPA must

demonstrate (a) that each possible combination of substances is substantially likely to occur with a frequency and at levels of public health concern; and (b) that the likely combinations have adverse effects on human health. 42 U.S.C. § 300g-1(b)(1)(A). EPA demonstrated neither.

1. EPA did not demonstrate a substantial likelihood of co-occurrence among the Index Substances

EPA has not identified a single sample containing detectable levels of all four Index Substances occurring together. PFAS Occurrence Ex. 11-6 thru 11-7 (JA__-__). Co-occurrence of even three of the Index Substances is extremely rare, at 0.1% of over 16,000 samples. *Id.* And for HFPO-DA and PFNA, the agency did not identify a single sample where those two compounds co-occur in *any* combination. *Id.* at Ex. 11-9. EPA admits that odds of co-occurrence for this mixture are 0.0%. *Id.*

Unable to establish a "substantial likelihood" for these mixtures, (42 U.S.C. § 300g–1(b)(1)(A)), EPA attempts a broad expansion of its authority: As long as enough compounds are added to the hazard index, EPA (under its preferred interpretation) can always claim the occurrence criterion is met. That would render the statutory criteria meaningless.

2. EPA did not demonstrate that combinations of Index Substances below the Levels adversely affect human health

EPA similarly failed to demonstrate that any combination of Index Substances "may have an adverse effect on the health of persons." 42 U.S.C.

§ 300g–1(b)(1)(A). Central to EPA's hazard-index grouping is the assumption that the compounds are "dose additive," meaning that "when two or more of the component chemicals exist in one mixture, the risk of adverse health effects following exposure to the mixture is equal to the sum of the individual doses or concentrations scaled for potency." 89-FR-32550 (parenthetical omitted). This assumption is flawed in multiple respects.

a. The SAB advises that dose additivity assumptions can be appropriate for "initial screening" of whether a mixture "should be further evaluated," but cannot sanction regulation. SAB.Report 90-91 (JA__-__). EPA attempts to prop up its dose-additivity assumption with studies evaluating other PFAS. 89-FR-32550. But the category of PFAS is extraordinarily broad and heterogenous—numbering in the thousands—and none of the relied-upon studies evaluates the specific mixtures regulated by EPA's hazard index here. Reliance on default assumptions and analogies to other compounds is insufficient to meet EPA's burden of demonstrating that a specific contaminant has sufficient risk of adverse health effects to justify regulation.

b. Even insofar as a "default" dose-additivity assumption is ever permissible, it requires proof of an overlap of critical effects. The SAB thus endorsed dose additivity "based on a common outcome" when evaluating PFAS mixtures "that have similar effects." 89-FR-32551; SAB.Report 90-91 (JA__-__). EPA has acknowledged that the hazard index approach "could

overestimate the hazard when . . . the critical effects . . . across mixture chemicals differ." EPA, *Advances in Dose Addition for Chemical Mixtures* 2-26 (Dec. 2023), https://perma.cc/2SGZ-ZXY9. That is the case here: EPA's own risk assessments for the Index Substances each identify a different critical effect. 89-FR-32546–32549.

That lack of similar critical effects is dispositive. A critical effect is the first relevant health effect to appear as dosage of a contaminant is increased, which in turn is used to set the reference dose at the maximum exposure that does not cause "an appreciable risk of deleterious effects during a lifetime." MCLG 1-18 (JA__-__). At concentrations below the reference dose, therefore, a compound does not show any appreciable risk of relevant adverse health effects, because even the most sensitive organ system is not yet harmed. Yet by grouping compounds with different critical effects, EPA's hazard index would regulate mixtures at concentrations far below where an appreciable risk arises for any identifiable adverse effect. As a result, countless permutations of the hazard-index mixtures may exceed the level set by the Rule despite having no possibility of causing any "adverse effect on the health of persons." 42 U.S.C. § 300g-1(b)(1)(A)(i).

An example illustrates the point. According to EPA, 10 ppt is the lowest concentration at which HFPO-DA could produce adverse health effects in the liver; and 10 ppt is the lowest concentration at which PFHxS could produce

adverse health effects on the thyroid. But *no* data—literally none—supports the conclusion that a mixture of 5 ppt HFPO-DA and 5 ppt PFHxS will trigger adverse health effects on either the liver or the thyroid.

Unable to show overlapping critical effects, EPA purports to show overlapping "health endpoints." 89-FR-32551. But that novel approach warps the available toxicity data. Any compound—even water itself—can be toxic at a high enough dosage. But it does not follow that, for example, if 2,000 ml of water and 0.0002 ml of cadmium can each cause kidney failure, those compounds would be "toxicologically similar." Indeed, some of the health outcomes EPA relies upon to show "similar toxicological effects" were only observed at doses over 300 million times higher than the reference dose for the Index Substances. MCLG Table 1-3 (JA__).

c. EPA's hazard-index approach also relies on such a broad interpretation of "toxicological similarity" that thousands of separate substances (PFAS or not) could be collectively regulated by the agency in a single rule. There are thousands of substances, and essentially infinite combinations, that could cause some overlapping health effects at high enough doses. *Id.*

Indeed, grouping these particular substances together makes especially little sense. The Index Substances have no overlapping critical effects, and EPA has not identified a single sample containing the four compounds together. One of the compounds (PFBS) is not even regulated by an individual

Level or Goal. *See* 89-FR-32533. Yet EPA has claimed near-unfettered authority to add any collection of compounds together in order to satisfy the SDWA regulatory criteria. The agency's broad interpretation of "toxicological similarity" would lift all limits to its authority. Such previously unheralded power is inherently suspect (*UARG v. EPA*, 573 U.S. 302, 324 (2014)), and illustrates how far EPA has strayed from its statutory authority to promulgate regulations of "a contaminant." 42 U.S.C. § 300g-1(b)(1)(A).

III. EPA'S REGULATION OF HFPO-DA IS IRREPARABLY FLAWED

EPA's regulation of HFPO-DA is a matter of particular importance to petitioner Chemours Company, as this compound is most closely associated with its manufacturing operations.

A. EPA erred in concluding that HFPO-DA occurs in public water systems with a frequency and at levels of public health concern.

The Act establishes a data-driven process for determining to regulate, and then regulating, contaminants. Central to this process are data about the prevalence of a contaminant in public water systems. Congress authorized EPA to regulate a contaminant only when the "best available" evidence shows it will occur "with a frequency" and at levels of public concern. 42 U.S.C. § 300g–1(b)(1)(A)(ii), (b)(1)(B)(ii)(II).

Here, UCMR data showed overwhelmingly that HFPO-DA does not frequently occur in public water systems, but EPA disregarded it—despite rely-

ing on that same data when it supported EPA's conclusions for other compounds.

Other data the agency cites *confirmed* HFPO-DA's non-occurrence in all states' samples other than North Carolina, where Chemours's Fayetteville Works facility is located. But as EPA admitted, even the occurrence data from North Carolina was tainted by failures to report complete information, making it impossible to know the proportion of samples where HFPO-DA was detected. The set also only included data more "likely to potentially over-represent concentrations at locations of known or suspected contamination." 89-FR-32553. That is arbitrary agency action at its worst.

1. EPA ignored UCMR data undermining its conclusions

a. The agency may regulate a contaminant only where it "is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern." 42 U.S.C. § 300g–1(b)(1)(A)(ii). Critically, this finding "shall be based on the best available public health information, including the occurrence data" in the UCMR database. *Id.* § 300g–1(b)(1)(B)(ii)(II). A separate provision similarly instructs EPA that "[t]he [UCMR] data shall be used by the Administrator in making determinations under section 300g–1(b)(1) of this title with respect to the occurrence of a contaminant in drinking water at a level of public health concern." *Id.* § 300j–4(g)(3).

In 2021, at Congress' direction, EPA promulgated regulations adding HFPO-DA to UCMR 5, with a study period of 2023-2025. 86-FR-73131. EPA then rushed to issue the Rule in April 2024, months before the study period was to conclude.

b. The UCMR 5 data available to EPA at the time of regulation overwhelmingly demonstrates that HFPO-DA does *not* "occur in public water systems with a frequency and at levels of public health concern." 42 U.S.C. § 300g–1(b)(1)(A). Such data, covering all 50 states, showed only a single sampling location out of 6,946 that detected HFPO-DA at levels greater than 10 ppt—an occurrence rate of 0.01%. And currently, the UCMR database shows one sampling location out of 8,893:

Regulated PFAS	MCL (µg/L)[1]	Total number of locations with a full set of results[2]	Number of locations with an average greater than MCL	% of locations with an average greater than MCL	Total number of PWSs with location(s) with a full set of results	Number of PWSs with average(s) greater than MCL	% of PWSs with average(s) greater than MCL
PFOS	0.0040	8,887	524	5.9%	3,459	316	9.1%
PFOA	0.0040	8,888	445	5.0%	3,460	246	7.1%
HFPO-DA (GenX chemicals)	0.01	8,893	1	0.0%	3,462	1	0.0%

EPA, *The Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Data Summary*, at 11, table 4 (July 2024), https://perma.cc/3XTG-UFJX (yellow highlights added).

EPA has never imposed a Level for any other contaminant so infrequently detected at levels of concern. And its refusal to use accessible UCMR 5 data on this point was plainly unlawful.

c. Given Congress's express instructions that "[t]he data shall be used by the Administrator in making [regulation] determinations . . . with respect to the occurrence of a contaminant" (42 U.S.C. § 300j–4(g)(3)), and that MCLs "shall be based on . . . the occurrence data base" (*id.* § 300g–1(b)(1)), EPA's refusal to consider information from the database is unlawful per se.

EPA rejoins that, since the UCMR 5 dataset was not "complete" when it promulgated the Rule, *none* of the UCMR data was "available." EPA-Response 6-68 (JA__). In the agency's view, it was "not required under the statute to wait for another round of UCMR data to be collected before proposing or finalizing a regulation." *Id.* Nor was it under any "legal obligation to consider the preliminary, partial UCMR 5 dataset prior to rule promulgation." EPA-Response 6-69 (JA__).

That position is untenable. EPA's argument is based on Section 300g-1(b)(1)'s instruction to treat the UCMR data as containing "the best available information," ignoring Congress's separate command that "[t]he data shall be used by the Administrator in making [regulatory] determinations." *Id.* § 300j-4(g)(3). The latter instruction does not contain the word "available."

In any event, UCMR occurrence data *was* "available" to EPA. Three rounds of UCMR-5 data were released and analyzed before EPA finalized the Rule. Data is "available" if it is "accessible" or "capable of being made use of." *Collins* 137; *accord Webster's* 150. Nothing in the Act suggests that data

is unavailable until the dataset of which it is a part is fully complete. *See Chlorine Chemical Council*, 206 F.3d at 1290-91 ("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"). The Act instructs that "information from the data base shall be *available* to the public in readily accessible form." 42 U.S.C. § 300j–4(g)(3) (emphasis added). That requires the data to be open to and able to be used by the public, *not* that it must be complete. And EPA has in fact made the database publicly accessible, without waiting for the data-collection cycle to conclude.

EPA's opposite position is contradicted by its reliance on other incomplete occurrence datasets. As explained more fully below, EPA relied on admittedly incomplete data from the states—but because it confirmed what EPA wanted to see, it insisted that those partial data should be "extrapolated to the nation." 89-FR-32557.

Likewise, EPA selectively relied on UCMR 5 data where it "confirm[ed] the EPA's conclusions" about the general prevalence of PFAS in public water systems. 89-FR-32526 (emphasis added); *see* EPA-Response 6-69–70 (JA__-__) ("[e]xtrapolat[ing]" from "preliminary UCMR 5 dataset" to assess prevalence of any contaminant combination "exceeding a PFAS MCL"). An agency errs when it includes incomplete data in support of a rule but excludes

similarly incomplete data in opposition to that rule. *See American Iron & Steel Institute v. OSHA*, 939 F.2d 975, 1009 (D.C. Cir. 1991).

At bottom, EPA's "refusal to consider evidence bearing on the issue before it" renders the Levels arbitrary and capricious. *Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010). Indeed, given Congress's express—and repeated—instructions to rely on UCMR data (42 U.S.C. §§ 300g-1(b)(1), 300j-4(g)(3)), EPA's refusal to consider information from the database is unlawful per se.

2. Alternative federal and state data sources do not support EPA's determination to regulate HFPO-DA

Ignoring UCMR 5 data, EPA "extrapolate[d]" from a collection of alternative federal and state occurrence data sources. 89-FR-32577. But those sources also fail to demonstrate a "substantial likelihood" that HFPO-DA occurs at a frequency and level that support nationwide regulation. 42 U.S.C. § 300g–1(b)(1)(A). Indeed, they show the opposite.

First, EPA relied on additional federal datasets (PFAS Occur. at 7.2.2 (JA__)), which confirm the UCMR 5 data that HFPO-DA does not occur frequently in public water systems. Department of Defense data showed *zero* reported detections of HFPO-DA at or above 10 ppt out of 1,178 samples. *Id.* at Ex.7-12; Ex.5-16. And for ambient water—based on National Water Information System and EPA Storage and Retrieval data from "monitoring

locations in all 50 states"—there were, again, *zero* such detections. *Id.* at Ex.7-13, -14.

Second, EPA relied on State monitoring data. *Id.* at 7.2.1.1. But just 25 States participated, only 19 of which used non-targeted analyses (as necessary to avoid selection bias); and most sampled only a small fraction of public water systems within the State. *Id.* at Ex.7-7. Indeed, the data's incompleteness is precisely why EPA insists it should be "extrapolated." 89-FR-32577.

EPA admits that even the selected sources contain numerous deficiencies. States used "various reporting thresholds" that were "not defined consistently"; some states had no "clearly defined reporting limits" at all; others used reporting thresholds that "varied" even within the state; still other data varied according to "the laboratory analyzing the data"; and some states reported finding HFPO-DA at levels lower than what "can be reliably measured based on precision and accuracy acceptance criteria" (PFAS Occurrence 21 (JA__)), rendering their results suspect. Some States failed to report samples when HFPO-DA was *not* detected. 89-FR-32554, 32557, 32583. UCMR data, by contrast, has none of these flaws.

Still, even the spotty, incomplete state dataset showed that detection of HFPO-DA above the Level is exceedingly rare. Excluding North Carolina, HFPO-DA was detected above the Level in only seven out of 35,755 total samples—a rate of less than 0.02%. PFAS Occurrence Ex. 7-8 (JA__). EPA

attempts to obscure this fact, stating that "HFPO-DA was reported in approximately 0.48 percent of monitored *systems*." 89-FR-32577 (emphasis added). But that is the percentage who reported the substance in *any* amount, not at levels above 10 ppt.

In North Carolina, there were 430 detections at six water treatment plants along the Cape Fear River, but that is also not a basis for an occurrence finding: The majority of sampling in North Carolina—representing 428 of the 430 detections at levels above the Level—did not report the total number of samples taken (*i.e.*, the denominator), making it impossible to know the relevant proportion of samples. Without a denominator, the data is unusable for establishing frequency. *See Bismullah v. Gates*, 501 F.3d 178, 186 (D.C. Cir. 2007) (noting the impossibility of "tell[ing] whether a fraction is more or less than one half by looking only at the numerator and not at the denominator"). And even if this denominator-free data could establish that HFPO-DA occurs frequently at levels of concern *in North Carolina* (it cannot), that would not by itself establish a frequency of public health concern for issuing national regulations.

Thus, the state data, incomplete and flawed as they are, confirm the UCMR dataset—like the other federal datasets—showing that HFPO-DA does not occur frequently at levels of public health concern.

B. The Level for HFPO-DA is arbitrary and capricious

Even if EPA's decision to regulate HFPO-DA were defensible, the Level it selected is not. The Level for HFPO-DA relies on several arbitrary and capricious assumptions: EPA used significantly inflated "uncertainty factors" to calculate its reference dose; applied a default relative source contribution, despite having access to concrete data about HFPO-DA's actual presence in the environment; relied on a toxicological effect irrelevant to humans, ignoring contrary evidence; and invented a new toxicological concept ("constellation of effects") with no valid basis. The Level for HFPO-DA must be vacated.

1. EPA relied on uncertainty factors that deviate from its own standard methods and ignored relevant evidence

EPA applied a 3000-fold uncertainty factor—the most-stringent value it could possibly have used. 89-FR-32546. That uncertainty factor is an order of magnitude greater than the one EPA had applied in its draft Toxicity Assessment. Yet EPA provided no reasoned explanation for increasing the uncertainty factor in this way. Chemours raised the contradiction in a request for correction (Chemours RFC 25-26 (JA__-__)) and again in regulatory comments (Chemours.Comment Ex. 1 at 11-12 (JA__-__)), but EPA ignored the point both times.

Insofar as EPA attempted to justify this factor at all, it relied on new studies that actually *reduced* uncertainty regarding toxicity. Chemours RFC

26-27 (JA__-__); Ex. 3.6 (JA__). "[T]he absence of any evidentiary basis" for the database uncertainty factor is thus especially glaring, given contrary "empirical evidence supporting a lower [uncertainty] factor." *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 233 (D.C. Cir. 2008). EPA's purported "complete discussion" of the uncertainty factors (89-FR-32546) contains no reasoned explanation. It simply parrots the database uncertainty factor and lists the studies consulted. MCLG 2-1 - 2, A-9-11 (JA__-__).

The higher database factor is also inconsistent with EPA's own guidance: Where a reference dose is "based on animal data, a factor of 3 is often applied if either a prenatal toxicity study or a two-generation reproduction study is missing, or a factor of 10 may be applied if both are missing." EPA, *Guidelines for Developmental Toxicity Risk Assessment*, 45 (Dec. 5, 1991), https://perma.cc/N7DG-GG3V (*Guidelines*) (emphasis added). Here, EPA had multiple prenatal toxicity studies available. EPA's failure to confront relevant data and its own guidance provides no "assurance that the [agency] considered the relevant factors" *American Radio*, 524 F.3d at 241.

There was similarly no valid basis for increasing the duration uncertainty factor from 3 in the draft assessment to 10 in the final assessment. Both assessments relied on the same study, yet EPA failed to "provide a scientific basis for increasing that factor." Chemours RFC 28-29 (JA__-__); Chemours.Comment Ex. 1, at 11 (JA__). While an agency may reevaluate

existing data, "an agency changing its course must supply a reasoned analysis" for doing so. *State Farm*, 463 U.S. at 57 (citation omitted). Moreover, where, as here, relevant data fail to show substantial "progression of" the observed effects "with longer exposure duration," (Chemours RFC 28 (JA__)), EPA guidance instructs that "an uncertainty factor is not applied to account for duration of exposure" at all. *Guidelines* 42.

EPA emphasizes that it sought "external peer review of the toxicity assessment twice," (89-FR-32548), but seeking peer review does not validate an agency's conclusions when it ignores the feedback it receives.

EPA's choice of uncertainty factors also reflects an improperly frozen-in-time understanding of HFPO-DA. Chemours pointed EPA to extensive new data in the years since the 2021 Toxicity Assessment, all of which further reduced any database uncertainty. EPA's uncertainty factors are therefore even less appropriate now than they were in 2021.

2. The HFPO-DA Level relies on a flawed exposure assumption

Yet another error dramatically reduced the Level's tolerance metric: EPA applied a relative source contribution (RSC) factor of 0.2. RSC "represents the proportion of an individual's total exposure to a contaminant that is attributed to drinking water ingestion . . . relative to other exposure pathways." 89-FR-32546. The 0.2 RSC assumes that drinking water accounts for only 20% of a person's exposure to the chemical, thus assuming that 80% of a

person's exposure will come from other sources, such as air, food, dust, and soil. 89-FR-32544. This assumption renders the Rule five times less tolerant of HFPO-DA in drinking water.

The agency based its exposure assumption on guidance that cabins the range of possible RSC values from 20% to 80%. EPA Office of Water, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, 4.4-8 (Oct. 2000), https://perma.cc/X6YS-LAMC (*Methodology*). Although the guidance allows the 20% minimum as a "default" assumption "when adequate exposure data do not exist," (*id.* at 4.1-7, 4-6), it strongly cautions against using the default when information is "available" that "more accurately reflects exposures." *Id.* at 4.4-6. The guidance thus underscores several times that the default will be appropriate only "infrequently," since information necessary to calculate the relative source contribution "should be available in most cases." *Id.* at 4.4-12.

Here, EPA had ample information to calculate a more-accurate RSC. EPA claims that "commenters did not offer a suggested alternative RSC." 89-FR-32456. That was not commenters' responsibility. But the claim is also false: Chemours commented that "the data support the use of an RSC value of at least 80%," and provided 22 independent studies for support. Chemours.Comment 22 (JA__).

These data uniformly showed that "the only relevant exposure pathway for HFPO is drinking water," and exposure from non-drinking-water pathways "is either non-existent or extremely minimal." Chemours.Comment at 14, n14 (JA__). Multiple studies showed no significant exposure levels through other pathways. Chemours.Comment at 13-14 & nn.5-16 (JA__). EPA simply disregarded them.

EPA also ignored data confirming these studies. The Agency for Toxic Substances and Disease Registry monitored HFPO-DA at eight separate "Exposure Assessment sites," but found none in "urine or dust samples." CA3JA1380. Though one EPA official observed that "[t]he lack of detects in dust etc will be interesting when considering a RSC," CA3JA1380, the agency failed to mention these data.

Instead, EPA asserted (without explanation) that it had "assessed the available scientific literature on potential sources of human exposure [to HFPO-DA] other than drinking water." 89-FR-32546. Curiously, although EPA claimed the data were "insufficient to allow for quantitative characterization of the different exposure sources" (89-FR-32546), it relied on the same studies to proclaim that "there are significant known or potential uses/ sources of HFPO-DA other than drinking water." MCLG A-15 (JA__). EPA then summarily concluded that the default RSC of 0.2 was appropriate. *Methodology* 4.4-12. This "mere[] assert[ion], without elaboration," is "insuf-

ficient to sustain the agency's decision." *Gerber v. Norton*, 294 F.3d 173, 183 (D.C. Cir. 2002).

3. The HFPO-DA Level relied upon toxicological effects on rodent livers that are irrelevant to humans

The reference dose underlying the Level is based on studies showing liver effects in rodents through a mode of action (PPAR-alpha) irrelevant to humans. In the Toxicity Assessment, EPA admitted that the PPAR-alpha mode of action "could be more relevant to rodents than humans." EPA Office of Water, *Human Health Toxicity Assessments for GenX Chemicals*, 29 (Oct. 2021) (*Assessments*). But the agency then speculated—without basis—that "other" modes of action for the observed liver effects might exist. *Assessments* 86. As Chemours explained to EPA, there is no "explanation, evidence, or analysis to support its hypotheses, and in some instances the citations relied upon by EPA are directly contrary to its theory." Chemours RFC 20 (JA__). EPA asserted that the studies it had examined supported the opposite conclusion. 89-FR-32548. That unsupported speculation cannot withstand scrutiny.

First, EPA has stated that Chemours's research focused on only one type of liver effect (apoptosis), while "the critical study selected by the EPA, and indeed other studies as well reported not only apoptosis but also other liver effects such as necrosis," and those other liver effects "are not associated with" the PPAR-alpha mode of action. 89-FR-32548. But Chemours's argu-

ment has never been limited to apoptosis: All rodent liver effects underpinning the MCL—including necrosis and enzyme concentrations—are related to the PPAR-alpha mode of action. Chemours RFC 18-22; Chemours.Comment 19-20 (JA__-__); Ex. 1, at 10-11 (JA__-__). Chemours supported this with substantial data. *See* Chemours RFC 22-23 (JA__-__); Ex. 2, at 6 (JA__); 9-11 (JA__-__) (necrosis); Ex. 2 at 17-18 (JA__-__); Ex. 3 at 11 (JA__) (enzymes). EPA again ignored it.

Second, EPA dismissed the peer-reviewed Chappell study, which found that the rodent liver effects underpinning the Toxicity Assessment "are PPAR-alpha effects." Chemours RFC 18 (JA__); Chemours.Comment 18 (JA__). EPA discounted the study on grounds that it "specifically assessed evidence for PPARα-driven apoptosis and did not investigate other potential modes of action or types of cell death." 89-FR-32548. That is also is incorrect: The Chappell study explicitly states that "other transcriptional targets and/or mechanisms related to liver toxicity were also investigated." CA3JA1082. Again, EPA simply "ignore[d] evidence contradicting its position." *Butte County*, 613 F.3d at 194.

4. The HFPO-DA Level relies on a novel toxicological endpoint to generate an artificially low reference dose

EPA's toxicity assessment is based on the National Toxicology Program Pathology Working Group, which reinterpreted a prior study in which liver

effects were observed in mice that were orally exposed to HFPO-DA. *Assessments* 41-44, 51-52, App. D (JA__-__); 89-FR-32548. In the draft toxicity assessment, consistent with standard practice, EPA relied on a single "toxicological endpoint." *Draft Assessments* vii-viii, 23 (JA__-__).

In the final Toxicity Assessment, however, EPA combined four different effects, thereby producing a so-called "constellation of liver effects." [Tox.Assessment.52; MCL.32544]. As Chemours explained, "[n]ot only is EPA's 'constellation of liver effects' unprecedented and a significant deviation from its standard toxicity assessment methods, but it is also erroneous and at odds with the science." Chemours RFC 24 (JA__); *see* Chemours.Comment 18 (JA__); Ex. 1 at 9-10 (JA__).

EPA again relied on the supposed "constellation of liver effects." 89-FR-32544. And again, the agency failed to acknowledge (much less rebut) contrary evidence. EPA seeks to defend its invented concept by emphasizing that the agency "engaged a pathology working group within the [National Toxicology Program] at the National Institutes of Health to perform an independent analysis of the liver tissue slides." 89-FR-32548. But, notably, the Pathology Working Group never claimed that rodent-study findings were indicative of effects in humans, much less "agreed with the selection of the constellation of liver lesions as the critical effect." 89-FR-32548. The Group in

fact distinguished between separate effects. It was EPA that (improperly) combined them into a single dataset.

CONCLUSION

The Court should vacate the Rule in its entirety.

Respectfully submitted October 7, 2024,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(g), I certify that this brief:

(i) complies with the type-volume limitation of Rule 32(a)(7) because it contains 12,994 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f) and Circuit Rule 32(e)(1); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word 2016 and is typeset in Century Supra in font size 14.

Dated: October 7, 2024 /s/ *Michael B. Kimberly*

CERTIFICATE OF SERVICE

I hereby certify that, on October 7, 2024, I electronically filed the foregoing brief with the Clerk of the Court using the appellate CM/ECF system, which served copies of the brief via on all ECF-registered counsel.

Dated: October 7, 2024 /s/ *Michael B. Kimberly*

ADDENDUM A

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42 U.S.C. § 300g-1(b)(1) provides:

(1) Identification of contaminants for listing.—

(A) General authority.—The Administrator shall, in accordance with the procedures established by this subsection, publish a maximum contaminant level goal and promulgate a national primary drinking water regulation for a contaminant (other than a contaminant referred to in paragraph (2) for which a national primary drinking water regulation has been promulgated as of August 6, 1996) if the Administrator determines that—

(i) the contaminant may have an adverse effect on the health of persons;

(ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

(iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

(B) Regulation of unregulated contaminants.—

(i) Listing of contaminants for consideration.—

(I) Not later than 18 months after August 6, 1996, and every 5 years thereafter, the Administrator, after consultation with the scientific community, including the Science Advisory Board, after notice and opportunity for public comment, and after considering the occurrence data base established under section 300j–4(g) of this title, shall publish a list of contaminants which, at the time of publication, are not subject to any proposed or promulgated national primary drinking water regulation, which are known or anticipated to occur in public water systems, and which may require regulation under this subchapter.

(II) The unregulated contaminants considered under subclause (I) shall include, but not be limited to, substances referred to in

section 9601(14) of this title, and substances registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(III) The Administrator's decision whether or not to select an unregulated contaminant for a list under this clause shall not be subject to judicial review.

(ii) Determination to regulate.—

(I) Not later than 5 years after August 6, 1996, and every 5 years thereafter, the Administrator shall, after notice of the preliminary determination and opportunity for public comment, for not fewer than 5 contaminants included on the list published under clause (i), make determinations of whether or not to regulate such contaminants.

(II) A determination to regulate a contaminant shall be based on findings that the criteria of clauses (i), (ii), and (iii) of subparagraph (A) are satisfied. Such findings shall be based on the best available public health information, including the occurrence data base established under section 300j–4(g) of this title.

(III) The Administrator may make a determination to regulate a contaminant that does not appear on a list under clause (i) if the determination to regulate is made pursuant to subclause (II).

(IV) A determination under this clause not to regulate a contaminant shall be considered final agency action and subject to judicial review.

(iii) Review.—

Each document setting forth the determination for a contaminant under clause (ii) shall be available for public comment at such time as the determination is published.

(C) Priorities.—

In selecting unregulated contaminants for consideration under subparagraph (B), the Administrator shall select contaminants that present the greatest public health concern. The Administrator, in making such selection, shall take into consideration, among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.

(D) Urgent threats to public health.—

The Administrator may promulgate an interim national primary drinking water regulation for a contaminant without making a determination for the contaminant under paragraph (4)(C), or completing the analysis under paragraph (3)(C), to address an urgent threat to public health as determined by the Administrator after consultation with and written response to any comments provided by the Secretary of Health and Human Services, acting through the director of the Centers for Disease Control and Prevention or the director of the National Institutes of Health. A determination for any contaminant in accordance with paragraph (4)(C) subject to an interim regulation under this subparagraph shall be issued, and a completed analysis meeting the requirements of paragraph (3)(C) shall be published, not later than 3 years after the date on which the regulation is promulgated and the regulation shall be repromulgated, or revised if appropriate, not later than 5 years after that date.

(E) Regulation.—

For each contaminant that the Administrator determines to regulate under subparagraph (B), the Administrator shall publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations under this subsection. The Administrator shall propose the maximum contaminant level goal and national primary drinking water regulation for a contaminant 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. The Administrator shall publish a maximum contaminant level goal and promulgate a national primary drinking water regulation within 18 months after the proposal thereof. The Administrator, by notice in the Federal Register, may extend the deadline for such promulgation for up to 9 months.

(F) Health advisories and other actions.—

The Administrator may publish health advisories (which are not regulations) or take other appropriate actions for contaminants not subject to any national primary drinking water regulation.

42 U.S.C. § 300g-1(b)(2) provides:

(2) Schedules and deadlines.—

(A) In general.—In the case of the contaminants listed in the Advance Notice of Proposed Rulemaking published in volume 47, Federal Register, page 9352, and in volume 48, Federal Register, page 45502, the Administrator shall publish maximum contaminant level goals and promulgate national primary drinking water regulations—

(i) not later than 1 year after June 19, 1986, for not fewer than 9 of the listed contaminants;

(ii) not later than 2 years after June 19, 1986, for not fewer than 40 of the listed contaminants; and

(iii) not later than 3 years after June 19, 1986, for the remainder of the listed contaminants.

(B) Substitution of contaminants.—

If the Administrator identifies a drinking water contaminant the regulation of which, in the judgment of the Administrator, is more likely to be protective of public health (taking into account the schedule for regulation under subparagraph (A)) than a contaminant referred to in subparagraph (A), the Administrator may publish a maximum contaminant

level goal and promulgate a national primary drinking water regulation for the identified contaminant in lieu of regulating the contaminant referred to in subparagraph (A). Substitutions may be made for not more than 7 contaminants referred to in subparagraph (A). Regulation of a contaminant identified under this subparagraph shall be in accordance with the schedule applicable to the contaminant for which the substitution is made.

(C) Disinfectants and disinfection byproducts.—

The Administrator shall promulgate an Interim Enhanced Surface Water Treatment Rule, a Final Enhanced Surface Water Treatment Rule, a Stage I Disinfectants and Disinfection Byproducts Rule, and a Stage II Disinfectants and Disinfection Byproducts Rule in accordance with the schedule published in volume 59, Federal Register, page 6361 (February 10, 1994), in table III.13 of the proposed Information Collection Rule. If a delay occurs with respect to the promulgation of any rule in the schedule referred to in this subparagraph, all subsequent rules shall be completed as expeditiously as practicable but no later than a revised date that reflects the interval or intervals for the rules in the schedule.

42 U.S.C. § 300g-1(b)(3) provides:

(3) Risk assessment, management, and communication.—

(A) Use of science in decisionmaking.—In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—

(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and

(ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

(B) Public information.—In carrying out this section, the Administrator shall ensure that the presentation of information on public health effects

is comprehensive, informative, and understandable. The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable—

(i) each population addressed by any estimate of public health effects;

(ii) the expected risk or central estimate of risk for the specific populations;

(iii) each appropriate upper-bound or lower-bound estimate of risk;

(iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and

(v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

(C) Health risk reduction and cost analysis.—

(i) Maximum contaminant levels.—When proposing any national primary drinking water regulation that includes a maximum contaminant level, the Administrator shall, with respect to a maximum contaminant level that is being considered in accordance with paragraph (4) and each alternative maximum contaminant level that is being considered pursuant to paragraph (5) or (6)(A), publish, seek public comment on, and use for the purposes of paragraphs (4), (5), and (6) an analysis of each of the following:

(I) Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level.

(II) Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in

co-occurring contaminants that may be attributed solely to compliance with the maximum contaminant level, excluding benefits resulting from compliance with other proposed or promulgated regulations.

(III) Quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the maximum contaminant level, including monitoring, treatment, and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations.

(IV) The incremental costs and benefits associated with each alternative maximum contaminant level considered.

(V) The effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.

(VI) Any increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants.

(VII) Other relevant factors, including the quality and extent of the information, the uncertainties in the analysis supporting subclauses (I) through (VI), and factors with respect to the degree and nature of the risk.

(ii) Treatment techniques.—

When proposing a national primary drinking water regulation that includes a treatment technique in accordance with paragraph (7)(A), the Administrator shall publish and seek public comment on an analysis of the health risk reduction benefits and costs likely to be experienced as the result of compliance with the treatment technique and

alternative treatment techniques that are being considered, taking into account, as appropriate, the factors described in clause (i).

(iii) Approaches to measure and value benefits.—

The Administrator may identify valid approaches for the measurement and valuation of benefits under this subparagraph, including approaches to identify consumer willingness to pay for reductions in health risks from drinking water contaminants.

(iv) Authorization.—

There are authorized to be appropriated to the Administrator, acting through the Office of Ground Water and Drinking Water, to conduct studies, assessments, and analyses in support of regulations or the development of methods, $35,000,000 for each of fiscal years 1996 through 2003.

42 U.S.C. § 300g-1(b)(4) provides:

(4) Goals and standards.—

(A) Maximum contaminant level goals.—

Each maximum contaminant level goal established under this subsection shall 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.

(B) Maximum contaminant levels.—

Except as provided in paragraphs (5) and (6), each national primary drinking water regulation for a contaminant for which a maximum contaminant level goal is established under this subsection shall specify a maximum contaminant level for such contaminant which is as close to the maximum contaminant level goal as is feasible.

(C) Determination.—

At the time the Administrator proposes a national primary drinking water regulation under this paragraph, the Administrator shall publish a

determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C).

(D) Definition of feasible.—

For the purposes of this subsection, the term "feasible" means feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration). For the purpose of this paragraph, granular activated carbon is feasible for the control of synthetic organic chemicals, and any technology, treatment technique, or other means found to be the best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon.

(E) Feasible technologies.—

(i) In general.—

Each national primary drinking water regulation which establishes a maximum contaminant level shall list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting such maximum contaminant level, but a regulation under this subsection shall not require that any specified technology, treatment technique, or other means be used for purposes of meeting such maximum contaminant level.

(ii) List of technologies for small systems.—The Administrator shall include in the list any technology, treatment technique, or other means that is affordable, as determined by the Administrator in consultation with the States, for small public water systems serving—

(I) a population of 10,000 or fewer but more than 3,300;

(II) a population of 3,300 or fewer but more than 500; and

(III) a population of 500 or fewer but more than 25;

and that achieves compliance with the maximum contaminant level or treatment technique, including packaged or modular systems and point-of-entry or point-of-use treatment units. Point-of-entry and point-of-use treatment units shall be owned, controlled and maintained by the public water system or by a person under contract with the public water system to ensure proper operation and maintenance and compliance with the maximum contaminant level or treatment technique and equipped with mechanical warnings to ensure that customers are automatically notified of operational problems. The Administrator shall not include in the list any point-of-use treatment technology, treatment technique, or other means to achieve compliance with a maximum contaminant level or treatment technique requirement for a microbial contaminant (or an indicator of a microbial contaminant). If the American National Standards Institute has issued product standards applicable to a specific type of point-of-entry or point-of-use treatment unit, individual units of that type shall not be accepted for compliance with a maximum contaminant level or treatment technique requirement unless they are independently certified in accordance with such standards. In listing any technology, treatment technique, or other means pursuant to this clause, the Administrator shall consider the quality of the source water to be treated.

(iii) List of technologies that achieve compliance.—

Except as provided in clause (v), not later than 2 years after August 6, 1996, and after consultation with the States, the Administrator shall issue a list of technologies that achieve compliance with the maximum contaminant level or treatment technique for each category of public water systems described in subclauses (I), (II), and (III) of clause (ii) for each national primary drinking water regulation promulgated prior to June 19, 1986.

(iv) Additional technologies.—

The Administrator may, at any time after a national primary drinking water regulation has been promulgated, supplement the list of technologies describing additional or new or innovative treatment

technologies that meet the requirements of this paragraph for categories of small public water systems described in subclauses (I), (II), and (III) of clause (ii) that are subject to the regulation.

(v) Technologies that meet surface water treatment rule.—

Within one year after August 6, 1996, the Administrator shall list technologies that meet the Surface Water Treatment Rule for each category of public water systems described in subclauses (I), (II), and (III) of clause (ii).

42 U.S.C. § 300g-1(b)(6) provides:

(6) Additional health risk reduction and cost considerations.—

(A) In general.—

Notwithstanding paragraph (4), if the Administrator determines based on an analysis conducted under paragraph (3)(C) that the benefits of a maximum contaminant level promulgated in accordance with paragraph (4) would not justify the costs of complying with the level, the Administrator may, after notice and opportunity for public comment, promulgate a maximum contaminant level for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits.

(B) Exception.—The Administrator shall not use the authority of this paragraph to promulgate a maximum contaminant level for a contaminant, if the benefits of compliance with a national primary drinking water regulation for the contaminant that would be promulgated in accordance with paragraph (4) experienced by—

(i) persons served by large public water systems; and

(ii) persons served by such other systems as are unlikely, based on information provided by the States, to receive a variance under section 300g–4(e) of this title (relating to small system variances);

would justify the costs to the systems of complying with the regulation. This subparagraph shall not apply if the contaminant is found almost

exclusively in small systems eligible under section 300g–4(e) of this title for a small system variance.

(C) Disinfectants and disinfection byproducts.—

The Administrator may not use the authority of this paragraph to establish a maximum contaminant level in a Stage I or Stage II national primary drinking water regulation (as described in paragraph (2)(C)) for contaminants that are disinfectants or disinfection byproducts, or to establish a maximum contaminant level or treatment technique requirement for the control of cryptosporidium. The authority of this paragraph may be used to establish regulations for the use of disinfection by systems relying on ground water sources as required by paragraph (8).

(D) Judicial review.—

A determination by the Administrator that the benefits of a maximum contaminant level or treatment requirement justify or do not justify the costs of complying with the level shall be reviewed by the court pursuant to section 300j–7 of this title only as part of a review of a final national primary drinking water regulation that has been promulgated based on the determination and shall not be set aside by the court under that section unless the court finds that the determination is arbitrary and capricious.

42 U.S.C. § 300g-1(e) provides:

(e) Science Advisory Board comments

The Administrator shall request comments from the Science Advisory Board (established under the Environmental Research, Development, and Demonstration Act of 1978) prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. The Board shall respond, as it deems appropriate, within the time period applicable for promulgation of the national primary drinking water standard concerned. This subsection shall, under no circumstances, be used to delay final promulgation of any national primary drinking water standard.

42 U.S.C. § 300j-4(g)

(g) Occurrence data base

(1) In general

Not later than 3 years after August 6, 1996, the Administrator shall assemble and maintain a national drinking water contaminant occurrence data base, using information on the occurrence of both regulated and unregulated contaminants in public water systems obtained under subsection (a)(1)(A) or subsection (a)(2) and reliable information from other public and private sources.

(2) Public input

In establishing the occurrence data base, the Administrator shall solicit recommendations from the Science Advisory Board, the States, and other interested parties concerning the development and maintenance of a national drinking water contaminant occurrence data base, including such issues as the structure and design of the data base, data input parameters and requirements, and the use and interpretation of data.

(3) Use

The data shall be used by the Administrator in making determinations under section 300g–1(b)(1) of this title with respect to the occurrence of a contaminant in drinking water at a level of public health concern.

(4) Public recommendations

The Administrator shall periodically solicit recommendations from the appropriate officials of the National Academy of Sciences and the States, and any person may submit recommendations to the Administrator, with respect to contaminants that should be included in the national drinking water contaminant occurrence data base, including recommendations with respect to additional unregulated contaminants that should be listed under subsection (a)(2). Any recommendation submitted under this clause shall be accompanied by reasonable documentation that—

(A) the contaminant occurs or is likely to occur in drinking water; and

(B) the contaminant poses a risk to public health.

(5) Public availability

The information from the data base shall be available to the public in readily accessible form.

(6) Regulated contaminants

With respect to each contaminant for which a national primary drinking water regulation has been established, the data base shall include information on the detection of the contaminant at a quantifiable level in public water systems (including detection of the contaminant at levels not constituting a violation of the maximum contaminant level for the contaminant).

(7) Unregulated contaminants

With respect to contaminants for which a national primary drinking water regulation has not been established, the data base shall include—

(A) monitoring information collected by public water systems that serve a population of more than 10,000, as required by the Administrator under subsection (a);

(B) monitoring information collected from a representative sampling of public water systems that serve a population of 10,000 or fewer;

(C) if applicable, monitoring information collected by public water systems pursuant to subsection (j) that is not duplicative of monitoring information included in the data base under subparagraph (B) or (D); and

(D) other reliable and appropriate monitoring information on the occurrence of the contaminants in public water systems that is available to the Administrator.

ADDENDUM B

ADDENDUM B
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No. 24-1191

United States Court of Appeals
District of Columbia Circuit

National Association of Manufacturers *and*
American Chemistry Council,

Petitioners,

– v. –

United States Environmental Protection Agency *and*
Michael S. Regan, *in his official capacity as EPA Administrator*,

Respondents.

DECLARATION OF CHRISTOPHER NETRAM IN SUPPORT OF PETITIONERS

I, Christopher Netram, hereby declare as follows:

1. I am over the age of eighteen. If called as a witness in this action, I could testify to the facts stated herein.

2. I am the Managing Vice President of Policy at the National Association of Manufacturers (NAM). I am authorized to make this declaration on the NAM's behalf. The NAM's headquarters are located at 733 10th St NW, Suite 700, Washington, D.C., 20001.

3. The NAM advocates for the nearly 13 million people who make things in America. Founded in 1895, the NAM is the nation's largest manufacturing industrial trade association. Its 14,000 member companies range from small businesses to multinational firms operating in all 50

states. Its members are engaged in every manufacturing sector, from energy to healthcare to national defense.

4. The NAM advances its members' interests by interfacing directly with law and policymakers on every facet of manufacturing policy. Its work includes litigation to protect and advance its members interests, as well as education and advocacy work.

5. Several NAM members have manufactured perfluoroalkyl and polyfluoroalkyl substances (PFAS) for use in their operations and products. And many more have used or relied on PFAS in their supply chain. PFAS have played a critical role in developing the products that have sustained modern America, such as medical technologies, semiconductors, batteries, phones, cars, and airplanes. For many of the NAM's members, the unique properties of PFAS have been indispensable.

6. In recent years, the NAM's members have begun innovating new chemicals that might replace PFAS throughout America's critical industries, and several have begun phasing certain PFAS compounds out of their manufacturing. But despite these efforts, the NAM's members remain under persistent threat of legal action, including from state water systems and private parties. *See* Hiroko Tabuchi, *Lawyers to Plastics Makers: Prepare for 'Astronomical' PFAS Lawsuits*, New York Times (May 28, 2024), https://nyti.ms/4glJWEm; Jeffrey Kluger, *'Forever Chemical' Lawsuits Could Ultimately Eclipse the Big Tobacco Settlement*, TIME (July 12, 2023), https://bit.ly/3Xmy2B8.

7. I have reviewed and am familiar with the petition for review and opening brief filed in this case. I understand that the lawsuit challenges EPA's final rule, *PFAS National Primary Drinking Water Regulation*, 89 Fed. Reg. 32532 (Apr. 26, 2024) (the Rule). I further understand

that the Rule establishes National Primary Drinking Water Regulations (NPDWR) for six PFAS substances: PFOA, perfluoro-octane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA), and perfluorobutane sulfonic acid (PFBS). The Rule establishes maximum contaminant level goals (MCLGs) of 0 ng/L and enforceable maximum contaminant levels (MCLs) of 4 ng/L, for PFOA and PFOS. It also establishes MCLGs and MCLs of 10 ng/L for PFHxS, PFNA, and HFPO-DA, as well as a Hazard Index of 1.0 for a mixture of two or more of PFHxS, PFNA, HFPO-DA, or PFBS.

8. Compliance with the Rule's MCLs will generate enormous costs, much borne by the NAM's members. EPA estimates the Rule's total annualized cost will be over $1.5 billion. 89 Fed. Reg. at 32665-32666.

9. Advocating for a Rule that complies with the requirements of the Safe Drinking Water Act and the Administrative Procedure Act and challenging the Rule as arbitrary and capricious and beyond the Agency's authority falls within the NAM's mission to advance its members' longstanding interests. The NAM commented on the proposed rule before it was finalized. Comment by the National Association of Manufacturers on EPA PFAS National Primary Drinking Water Regulation Rulemaking Preliminary Regulatory Determination and Proposed Rule, Docket No. EPA-HQ-OW-2022-0114 (May 30, 2023).

10. The NAM also assists its members and the manufacturing industry more broadly by educating its members and the public. The NAM has expended resources to educate its members on the complexities and uncertainties of the Rule.

11. The immediate harm the NAM's members face from PFAS-related litigation includes the risks associated with lawsuits filed by municipal water systems and others required

to comply with the Rule, including the costs of defending against such suits. Indeed, these are costs manufacturers have already begun to bear. *See, e.g.*, Clark Mindock, *New PFAS Lawsuit Cites EPA's 'Forever Chemicals' Drinking Water Rules*, Reuters (Apr. 15, 2024), https://www.reuters.com/legal/litigation/new-pfas-lawsuit-cites-epas-forever-chemicals-drinking-water-rules-2024-04-15/ (discussing PFAS remediation suit filed against PFAS manufacturers). Several states and municipalities have recently filed lawsuits across the country seeking to hold manufacturers, including several NAM members, liable for the cleanup costs they stand to incur to come into compliance. *See, e.g.*, Compl. ¶¶ 115-120, 130-138, *City of Columbia v. 3M et al*, 24-CP-40-03392 (June 4, 2024). The Columbia, South Carolina suit relies on the Rule to provide the standard for liability, meaning that the Rule is directly increasing the liability risk that the NAM's members are facing in pending litigation.

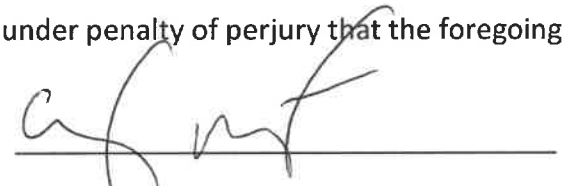
12. The Rule's immediate impact on the NAM's members stems also from the contemporaneous promulgation of the final rule, *Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, 89 Fed. Reg. 39124 (May 8, 2024). This rule designates two PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). This designation confers EPA with cleanup and enforcement authority to require regulated entities, including NAM members, to pay cleanup costs for PFAS contamination under certain circumstances.

13. MCLs under the SDWA can provide "a relevant and appropriate standard" for determining remedial action under CERCLA. *See* 42 U.S.C. § 9621(d)(2)(A). The collective impact of the CERCLA rule and the Rule's MCLs create a risk of CERCLA liability and litigation defense costs where MCLs are allegedly exceeded. EPA has stated expressly that it plans to subject PFAS

manufacturers to such liability, recently announcing in a guidance memorandum that the agency will "focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process." *PFAS Enforcement Discretion and Settlement Policy Under CERCLA*, EPA (Apr. 19, 2024), https://perma.cc/P9NP-5GUR. This threat of imminent enforcement impacts not only NAM members who have manufactured PFAS themselves, but its many members who have used PFAS in producing myriad medical devices, automobiles, airplanes, consumer goods, defense systems, and more.

14. In sum, the NAM's members face immediate and ongoing risk of enormous economic harm stemming directly from the Rule and its new MCLs for several PFAS compounds. An order from the Court vacating the Rule would redress these harms.

I declare under penalty of perjury that the foregoing is true and correct.

Signed: 

Name & Title: Christopher Nctram, Manager VP, Policy

Date: 10/7/2024

No. 24-1191

United States Court of Appeals
District of Columbia Circuit

National Association of Manufacturers *and*
American Chemistry Council,

Petitioners,

– v. –

United States Environmental Protection Agency *and*
Michael S. Regan, *in his official capacity as EPA Administrator*,

Respondents.

DECLARATION OF ROBERT J. SIMON IN SUPPORT OF PETITIONERS

I, Robert J. Simon, hereby declare as follows:

1. I am over the age of eighteen. If called as a witness in this action, I could testify to the facts stated herein.

2. I am the Vice President, Chemical Products & Technology Division, at the American Chemistry Council (ACC). I am authorized to make this declaration on the ACC's behalf. ACC's headquarters are located at 700 2nd St NE, Washington, DC 20002.

3. The ACC represents more than 190 companies engaged in the business of chemistry—an innovative, economic growth engine that is helping to solve the biggest challenges facing the nation and the world. Its members are the leading companies engaged in all aspects of the business of chemistry, from large corporations to small businesses. ACC's members'

groundbreaking innovations improve the world around us by making it healthier, safer, more sustainable, and more productive. The industry's products make it possible to sustain a growing world population, including by protecting food, air, and water supply, supplying affordable energy sources, and delivering new medical treatments.

4. ACC's core vision is to protect the chemistry industry's unique role in facilitating the growth and global leadership of American industry. Its member-driven philosophy makes ACC the leading, collective voice of the chemistry business. It advocates a science-based public policy agenda to create jobs, spur economic growth, and enhance public and environmental health and safety. This work includes participating in litigation on its members' behalf to promote or combat policies affecting their interests where warranted.

5. ACC's members have manufactured and still manufacture a multitude of chemistries that may be defined as perfluoroalkyl and polyfluoroalkyl substances (PFAS) for use in their operations and as their products, as well as for use throughout industrial manufacturing and other value chains. PFAS have played a critical role in developing the products that have sustained modern America, such as medical technologies, semiconductors, batteries, phones, cars, and airplanes. For ACC members developing products in, for example, the national security aerospace, medical and renewable energy industries, the unique properties of PFAS have been indispensable.

6. The Chemours Company, a co-petitioner here, is an ACC member.

7. In recent years, a number of federal and state legislative and regulatory actions have been undertaken to regulate PFAS compounds, including the action challenged in this case. ACC's members also remain under persistent threat of legal action, including from state water

systems and private parties. *See* Hiroko Tabuchi, *Lawyers to Plastics Makers: Prepare for 'Astronomical' PFAS Lawsuits*, New York Times (May 28, 2024), https://nyti.ms/4glJWEm; Jeffrey Kluger, *'Forever Chemical' Lawsuits Could Ultimately Eclipse the Big Tobacco Settlement,* TIME (July 12.2023), http://bit.ly/3Xmy2B8.

8. I have reviewed and am familiar with the petition for review and opening brief filed in this case. I understand that the lawsuit challenges EPA's final rule, *PFAS National Primary Drinking Water Regulation*, 89 Fed. Reg. 32532 (Apr. 26, 2024) (the Rule). I further understand that the Rule establishes National Primary Drinking Water Regulations (NPDWR) for six PFAS substances: perfluorooctanoic acid (PFOA), perfluoro-octane sulfonic acid (PFOS), per-fluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA), and perfluorobutane sulfonic acid (PFBS). The Rule establishes maximum contaminant level goals (MCLGs) of 0 ng/L and enforceable maximum contaminant levels (MCLs) of 4 ng/L, for PFOA and PFOS. It also establishes MCLGs and MCLs of 10 ng/L for PFHxS, PFNA, and HFPO-DA, as well as a Hazard Index of 1.0 for a mixture of two or more of PFHxS, PFNA, HFPO-DA, or PFBS.

9. Compliance with the Rule's MCLs will cost more than $1.5 billion annually according to EPA's own estimates (89 Fed. Reg. at 32665-32666).

10. Advocating for a Rule that complies with the requirements of the Safe Drinking Water Act and the Administrative Procedure Act and challenging the Rule as beyond the Agency's authority and arbitrary and capricious falls within the ACC's mission to advance its members' longstanding interests. ACC filed a comment letter on the proposed rule before it was finalized.

See Comments of the American Chemistry Council on Proposed National Primary Drinking Water Regulation for PFAS, Docket No. EPA-HQ-OW-2022-0114 (June 5, 2023).

11. ACC also assists its members and the chemistry industry more broadly by educating its members and the public. It has expended resources to educate its members on the complexities and uncertainties of the Rule.

12. The immediate harm ACC's members face from PFAS-related litigation includes the risks associated with lawsuits filed by water providers and others required to comply with the Rule, including the costs of defending against such suits. Indeed, these are costs ACC's members and similarly situated companies have already begun to bear. *See, e.g.,* Clark Mindock, *New PFAS Lawsuit Cites EPA's 'Forever Chemicals' Drinking Water Rules,* Reuters (Apr. 15, 2024), https://www.reuters.com/legal/litigation/new-pfas-lawsuit-cites-epas-forever-chemicals-drinking-water-rules-2024-04-15/ (discussing PFAS remediation suit filed against PFAS manufacturers). Several states and municipalities have recently filed lawsuits across the country seeking to hold manufacturers, including Chemours and other ACC members, liable for the cleanup costs they stand to incur to come into compliance. For example, a lawsuit brought by the City of Columbia, South Carolina suit relies on the Rule to provide the standard for liability, meaning that the Rule is directly increasing the liability risk that the ACC's members are facing pending litigation. *See* Compl. ¶¶ 115-120, 130-138, *City of Columbia v. 3M et al.,* 24-CP-40-03392 (June 4, 2024).

13. The Rule's immediate impact on ACC's members stems also from the contemporaneous promulgation of the final rule, *Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, 89 Fed. Reg. 39124 (May

8, 2024). This rule designates two PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). This designation confers EPA with cleanup and enforcement authority to require regulated entities, including ACC members, to pay cleanup costs for PFAS contamination under certain circumstances.

14. MCLs under the SDWA can provide "a relevant and appropriate standard" for determining remedial action under CERCLA. *See* 42 U.S.C. § 9621(d)(2)(A). The collective impact of the CERCLA rule and the Rule's MCLs create a risk of CERCLA liability and litigation defense costs where MCLs are allegedly exceeded. EPA has stated expressly that it plans to subject PFAS manufacturers and other companies that have used PFAS in manufacturing to such liability, recently announcing in a guidance memorandum that the agency will "focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process." *PFAS Enforcement Discretion and Settlement Policy Under CERCLA*, EPA (Apr. 19, 2024), https://perma.cc/P9NP-5GUR.

15. In sum, ACC members face an immediate and ongoing risk of enormous economic harm, including the cost of more frequent litigation and higher liability risks, stemming directly from the Rule and its new MCLs for several PFAS compounds. An order from the Court vacating the Rule would redress these harms.

I declare under penalty of perjury that the foregoing is true and correct.

Signed: _____

Name & Title: Robert J Simon, Vice President Chemical Products and Technology

Date: October 7, 2024

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

THE CHEMOURS COMPANY FC, LLC, *Petitioner*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY and MICHAEL S. REGAN, in his official capacity as Administrator of the United States Environmental Protection Agency, *Respondents*.	)	No. 24-1192

DECLARATION OF TODD A. COOMES

I, Todd A. Coomes, state as follows:

1. I am the Deputy General Counsel at The Chemours Company FC, LLC (Chemours).

2. I am over 18 years of age and am competent to testify to the matters stated in this declaration.

3. Chemours is a chemistry company that manufactures and uses hexafluoropropylene oxide dimer acid and its ammonium salt (collectively, "HFPO-DA") as a component of a patented technology platform used as a polymerization aid in the manufacture of fluoropolymers. Fluoropolymers—extremely stable molecules composed of multiple carbon-fluorine bonds—

are essential to a variety of key industries, including the medical, transportation, semiconductor, electronic/communications, and green energy industries.

4. The technology platform in which Chemours uses HFPO-DA is sometimes referred to as HFPO-DA or by the trade name "GenX."

5. Chemours manufactures HFPO-DA at its Fayetteville Works facility in North Carolina. Chemours uses HFPO-DA in manufacturing processes at its Washington Works facility in West Virginia and at its Chambers Works facility in New Jersey. HFPO-DA is also formed or may be present as an unintended byproduct or impurity from other manufacturing processes at the Fayetteville Works facility and, to a lesser degree, at Chemours's Chambers Works and Parlin facilities in New Jersey.

6. On April 26, 2024, the U.S. Environmental Protection Agency issued a Final Drinking Water Health Advisory entitled *PFAS National Primary Drinking Water Regulation*, 89 Fed. Reg. 32,532 (April 26, 2024) (the Rule). The Maximum Contaminant Levels (MCLs) set forth in that rule have concrete effects on Chemours.

7. North Carolina must issue its Groundwater Quality Standards at levels at least as stringent as the MCL. 15A N.C. Admin. Code 02L .0202. Indeed, North Carolina has proposed such Standards for HFPO-DA at the MCL concentration and has indicated the Standards will be finalized in October 2024. *See*

Public Notice on PFAS Groundwater IMACs (Sep. 4, 2024), https://www.deq.nc.gov/public-notice-imacs-eight-pfas-september-4-2024/download?attachment.

8. The 2019 Consent Order with the North Carolina Department of Environmental Quality (NCDEQ) and Cape Fear River Watch concerning the Fayetteville Works facility and its surrounding areas, which was approved and entered by the North Carolina Superior Court, incorporates requirements "for the remediation of groundwater to the standards set forth in 15A N.C. Admin. Code 02L .0202" (referencing the Groundwater Quality Standards). *See* Consent Order, *North Carolina v. The Chemours Co. FC, LLC* (N.C. Super. Ct., Feb. 25, 2019), https://deq.nc.gov/media/12453/download.

9. A North Carolina statute also authorizes NCDEQ to require the provision of replacement drinking water to parties with private drinking water wells with concentrations of HFPO-DA above the Groundwater Quality Standards. *See* N.C. Gen. Stat. § 143-215.2A.

10. Additionally, Chemours has operations throughout the country, including its facilities in West Virginia and New Jersey. Chemours's operations between its facilities are interconnected, such that an impact on the manufacture of HFPO-DA at Chemours's Fayetteville Works facility in North Carolina may affect its operations at Chemours's facilities in other states.

11. Chemours' immediate harm from the Rule also includes the threat of lawsuits or use in current lawsuits for those required to comply with the Rule or its incorporation into other regulatory programs, including the costs and other burdens of defending against such suits.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 7, 2024.

/s/ Todd A. Coomes

Todd. A. Coomes
Deputy General Counsel
The Chemours Company FC, LLC