ORAL ARGUMENT NOT YET SCHEDULED
Nos. 24-1188 (lead), 24-1191, 24-1192

In the United States Court of Appeals for the District of Columbia Circuit

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

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY & LEE ZELDIN, *in his official capacity as EPA Administrator*, *Respondents*.

THE CHEMOURS COMPANY FC, LLC, *Petitioner*,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY & LEE ZELDIN, *in his official capacity as EPA Administrator*, *Respondents*.

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

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

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GLOSSARY

EPA	Environmental Protection Agency
HFPO-DA	hexafluoropropylene oxide dimer acid
Index Substances	PFHxS, PFBS, PFNA, and HFPO-DA
Level	maximum contaminant level
Goal	maximum contaminant level goal
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
SDWA (the Act)	Safe Drinking Water Act
UCMR3	Third Unregulated Contaminant Monitoring Rule
UCMR5	Fifth Unregulated Contaminant Monitoring Rule

INTRODUCTION AND SUMMARY OF ARGUMENT

At every turn, EPA tries to sidestep the constraints that Congress wrote into SDWA's rulemaking scheme. EPA doesn't deny that its view on cost-benefit analyses would allow it to sneak unjustifiable regulations under the cover of a single cost-justified contaminant level. Nor does EPA deny that its capacious reading of the word "contaminant" would allow the same move through bundling distinct substances into one "mixture." And EPA admits that its view of SDWA's procedural framework would allow it to regulate more substances more hastily than the deliberative cadence Congress mandated.

And for what? According to EPA's flawed methodology, the final Rule's benefits outweigh its costs by a vanishingly slim margin—and that math isn't even accurate. The agency excluded unwanted costs by calling them unquantifiable and minimized compliance costs by ignoring monitoring data already in its possession. Meanwhile, EPA's own data reveals Index Substances contamination to be a rare and isolated issue of the sort EPA has previously (and rightly) declined to regulate.

These pervasive flaws warrant vacatur.

ARGUMENT

I. EPA did not adequately support the Levels selected.

A. EPA's cost-benefit determination is unlawful.

EPA's mashed-up cost-benefit analysis is legally and substantively defective. These errors taint all the final Levels.

1. EPA's cost-benefit determination is reviewable.

a. SDWA does not bar judicial review. *Contra* EPA 99–102. EPA's determination that a Level's benefits "justify or do not justify the costs of compl[iance]" is reviewable "as part of a review of a final national primary drinking water regulation that has been promulgated based on the determination." § 300g-1(b)(6)(D). The regulation challenged here is "based on" EPA's cost-benefit determination: EPA decided that, because the lowest feasible Levels were cost-justified, it could use those Levels without further analysis. *See* 89-FR-32651; *EPA v. Calumet Shreveport Refining, L.L.C.*, 145 S. Ct. 1735, 1750 (2025) ("based on" connotes "lenient" but-for relationship).

EPA rejoins (at 101) that the Rule is not "based on" the cost-benefit determination because the agency "may" use the lowest feasible Level even if costs outweigh benefits. But even then, the cost-benefit determination plays a key role. If the lowest feasible Level is cost-justified, EPA

can stop there, § 300g-1(b)(4)(B), as it did in the Rule, *see* 89-FR-32651. But if not, the agency must either adopt a less-stringent Level or reasonably exercise its discretion to adopt the lowest feasible Level anyway. § 300g-1(b)(6)(A); 5 U.S.C. § 706(2)(A). Either way, the initial cost-benefit determination dictates the regulatory steps the agency takes. That is, in analyzing whether the lowest feasible Level can be used *without further evaluation*, EPA has made a reviewable determination of whether "the benefits … justify or do not justify the costs." § 300g-1(b)(6)(D).

This does not mean *every* cost-benefit determination is reviewable. *Contra* EPA 102. The statute contemplates EPA determining that the lowest feasible Level's benefits don't justify its costs, then, "after" notice and comment, promulgating a cost-justified level. § 300g-1(b)(6)(A). The initial, pre-notice-and-comment determination isn't reviewable because it isn't "part of" a final Regulation "based" thereon. Nor is the cost-benefit analysis reviewable in an action to enforce a final rule. So the review bar still does real work.

EPA also incorrectly infers (at 101–02) from the review bar's location in paragraph (b)(6) that cost-benefit determinations under other paragraphs are wholly unreviewable. The review bar's text disproves that

claim by authorizing review of cost-benefit assessments accompanying "treatment requirement[s]," § 300g-1(b)(6)(D), which occur under paragraph (b)(7). Besides, "[t]he mere fact that" the Act expressly permits review of (b)(6) Levels cannot "support an implication of exclusion as to [review of] others." *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967).

"Any lingering doubt" about reviewability should be "dispelled by" the "presumption favoring judicial review," *Kucana v. Holder*, 558 U.S. 233, 251–52 (2010), which mandates reading judicial-review bars "narrowly," *El Paso Nat. Gas Co. v. United States*, 632 F.3d 1272, 1276 (D.C. Cir. 2011).

b. EPA says any cost-benefit errors are harmless because its feasibility determination "does not depend" on the cost-benefit balance. EPA 95–99. But Petitioners' cost-benefit arguments address EPA's decision that the lowest feasible Level was cost-justified. And if that decision was wrong, EPA had to take another step—deciding whether to use higher, cost-justified Levels. *See* § 300g-1(b)(6)(A). EPA was clear that it never took that step, even in the alternative. 89-FR-32651. If it had done so, then EPA may have set higher Levels. That shows prejudice. *See Calcutt*

v. FDIC, 598 U.S. 623, 630 (2023); *Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 839 (D.C. Cir. 2006).

City of Portland v. EPA doesn't hold otherwise. *Contra* EPA 96–98. There, EPA's error was harmless because the contaminant at issue (cryptosporidium) triggered a special provision barring EPA from adopting a higher Level based on its cost-benefit analysis. 507 F.3d 706, 711 (D.C. Cir. 2007). No such bar exists here.

2. A combined cost-benefit analysis violates SDWA.

a. SDWA mandates a Level-by-Level cost-benefit analysis. It requires considering the benefits of "*each* level" and accounting for the costs of "*the* level." § 300g-1(b)(3)(C)(i)(I), (III) (emphases added). This singular phrasing suggests "Congress did not intend for any and all" proposed Levels to be lumped together. *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 587 U.S. 262, 272 (2019); *see* Industry Br. 16.

Bolstering that conclusion is SDWA's treatment of co-occurrence in the cost-benefit context. EPA must account for the benefits "likely to occur from reductions in *co-occurring contaminants* that may be attributed solely to compliance with the [proposed Level]," unless those benefits result "from compliance with other proposed or promulgated regulations."

§ 300g-1(b)(3)(C)(i)(II); *see* § 300g-1(b)(3)(C)(i)(III) (similar, for costs). Here too, the Act contemplates a Level-by-Level analysis.

Allowing undifferentiated cost-benefit determinations also undermines SDWA's cost-justification requirement. "If EPA had free rein to group [Levels] into a single" cost-benefit determination, "then it could bundle" dozens of non-cost-justified Levels with one strongly justified Level, "effectively giv[ing] EPA a veto power over" the statutory requirement. *Calumet*, 145 S. Ct. at 1748. A grant of "such broad discretion" is unlikely, *id.*, especially since Congress amended SDWA specifically to require cost-justification, *see Stone v. INS*, 514 U.S. 386, 397 (1995) (amendments should "have real and substantial effect").

b. EPA's sole textual response is that a single Regulation may cover multiple contaminants and thus contain multiple Levels. EPA 112–13. But it doesn't follow that each Regulation requires just one cost-benefit analysis. "[E]ach … contaminant" within a Regulation has a distinct Level, § 300f(1)(C)(i), and EPA must make "a determination" of whether the benefits of "the Level" (singular) justify its costs, § 300g-1(b)(4)(C). So if a Regulation addresses multiple contaminants, SDWA requires multiple cost-benefit determinations.

City of Waukesha v. EPA rejected only the need for a new cost-benefit analysis, under the APA's "logical outgrowth" test, when the final level differs from the proposal. 320 F.3d 228, 244–45 (D.C. Cir. 2003) (per curiam). It said nothing about cost-benefit analyses for multi-contaminant rules. *Contra* EPA 113 n.17.

Intervenors invoke (at 41–42) the singular-includes-the-plural presumption. But that presumption "rare[ly]" holds, *United States v. Hayes*, 555 U.S. 415, 422 n.5 (2009), because it is often rebutted by "context," 1 U.S.C. § 1; *see Niz-Chavez v. Garland*, 593 U.S. 155, 164 (2021). Likewise here, no plural construction is possible for the word "each," § 300g-1(b)(3)(C)(i)(I), or the directive to assess "reductions in co-occurring contaminants that may be attributed solely to compliance" with "the" Level, § 300g-1(b)(3)(C)(i)(II), (III).

Intervenors also say (at 42–43) Petitioners' interpretation requires reading "maximum contaminant level" as singular and plural in different parts of § 300g-1(b)(3)(C)(i). Not so. The reference to any "regulation that includes a maximum contaminant level" is singular too; it tells EPA to conduct a cost-benefit analysis any time the agency "propose[s]" a regulation that includes at least one Level.

Finally, EPA's prior practice carries scant weight. *Contra* Intervenors 44–45. EPA has never expressly considered its statutory authority to conduct a combined cost-benefit analysis, let alone "thorough[ly]." *Loper Bright Enters., Inc. v. Raimondo*, 603 U.S. 369, 388 (2024).

c. EPA claims its approach was reasonable because "disentangling" the impacts of regulating each substance was unrealistic and the agency had to assume the existence of the PFOS and PFOA standards. EPA 112–14. Such administrability concerns are for Congress. Anyway, EPA's adopted approach undermines the statutory scheme. As this case shows, a combined cost-benefit analysis lets EPA bootstrap unjustifiable Levels and obscure the true costs of regulation, Industry Br. 17—consequences EPA doesn't deny. In amending SDWA to require cost-justification, Congress is not likely to have allowed such an easy workaround.

Finally, EPA briefly contends (at 111) that it "used contaminant-specific information to analyze the Rule's costs and benefits." Even if that were true, EPA undisputedly made a single cost-benefit determination for *all* the Levels. 89-FR-32651. That's what the statute forbids.

3. EPA ignored significant costs.

Even on its own terms, EPA's cost-benefit analysis is arbitrary and capricious.

a. EPA irrationally excluded an $82 million treatment cost that would flip the quantified cost-benefit analysis. Industry Br. 18–19. EPA's economic analysis lists the mean "quantified total national annualized costs" of the Rule as $1,548.64 million. JA__[EPA-815-R-24-001_at_1-6]. But EPA admits this figure does "not include quantified sensitivity analysis results for PFNA, PFBS, and HFPO-DA" that would have "increase[d] total annualized costs" to "$1,631.05 million"—more than the quantified benefits of $1,549.40 million. JA__[EPA-815-R-24-001_at_1-5, 1-6]. By discounting this evidence, EPA acted arbitrarily and capriciously. *See Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018).

EPA's first rejoinder (at 119)—that it accounted for these costs as *non*quantifiable—makes no sense. The agency could and did quantify them, 89-FR-32672—it conducted a "quantified sensitivity analysis," JA__[EPA-815-R-24-001_at_1-6]. EPA's response illustrates its inconsistent use of the "nonquantifiable" label to paper over unwanted

quantifiable costs. *See infra* § I.A.4. Indeed, EPA saw no problem with "[u]ncertant[ies]" and "[a]ssumption[s]" that "[o]verestimate[d]" the quantified *benefits*. 89-FR-32694–95. But when faced with an $82 million *cost*, EPA balked and deemed an already-quantified cost "unquantifiable." *See* JA__[EPA-815-R-24-001__at_5-28–5-29]. This "internally inconsistent" approach is improper. *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1153–54 (D.C. Cir. 2011).

EPA's second rejoinder (at 119)—that these treatment costs were outweighed by nonquantifiable benefits anyway—fares no better. EPA declared that the "small" $82 million cost "would not change [EPA's] determination" that "the benefits of the rule justify its costs." JA__[EPA-815-R-24-001_Appendix_N.3]. It did not explain why it viewed "a 5 percent increase in national costs" as "small." *Id.* Nor did it say why it deemed the Rule cost-justified even though it had just identified a cost that flipped a putative net benefit of $760,000 to a net cost of over $80 million. Faced with such a massive shift, EPA cannot simply play an "unquantified benefits" "trump card," *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1219 (5th Cir. 1991), or rely on the "conclusory assertion

that" the "benefits of the rule justify" this transformative "cost." *Bus. Roundtable*, 647 F.3d at 1155 (cleaned up).

b. EPA also irrationally ignored the UCMR5 data in estimating the number of affected systems. Industry Br. 19–20. EPA's responses fail.

EPA claims (at 117) that because it had received only 24% of the UCMR5 data, the data "was not actually 'available' for use in the rule-making." But data can be "available" even if more data may be received later.

If EPA means the UCMR5 data would not have been helpful yet, its own statements say otherwise. EPA incorporated state datasets into its occurrence model precisely because that data—like the UCMR5 data—used detection thresholds lower than those in UCMR3. EPA 117; 89-FR-32597; *see* JA__[Cadwallader_4] (describing criteria for acceptance of state datasets). That makes EPA's decision to include state data but exclude comparable UCMR5 data "illogical on its own terms." *GameFly, Inc. v. Postal Regul. Comm'n*, 704 F.3d 145, 148 (D.C. Cir. 2013); *see also infra* § III.A.1 (addressing other flaws in EPA eschewing UCMR5 data).

EPA also says (at 118) the UCMR5 data actually supports its occurrence estimate if one focuses only on the running-annual-average figures. But here too, EPA's justification is illogical. The state-level data included in EPA's occurrence model were not exclusively running annual averages, *see* JA__[Cadwallader_4], yet EPA did not discount that model's conclusions as a result. If running annual averages are the only reliable data (as EPA now claims), its model was fatally flawed from the start. But if other data increases the model's accuracy (as EPA previously claimed), EPA irrationally excluded the UCMR5 data. Either way, EPA's occurrence model is arbitrary and capricious.

4. EPA's analysis of nonquantifiable benefits was arbitrary and capricious.

a. Petitioners did not waive any argument about EPA's use of unquantified benefits and costs. *Contra* EPA 107–08. Commenters faulted EPA for failing to do a "quantitative benefit analysis," JA_[3M_Comment_80], and for "underestimat[ing]" costs by excluding costs for which it lacked data, JA__[Chemours_Comment_25–26]. So EPA was "alert[ed]" to the need to quantify costs and benefits even if it lacked perfect data. *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1036 (D.C. Cir. 2001).

b. EPA's only excuse for deeming numerous purported benefits "nonquantifiable" is that the agency lacked data to do more. EPA 108–09. But while such uncertainty "may mean the [agency] can determine only [a] range" instead of a specific figure, it doesn't "excuse the [agency] from its statutory obligation to determine as best it can the economic implications of the rule it has proposed." *Chamber of Comm. v. SEC*, 412 F.3d 133, 143 (D.C. Cir. 2005). When faced with "cost estimates" that "vary enormously," an agency must "hazard a guess as to which is correct." *Pub. Citizen v. FMCSA*, 374 F.3d 1209, 1221 (D.C. Cir. 2004). EPA failed to do that.

Countenancing EPA's approach would again subvert SDWA's cost-benefit mandate—particularly for a rule, like this one, with a near-zero quantifiable net benefit. An agency faced with costs too high or benefits too small to justify its preferred rule can just duck the problem with a "nonquantifiable" label. "Regulators by nature work under conditions of serious uncertainty, and regulation would be at an end if uncertainty alone were an excuse to ignore a congressional command to 'deal[ ] with' a particular regulatory issue." *Id.*

c. To be sure, SDWA permits EPA to consider "nonquantifiable health risk reduction benefits" if "such benefits are likely to occur." § 300g-1(b)(3)(C)(i)(I), (II). Yet for ten of the thirteen "nonquantifiable" health effects EPA considered, the agency admittedly lacked evidence showing the benefit was likely to occur for the Hazard Index PFAS. *See* 89-FR-32700–02 (COVID-19 severity and cardiovascular, endocrine, metabolic, renal, reproductive, musculoskeletal, hematological, other noncancer, and cancer effects). On EPA's own telling, then, these "nonquantifiable" benefits never should have entered the calculus.

B. EPA's feasibility analysis is fatally flawed.

1. EPA's feasibility analysis did not adequately consider laboratory testing capacity. Industry Br. 23–27.

a. EPA first responds (at 71) that current lab capacity is adequate because the 53 UCMR5-participant labs have sufficed for that program. But compliance will require more frequent testing by many more water systems. While the agency nominally requires only quarterly sampling to prove compliance, that testing frequency "is not the reality for many water systems," who "need[] to know how often [they] need[] to replace [their treatment] media," and thus will have to conduct

"significantly more" testing than "the four per year per entry point required under the rule." JA__[AMWA_Comment_16]. One system, for example, anticipates needing 720 samples per year. *Id.* Scaled to all water systems subject to the rule, each of the 54 currently approved labs will need to test an unsustainable 4,700 more samples every month. JA__[*Id.*_at_17].

That burden becomes even more crushing when concentrated on the 38 laboratories that accept commercial water samples—a limitation EPA failed to consider. EPA claims (at 71) its capacity predictions "were corroborated by the commercial environmental testing community," but the Rule's preamble says no such thing. Nor does it matter that EPA identified 25 labs additional to the UCMR5 participants. Number alone is a poor indicator of capacity, and it's not clear these additional labs accept commercial samples anyway. JA__[3M_Comment_60–61].

b. EPA pivots to predicting that testing supply will increase along with the Rule's forced demand. But SDWA demands that compliance "is feasible" using means that "are available"—present tense. § 300g-1(b)(4)(B), (D); *see United States v. Wilson*, 503 U.S. 329, 333 (1992) ("verb tense is significant in construing statutes"). Regardless,

EPA's prediction is "sheer speculation." *Sorenson Commc'ns, Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014).

c. EPA cannot avoid the capacity shortfall by minimizing expected demand. EPA says (at 71) the testing burden is exaggerated because "many systems will qualify for reduced monitoring." But reduced monitoring is available only if a system "reliably and consistently" tests below 4.0 ppt, 40 C.F.R. § 141.902(b)(2)(iii), and EPA admitted that "many water systems would not be able to secure" testing services that can "consistently" quantify PFOA and PFOS concentrations at those levels, 88-FR-18667.

EPA similarly overstates the impact of water systems' use of "previously collected data to meet their initial monitoring requirements." EPA 71. Most of the systems EPA believes will have this option are UCMR5 participants, *see* 89-FR-32615, but that group makes up fewer than 20% of affected systems. *Compare* 86-FR-73143–44 (10,311 anticipated UCMR5 participants), *with* 89-FR-32661 (approximately 61,000–72,000 systems subject to the Rule).

And even that 20% figure overestimates the systems that could use previously collected data. Such data must be "below the [monitoring]

trigger levels," 40 C.F.R. § 141.902(b)(1)(vi), which, again, are below the level at which laboratories can "consistently" provide "precise and accurate" results, 88-FR-18667. And many UCMR5-participating systems do not have to collect data often enough to satisfy the initial monitoring requirement. *Compare* 40 C.F.R. § 141.902(b)(1)(viii) (four consecutive quarters of data), *with id.* § 141.40(a)(4)(i)(B) (just two samples each year).

2. EPA also failed to adequately consider the limited supply of treatment technology operators. To be sure, the agency considered comments from treatment-system suppliers showing "excess capacity" of *materials*, EPA 70 (citing 89-FR-32623), but that merely "sidestep[s]" concerns about *operational* capacity, *Ohio v. EPA*, 603 U.S. 279, 295 (2024). On that front, EPA says (at 70) only that demand increases will cause supply increases; but again, feasibility is a present-tense inquiry, and anyway, EPA cannot just assume additional operators will be affordable, *see supra* at 15–16.

C. EPA failed to consider significant alternative Levels.

EPA doesn't deny that it failed to seriously consider the tradeoffs of setting the Levels at 20 or 40 ppt. *See* EPA 72–73. Its only reason for

rejecting those alternatives—that they "no longer represented the analytical limits of the best available technology," *id.* at 73—is not rational. Just because technology *can* detect lower levels doesn't make it logical or appropriate to set the compliance threshold at that level if the costs of doing so outweigh the marginal benefits. *See Michigan v. EPA*, 576 U.S. 743, 752–53 (2015). But EPA never even asked that question.

The agency retorts (at 73–74) that SDWA doesn't require it to consider the cost-benefit tradeoffs of a higher alternative Level. But doing so has long been a "quintessential aspect[] of reasoned decisionmaking," *Int'l Ladies Garment Workers' Union v. Donovan*, 722 F.2d 795, 818 (D.C. Cir. 1983), and "absent a clear statement, this court will not assume that a statute modifies the reasoned decisionmaking requirements of the APA," *Carlson v. Postal Regul. Comm'n*, 938 F.3d 337, 348 (D.C. Cir. 2019); *e.g.*, *Waukesha*, 320 F.3d at 245 (applying "traditional APA" standards under SDWA). SDWA doesn't plainly override the "established administrative practice" of weighing "the advantages *and* the disadvantages of agency decisions," *Michigan*, 576 U.S. at 753, so EPA's failure to engage with alternative Levels renders its decision arbitrary and capricious.

II. The Hazard Index and individual Levels for the Index Substances are unlawful.

A. EPA cannot regulate mixtures through a multi-contaminant index.

SDWA requires a distinct Level for each "contaminant." Industry Br. 31. EPA agrees, but contends (at 25–26) that it permissibly used a single Level for the four Index Substances (when they co-occur) because "contaminant" means "any … substance or matter in water" and "matter" includes "mixtures or groups" of substances.

EPA's reading "violates the rule against 'ascribing to one word a meaning so broad' that it assumes the same meaning as another statutory term." *Ysleta Del Sur Pueblo v. Texas*, 596 U.S. 685, 698 (2022). EPA says the definition of "matter" "encompasses … substances." EPA 25. But if so, SDWA wouldn't need the word "substance" at all, since "matter" alone "would do all the necessary work." *Hibbs v. Winn*, 542 U.S. 88, 101 (2004).

EPA's reading also conflicts with the ordinary meaning of "contaminant." *See Bond v. United States*, 572 U.S. 844, 861 (2014) (considering "the ordinary meaning of a defined term"). A contaminant is "[o]ne that contaminates." *Contaminant*, *Am. Heritage Dictionary* (5th ed. 2022). Ordinarily, you wouldn't say that a mixture of multiple substances that

can each "contaminate" (say, lead and arsenic) are one "contaminant" whenever they appear together. That is, water with both PFHxS and PFNA—each of which can occur on its own, and each of which can independently (per EPA) "contaminate" water—has two "contaminants," not one. When Congress wants to depart from this ordinary meaning, it does so expressly. *E.g.*, 42 U.S.C. § 9601(33) (in CERCLA, defining "contaminant" to include "mixture").

EPA's contrary reading allows an end-run around a central statutory requirement. EPA must cost-justify, or at least explain its decision *not* to cost-justify, each selected Level. *Supra* § I.A.2. That restriction vanishes if EPA can just bundle together unjustified contaminants with a strongly justified one into a "mixture." "The risk of such end-runs around the core function" of SDWA's cost-benefit rules "confirms" EPA's error. *Newman v. FERC*, 27 F.4th 690, 703 (D.C. Cir. 2022).

EPA's appeal to historical practice (at 28–29) also fails. EPA has never grappled with SDWA's text in deciding to regulate a group of chemicals. *See Loper Bright*, 603 U.S. at 388.

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

On the legal deficiencies in the Hazard Index and Index Substance Levels, Industry Petitioners adopt Utility Petitioners' arguments in reply and add the following.

1. EPA's simultaneous proposal to regulate and proposal of Goals and Levels violated the Act.

As EPA admits in its motion to vacate, SDWA doesn't allow it to simultaneously propose to regulate a particular contaminant and propose Goals and Levels for it. Doc. 2134523 at 10; Industry Br. 34–35. Any contrary view requires reading "determination to regulate" to mean a "final determination" in the first clause of § 300g-1(b)(1)(E) but "preliminary determination" in the second. EPA 30. That's a doubtful construction to begin with—but especially so given that Congress omitted the qualifier "preliminary" in the second clause, despite using that term everywhere else it used "determination" to refer to a contaminant which "may require regulation," § 300g-1(b)(1)(B)(i)(I), (b)(1)(B)(ii)(I).

Reading paragraph (b)(1)(E)'s "concurrent with" clause to refer to a final determination to regulate doesn't make it "superfluous." *Contra* EPA 31. Congress "could well have added" the "concurrent with" clause "to remove any doubt as to things not particularly doubtful in the first

instance." *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund*, 583 U.S. 416, 435 (2018). There's no reason to adopt a strained reading of the statutory text in order to avoid redundancy with unstated background principles.

EPA's procedural error was prejudicial—again, as EPA now admits. Doc. 2134523 at 16–19. An agency's "utter failure" to comply with a mandatory procedure is not harmless "if there is any uncertainty at all as to the effect." *Sprint Corp. v. FCC*, 315 F.3d 369, 376–77 (D.C. Cir. 2003). EPA cannot meet that high bar. Had EPA not unlawfully combined the Act's separate steps, Petitioners could have focused their comments on the preliminary determination to regulate, and EPA may have given those comments additional consideration.

EPA also may not have finalized its regulatory determination for the Index Substances and Hazard Index. Simultaneously proposing to regulate and proposing specific Goals and Levels likely had a lock-in effect. EPA would not have gone through the trouble of developing proposed Goals and Levels if it weren't set on regulating. So EPA's procedural error taints every aspect of the final Rule with respect to the Index Substances and Hazard Index.

2. EPA failed to adequately consult the Science Advisory Board.

SDWA commands that EPA "shall request" input from the Science Advisory Board "prior to proposal of" Goals and Levels. § 300g-1(e). EPA admits it did not consult the Board about its proposed Goals and Levels for the Hazard Index and Index Substances, but claims it can satisfy the statute by consulting the Board *at all*, on any topic. EPA 92–94. That strips the statutory directive of any meaning. EPA must consult the Board "prior to proposal of" Goals and Levels because those are the things the Board must weigh in on. On EPA's contrary view, Congress had no reason to make consultation mandatory in the first place.

This failure was prejudicial. *Contra* EPA 94–95. This Court has "not been hospitable to government claims of harmless error" when an agency just skips a procedural step, because the agency's failure alone may make showing harm "impossible." *Oglala Sioux Tribe v. NRC*, 896 F.3d 520, 534–35 (D.C. Cir. 2018). Likewise here, Petitioners cannot point to specific effects because we don't know what the Board would have said. That suffices to show prejudice. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1109–10 (D.C. Cir. 2014).

C. The Hazard Index lacks substantial evidence of occurrence at levels of public health concern.

EPA can't regulate a contaminant unless it "occur[s]" or "will occur in public water systems with a frequency and at levels of public health concern." § 300g-1(b)(1)(A)(ii), (b)(1)(B)(ii)(II). EPA's own occurrence data confirms that Index Substance combinations fail this test.

EPA's sample-level data show just how rarely Index mixtures exceed the Hazard Index's 1.0 threshold, below which "no known or anticipated adverse effects on the health of persons occur." 89-FR-32533. Of the almost 12,000 systems sampled, only 203—or just 1.7%—reported Hazard Index values above 1.0. JA__[Occurrence_Support_226–35]; *see* 89-FR-32595 (state-level data). And just 1.78% of almost 47,000 total samples exceeded this threshold. Most states had fewer than 4% of samples over the threshold, and even that figure is skewed by outliers. JA__[Occurrence_Support_220–25]. Colorado's exceedance rate dropped from 35.06% in 2013–2017 to just 0.34% in 2020, but EPA still included the older data. JA__[Occurrence_Support_221]. In short, exceedances are rare and often reflect dated or limited information.

Intervenors retort (at 18) that 4.7 million people are exposed to water with a Hazard Index greater than 1.0. But that is still just 5.62% of

the 84 million people served by sampled systems. JA__[Occurrence_Support_226–35]. And of those, nearly 60% (2.8 million people) are concentrated in California. JA__[Occurrence_Support_226]. Excluding California, the national exposure rate drops to just 2.3% of the sampled population. That is not the "public health concern" required for federal action. *See* § 300g-1(b)(1)(A)(ii).

III. EPA's regulation of HFPO-DA is irreparably flawed.

A. EPA has not demonstrated that HFPO-DA occurs at a frequency and at levels of public health concern.

1. The occurrence database refutes EPA's occurrence determination.

Any occurrence finding "shall be based on the best available public health information, including the occurrence data base established under § 300j-4(g)." § 300g-1(b)(1)(B)(ii)(II). This occurrence database includes Unregulated Contaminant Monitoring Rule data; Department of Defense data; and National Water Information System data. Yet EPA effectively disregarded those data sources, all three of which undermine EPA's occurrence determination.

EPA no longer disputes—because it cannot—that UCMR5 data *were* available when it determined to regulate. So instead, EPA argues that no UCMR5 data were available when it "proposed" to regulate. EPA

50. But that is irrelevant: SDWA mandates that the "determination to regulate"—not the proposal—"shall" be based on the occurrence data base. § 300g-1(b)(1)(B)(ii). EPA's admitted failure to follow that command is fatal.

EPA's other reasons for ignoring the UCMR5 data are similarly unavailing. Petitioners never claimed that "EPA should have relied *exclusively* on" UCMR5, EPA 50—only that ignoring it altogether was unlawful. And EPA's argument (at 50) that it relied instead on state data because they were more "robust" is post-hoc reasoning: During the rulemaking, EPA said it rejected UCMR5 on the *legal* ground that none of the data was "available." JA__[EPA_Response_6-68]; *see* JA__[EPA_Response_6-69] (claiming no "legal obligation" to consider UCMR5). In any event, EPA *did* rely on UCMR5 data, but only where it supposedly "confirm[ed] the EPA's conclusions" about the general prevalence of other PFAS in public water systems. 89-FR-32526; *see* JA__[EPA_Response_6-69–70]. That sort of selective reliance constitutes reversible error. *See Am. Iron & Steel Inst. v. OSHA*, 939 F.2d 975, 1009 (D.C. Cir. 1991) (per curiam).

The other federal databases further undercut EPA's determination. Department of Defense data showed *zero* reported HFPO-DA detections at or above 10 ppt out of 1,178 samples, JA__[PFAS_Occurrence_Ex._7-12], and National Water Information System data showed *zero* out of 170 samples. EPA retorts (at 53) that non-detection "simply shows that HFPO-DA did not occur at those particular test sites" but cannot "negate" data from "other sites where contamination is known to occur." This heads-we-win, tails-you-lose reasoning is incompatible with the statutory mandate that any occurrence finding "shall be based on … the occurrence data base." § 300g-1(b)(1)(B)(ii)(II).

In total, the federal occurrence database showed only *two* samples out of 18,261 (0.01%) where HFPO-DA occurred at the "levels of public health concern" determined by EPA. § 300g-1(b)(1)(A)(ii). As Petitioners noted—and EPA does not dispute—the agency "has never imposed a Level for any other contaminant so infrequently detected at levels of concern." Industry Br. 46.

2. The state data do not support EPA's occurrence finding.

Even if it were appropriate to prioritize the state data over the statutorily mandated federal occurrence data—it was not—the state data

further confirm that HFPO-DA occurrence is extremely rare. HFPO-DA was found at or above 10 ppt in only 0.02% of the 35,917 samples in EPA's state data for which an occurrence rate can be calculated. Industry Br. 50; JA__[PFAS_Occurrence_Ex._7-8]. EPA tries (at 53) to conjure the impression that contamination is widespread by describing that 0.02% as being "in five geographically dispersed states." But it neglects to note that four of those states had fewer than *three* detections out of more than 12,000 total samples: Virginia (1), Ohio (1), Kentucky (2), and Michigan (3). JA__[PFAS_Occurrence_Ex._7-8].

The only state with more than three reported detections was North Carolina, which did *not* report the total number of samples taken. As Petitioners argued, this failure to identify a denominator "mak[es] it impossible to know the relevant proportion," rendering the data "unusable for establishing frequency." Industry Br. 51; *see Bismullah v. Gates*, 501 F.3d 178, 186 (D.C. Cir. 2007). EPA has no response.

EPA dismisses (at 42) the numerous flaws in the state data—including serious selection-bias problems, *see* Industry Br. 50—on the ground that "ignoring it would arbitrarily exclude relevant information and known exposures to the contaminant." But the statute requires a

finding that a contaminant to occurs "*with a frequency* and at levels of public health concern." § 300g-1(b)(1)(A)(ii) (emphasis added). A "frequency" determination requires establishing a baseline, which selection-bias makes impossible.

In any event, North Carolina—the only state with any meaningful HFPO-DA detections—*already* addresses the sole source of emissions at the same concentration (10 ppt) that EPA's rule would require. *See* Consent Order, *North Carolina v. The Chemours Co. FC, LLC* (N.C. Super. Ct., Feb. 25, 2019), tinyurl.com/2mj8jncj.[1] A nationwide rule therefore does not "present[] a meaningful opportunity for health risk reduction." § 300g–1(b)(1)(A)(iii).

3. No evidence supports EPA's reliance on HFPO-DA's supposed presence in consumer products.

Lacking *current* data showing widespread HFPO-DA occurrence, EPA argues (at 47–48) that it may regulate where there is "substantial likelihood" a compound "will" occur. To support its prediction of future HFPO-DA contamination, EPA asserted that the chemical has a

[1] This regulation has proven effective: Contrary to Intervenors' misstated claims (at 15) of "thousands of pounds" of environmental releases, this facility emitted only 13 pounds of HFPO-DA in 2023. *See* EPA, *Toxics Release Inventory (TRI) Program* (Jan. 27, 2026), tinyurl.com/4rtyvrv5.

"continued and possibly increasing presence in consumer products and use." 89- FR-32557. Literally no evidence supports that assertion. To the contrary, unlike PFOA and PFOS, HFPO-DA is not known to be used in consumer products *at all*. Its one approved use under the Toxic Substances Control Act is as a manufacturing-processing aid, and it has only one known relevant exposure pathway: drinking water near a small number of processing facilities. *See infra* § III.B.1. Indeed, EPA itself admitted that "no specific studies on the occurrence of HFPO-DA in consumer products were identified." JA__[MCLG_A-12]. Absent *any* evidence, EPA's assertion of consumer-product exposure is purely speculative.

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

1. EPA failed to justify its exposure assumption.

In identifying a relative source contribution, EPA's own guidance precludes reliance on the 20% default exposure assumption unless "adequate exposure data do not exist." EPA Office of Water, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, 1-7 (Oct. 2000), tinyurl.com/2kzvsx3x. Yet despite dozens of exposure studies for HFPO-DA, EPA relied on the default here.

EPA defends that reliance (at 83–84) by asserting that "potential sources other than drinking water ingestion were identified, but the available information [wa]s limited and d[id] not allow for the quantitative characterization of the relative levels of exposure among these different sources." JA__[MCLG_2-3]. That response misses the point: EPA never explained *why* the vast HFPO-DA-specific data—including dozens of studies, gray-literature sources, and references, JA__[MCLG_A-9–A-11]—nevertheless qualified as "limited." Nor did EPA explain *why* "quantitative characterization" was impossible, given that quantitative data were available in all but one of the categories EPA considered. JA__[MCLG_A-11–A-15].

EPA emphasizes (at 83) "studies show[ing] people may be exposed to HFPO-DA through non-drinking water exposure routes." That's a red herring: EPA didn't choose a 20% exposure assumption *affirmatively*, based on evidence showing that 80% of exposure to HFPO-DA would come through other sources; the agency chose 20% *as a default* because "available information [wa]s" purportedly "limited." JA__[MCLG_2-3]. *That* is the conclusion EPA was required to justify—but didn't. And again, EPA fails to explain why the data were apparently sufficient for

EPA to make the (inaccurate) pronouncement that "there are significant known or potential uses/sources of HFPO-DA other than drinking water," JA__[MCLG_A-15], yet simultaneously *insufficient* to calculate a relative source contribution.

Finally, EPA blames Chemours (at 84) for not "identify[ing]" studies "that quantif[y] HFPO-DA exposure through drinking water as compared to other exposure media," and not "offer[ing] any evidence to *specifically calculate* a relative source contribution value EPA should have used." But EPA *itself*—the regulating agency—must identify a relative source contribution, following the methodology in its own guidance. Having chosen to rely on the 20% default, the agency bears responsibility for sustaining that choice.

2. EPA relied on unsupported toxicity assumptions.

Inflated uncertainty factors. EPA asserts (at 90) that increasing the subchronic-to-chronic uncertainty factor became necessary when EPA "revised its assessment of the most sensitive population from parental males to lactating females," since females were tested for shorter durations. But as Chemours explained, EPA's guidance *already* addressed both "developmental" and "maternal toxicity" endpoints, stating that "*an*

uncertainty factor is not applied to account for duration of exposure." JA__[Chemours_RFC_Ex.3_17] (citation omitted); *accord* JA__[Chemours_Comment_16].

To support increasing the database uncertainty factor from 3 to 10, EPA references (at 91) studies that supposedly "identified new health effects needing more study—specifically, reproductive, developmental, and neurotoxic effects." But Chemours addressed those studies in its Request for Correction, explaining why they do not justify increasing the database uncertainty factor. JA__[Chemours_RFC_26–27]. Chemours also submitted an expert report that reviewed those studies and found "'no scientifically defensible way to justify increasing the database uncertainty factor based on [EPA's new] studies.'" JA__[Chemours_RFC_27] (quoting JA__[Chemours_RFC_Ex.4_6]). EPA never responded.

Irrelevant rodent effects. EPA repeatedly urges the Court to ignore the flaws in its toxicological analysis. EPA Br. 23–24, 85, 88. But drinking water regulations must be based upon "the best available, peer reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." § 300g-1(b)(3)(A)(i). Here, EPA invented an entirely new toxicological endpoint—a so-called

"constellation of liver effects"—that appears neither in the scientific literature nor in the work of its external Working Group. *See* JA__[Chemours_RFC_23–25]; JA__[Chemours_Comment_18]; JA__[Chemours_Comment_Ex.1_9–10]. EPA argues (at 88) that because it could not definitively determine that *all* liver effects depend *solely* upon PPAR-α, it was reasonable for the agency to assume relevance to humans. But Chemours repeatedly submitted technical evidence illustrating the flaws of EPA's reasoning, JA__[Chemours_Comment]; JA__[Chemours_Comment_Ex.1]; JA__[Chemours_RFC], to which EPA never responded. EPA cannot justify that failure now.

IV. The Court should vacate the Rule.

The parties agree that vacatur should be tailored to the Rule's flaws. But together those flaws infect the entire Rule, so the Court should vacate it.

Remand *without* vacatur is not the appropriate remedy for EPA's cost-benefit errors. *Contra* EPA 121–22. Remand without vacatur is reserved for "rare cases" where (1) the agency is "likely" to justify the same action on remand and (2) vacatur would be "disruptive." *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019).

EPA likely cannot justify Levels whose cost outweighs their benefits. Commenters explained that EPA could have significantly increased the Levels without any reduction in health benefits. *See* JA__[3M.Comment.61–62]. Since EPA could set higher Levels without losing health-protection benefits, a higher, cost-justified level is likely the only rational result.

Nor would vacatur be disruptive, since it would not change the status quo. The Levels are not yet in effect, *see* 40 C.F.R. § 141.900(b), and EPA intends to extend the compliance date ever further for PFOA and PFOS. EPA, *EPA Announces It Will Keep Maximum Contaminant Levels for PFOA, PFOS* (May 14, 2025), tinyurl.com/4uxcc8bp. If anything, it is a no-vacatur remand that would be disruptive: if the levels stay in place, regulated parties would be forced to make costly infrastructure investments solely to comply with rules that may never take effect.

CONCLUSION

The Court should vacate the flawed portions of the Rule.

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CERTIFICATE OF COMPLIANCE

This brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)–(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook font. It complies with Rule 32(a)(7)(B)'s type-volume requirements because it contains 6,397 words, not counting the parts excluded by Rule 32(f) and Circuit Rule 32(e)(1).

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