SCHEDULED FOR ORAL ARGUMENT JANUARY 20, 2026

No. 24-1193
(consolidated with Nos. 24-1261, 24-1266, 24-1271, and 24-1272)

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

CHAMBER OF COMMERCE OF THE
UNITED STATES OF AMERICA, et al.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

On Petition for Review of Final Action by the
U.S. Environmental Protection Agency

FINAL BRIEF FOR U.S. ENVIRONMENTAL PROTECTION AGENCY

ADAM R.F. GUSTAFSON
Principal Deputy Assistant Attorney General
Environment & Natural Resources Division

JIN HYUNG LEE
United States Department of Justice
Environmental Defense Section
Environment & Natural Resources Division
P.O. Box 7611
Washington, D.C. 20044
(202) 598-7264
jin.hyung.lee@usdoj.gov

Of Counsel:

ELIZABETH G. BERG
NOEL M. JOHNSON
JEFFREY MANSBACH
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Except for the following, all parties, intervenors, and amici appearing in this court are listed in the Brief for Petitioners: National Association of Manufacturers, American Farm Bureau Federation, Printing United Alliance, National Association of Water Companies, National Association of Clean Water Agencies, Superfund Settlements Project, National Cattlemen's Beef Association, National Pork Producers Council, National Rural Water Association, WateReuse Association, and Water Environmental Federation, all of which appear as Amici Curiae in Support of Petitioners.

B. Rulings Under Review

Reference to the ruling at issue appears in the Brief for Petitioners Chamber of Commerce of the United States, et al.

C. Related Cases

There are no related cases within the meaning of Circuit Rule 28(a)(1)(C).

/s/ *Jin Hyung Lee*
JIN HYUNG LEE

Counsel for Respondents

TABLE OF CONTENTS

TABLE OF AUTHORITIES*

CASES

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

STATUTES

CODE OF FEDERAL REGULATIONS

FEDERAL REGISTER

LEGISLATIVE HISTORY

DICTIONARY

GLOSSARY

APA	Administrative Procedure Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
EA	Economic Assessment
EPA	U.S. Environmental Protection Agency
NCP	National Contingency Plan
NPL	National Priorities List
PFAS	Per- and polyfluoroalkyl substances
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
PRPs	Potentially Responsible Parties
RFA	Regulatory Flexibility Act
RIA	Regulatory Impact Analysis
RTC	Response to Comments

INTRODUCTION

Perfluorooctanoic acid ("PFOA") and perfluorooctanesulfonic acid ("PFOS") are two chemicals in the broader class of per- and polyfluoroalkyl substances ("PFAS"), a large group of human-made compounds whose extreme resistance to degradation has earned them the moniker "forever chemicals." Exposure to PFOA and PFOS is linked to many serious adverse health impacts, including various forms of cancer, pregnancy complications, low birth weight, immunosuppression, liver damage, increased cholesterol, and decreased bone-mineral density. Although their domestic manufacture has been phased out, PFOA and PFOS were produced for decades in large quantities. Because PFOA and PFOS are persistent and highly mobile, these substances can be found today in soil, drinking water, crops, livestock, game, and—most alarmingly—our blood.

Congress passed the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA" or "the Act") to address precisely the kind of legacy contamination problems that PFOA and PFOS pose. The Act authorizes EPA to investigate and clean up contaminated sites, and it ensures that costs of cleaning up "hazardous" substances are ultimately borne by those most directly responsible for contamination.

Petitioners challenge EPA's decision to designate PFOA and PFOS as "hazardous" and thus bring them fully within CERCLA's comprehensive cleanup

scheme. EPA acted under a provision of the Act authorizing designation of substances that "may present substantial danger to public health or welfare or the environment." 42 U.S.C. § 9602(a). PFOA and PFOS plainly meet that standard given the extensive record evidence of their adverse health impacts and chemical properties. At minimum, EPA acted reasonably by finding the standard satisfied.

Petitioners do not challenge EPA's technical judgment about the danger that PFOA and PFOS pose. Instead, they argue that EPA had to define the precise contours of the term "may present substantial danger" before designating any substance as hazardous. But this demand has no basis in CERCLA's text, and it would undermine Congress's purposes. Nor in any event would it justify Petitioners' request for vacatur.

Petitioners also argue that EPA could designate PFOA and PFOS as hazardous substances only after determining the nature and cost of future PFOA- and PFOS-related cleanups. This is exactly backwards. Hazardous-substance designation is a threshold step. Designation does not itself require anyone to clean up PFOA or PFOS. Any future cleanup action under CERCLA will hinge on site-specific assessments of risk and cost that are impossible to accurately predict in gross. EPA carefully assessed advantages and disadvantages of designation in the face of unavoidable uncertainty about future cleanup activity, and it concluded, based on

the information available, that designation was appropriate. That conclusion, and the analysis that led to it, were reasonable. The petitions should be denied.

STATEMENT OF JURISDICTION

This Court has jurisdiction under 42 U.S.C. § 9613(a). This action is timely because the Final Rule titled "Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances" was published on May 8, 2024, 89 Fed. Reg. 39124, and the petitions for review were filed on June 10, July 30, August 2, and August 5, 2024. *See* ECF 2059395, 2067736, 2068181, 2068230, 2068519.

STATEMENT OF THE ISSUES

1. Whether 42 U.S.C. § 9602(a) authorized EPA to designate PFOA and PFOS as hazardous substances based on a significant body of scientific evidence demonstrating that both substances may present a substantial danger upon release into the environment.

2. Whether EPA permissibly designated PFOA and PFOS despite unavoidable uncertainty about designation's impact on future, contingent, discretionary, and site-specific cleanup actions.

3. Whether EPA was required to take comment on the quantified estimates of costs and benefits associated with future PFOA- and PFOS-related cleanup

activity that were set out in the preamble to the Final Rule but were not critical material upon which the agency relied.

4. Whether EPA reasonably considered advantages and disadvantages of designating PFOA and PFOS as hazardous substances when deciding whether it was "appropriate" to act under 42 U.S.C. § 9602(a).

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in the addendum to this brief, except for 42 U.S.C. § 9602(a), which appears in the addendum to Petitioners' brief.

STATEMENT OF THE CASE

A. Statutory and regulatory background

Congress enacted CERCLA "in response to the serious environmental and health risks posed by industrial pollution." *Burlington N. & Santa Fe Ry. Co. v. United States*, 556 U.S. 599, 602 (2009). "The Act was designed to promote the timely cleanup of hazardous waste sites and to ensure that the costs of such cleanup efforts were borne by those responsible for the contamination." *Id.* To those ends, CERCLA delegates authority to the President, who in turn has delegated much of that authority to EPA. *See* 42 U.S.C. § 9615; *see also* Exec. Order No. 12580, 52 Fed. Reg. 2923 (Jan. 29, 1987).[2] Relevant provisions of the Act are discussed below.

[2] For simplicity, we generally refer throughout this brief to EPA's authority under CERCLA.

1. Section 9602 authorizes EPA to designate hazardous substances.

A "hazardous substance" under CERCLA is any substance designated under five enumerated provisions of other statutes or under 42 U.S.C. § 9602(a). 42 U.S.C. § 9601(14). Section 9602 authorizes EPA to "promulgate and revise as may be appropriate, regulations designating as hazardous substances . . . such elements, compounds, mixtures, solutions, and substances which, when released into the environment may present substantial danger to the public health or welfare or the environment." *Id.* § 9602(a). There are over 800 CERCLA hazardous substances, 40 C.F.R. § 302.4, but PFOA and PFOS are the first substances designated under Section 9602.[3]

Once a substance is designated as "hazardous," any release of that substance at or above a certain threshold must be reported to federal officials and, in some cases, to the public and to state, tribal, or local emergency planners. 42 U.S.C. §§ 9602(b), 9603, 9611, 11004. Federal agencies that sell or transfer real property must also disclose the presence of hazardous substances. *Id.* § 9620(h). And the U.S. Department of Transportation must regulate substances designated as hazardous under CERCLA in accordance with the Hazardous Materials

[3] Any references to PFOA and PFOS in this brief includes their salts and structural isomers. *See* 89 Fed. Reg. at 39125.

Transportation Act. *Id.* § 9656(a). There are no other direct effects of hazardous substance designation.

2. Section 9604 authorizes EPA to undertake Superfund-financed removal and remedial actions.

EPA can respond to "any" release or threatened release of a hazardous substance and to releases or threatened releases of a "pollutant or contaminant" that "may present an imminent and substantial danger to the public health or welfare." *Id.* § 9604(a)(1). Pollutants or contaminants "include . . . any . . . substance," which "after release into the environment . . . will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations." *Id.* § 9601(33).

Funds for EPA-led response actions come from the Hazardous Substances Trust Fund, commonly known as "the Superfund." *Id.* § 9611(a)(1).

CERCLA authorizes two types of response actions: "removal" and "remedial." *Id.* § 9601(25). Removal actions "are typically short-term response actions" that "address releases or threatened releases requiring prompt action" and "are limited in cost and duration unless specific criteria are met." 89 Fed. Reg. at 39137; 42 U.S.C. §§ 9601(23), 9604(a)–(b). Remedial actions may be "taken instead of or in addition to removal actions," 42 U.S.C. § 9601(24), and they "entail longer-term and more complex cleanup actions designed to provide permanent

solutions to mitigate risks typically associated with chronic exposures often not immediately life-threatening," 89 Fed. Reg. at 39137.

The President has delegated to federal agencies other than EPA the authority to undertake certain response actions under Section 9604 at sites within their jurisdiction or control. Exec. Order 12580, § 2(e)(1), 52 Fed. Reg. at 2924.

3. CERCLA response actions must be based on detailed site-specific assessments of relative risk and cost.

All CERCLA response actions must be "consistent with the national contingency plan." 42 U.S.C. § 9604(a); 40 C.F.R. § 300.400(a)(1)–(2). The "National Contingency Plan for the Removal of Hazardous Substances and Waste," or "NCP," is a body of regulations that prescribe methods and criteria for:

- Discovering and investigating facilities, 42 U.S.C. § 9605(a)(1); 40 C.F.R. §§ 300.405, 300.410, 300.420;
- Prioritizing actions based on site-specific risk-based factors such as hazard potential, population at risk, and the potential for drinking water contamination, 42 U.S.C. § 9605(a)(8); 40 C.F.R. § 300.425; 40 C.F.R. Pt. 300 App. A; and
- Tailoring response actions at given sites based on, among other things, "relative costs" and "cost-effective[ness]" of various alternative approaches, 42 U.S.C. § 9605(a)(2), (7); 40 C.F.R. §§ 300.415, 300.430, 300.435.

Only those sites that EPA deems "priorities" and adds to the "National Priorities List" ("NPL") are eligible for Superfund-financed remedial actions. 40 C.F.R. § 300.425(b)(1); *see also* 42 U.S.C. § 9605(a)(8)(A)–(B). Sites may be added to the NPL based on the presence of hazardous substances, pollutants or

contaminants, or a combination. *See* 42 U.S.C. § 9605(a)(8)(B); 40 C.F.R. § 300.425(b).

4. Hazardous substance designation unlocks core provisions of CERCLA.

While Section 9604 authorizes the federal government to respond to releases of hazardous substances *and* pollutants or contaminants, other core provisions of CERCLA are limited to releases of hazardous substances. Among them, Section 9606 authorizes EPA to bring enforcement actions to compel third parties to address hazardous substance releases that the agency determines "may" pose "an imminent and substantial endangerment to the public health or welfare or the environment." 42 U.S.C. § 9606(a).

Designation also enables parties, including EPA, to bring federal suits seeking reimbursement from "covered persons"—commonly known as potentially responsible parties ("PRPs")—that Section 9607 makes strictly liable for costs incurred responding to hazardous substance releases. *Id.* § 9607(a). Cost recovery is limited, however, to costs incurred by federal, state, or tribal governments that are "not inconsistent with the national contingency plan," or to costs incurred by "any other person" that are "consistent with the national contingency plan." *Id.* § 9607(a)(4)(A)–(B).

CERCLA contains several other mechanisms that limit liability. These include: an exclusion from liability for residential, small-business, and nonprofit

generators of municipal solid waste, *id.* § 9607(p); an affirmative defense for those who can show that contamination was solely caused by acts or omissions of a third party, *id.* § 9607(b)(3); and an affirmative defense for certain entities that acquire contaminated property with no knowledge of the contamination at the time of purchase, *id.* § 9601(35)(A)(i).

B. Factual background

PFAS, including PFOA and PFOS, had been widely manufactured and used in this country since the 1940s. Evidence of PFAS-related harms in occupationally exposed workers first emerged in the 1980s. 89 Fed. Reg. at 39140. Concerns about community-level exposures were first raised in 1998. *Id.*[4] And when the U.S. Centers for Disease Control and Prevention began screening for PFOA and PFOS the next year, it found both substances in the blood of 99 percent of participants in a nationally representative sample. 87 Fed. Reg. 54415, 54429 (Sep. 6, 2022).

In the decades since then, scientific studies have shown increasingly strong connections between exposure to PFAS, including PFOS and PFOA, and a range of

[4] In 2005, E.I. du Pont de Nemours and Company agreed to pay what was then the largest environmental administrative penalty in history to settle EPA's claims that the company had violated the Toxic Substances Control Act by failing for decades to disclose information about the substantial risks that PFOA posed to human health and the environment. EPA Settles PFOA Case Against DuPont for Largest Environmental Administrative Penalty in Agency History, (December 14, 2005), https://www.epa.gov/archive/epapages/newsroom_archive/newsreleases/fdcb2f665cac66bb852570d7005d6665.html

adverse health outcomes. *See* Section C.2, *infra*. That growing awareness has prompted actions aimed at reducing domestic manufacturing and use of PFOA and PFOS. For instance, from 2000 to 2002, the only domestic manufacturer of PFOS voluntarily phased out production of that substance. Regulatory Impact Analysis ("RIA") 72, JA453. In 2006, the eight largest domestic manufacturers of PFOA agreed, at EPA's request, to a 95-percent phasedown in PFOA production by 2010, and a complete halt to all domestic PFOA production by 2015. *Id.* at 73, JA454. In 2016, the U.S. Food and Drug Administration banned the use of PFAS in food packaging. 81 Fed. Reg. 5 (Jan. 4, 2016), 81 Fed. Reg. 83672 (Nov. 22, 2016). And in 2017, the U.S. Department of Defense began to phase out its use of PFOS-containing fire-fighting foam. 87 Fed. Reg. at 54431.[5]

Along with these source-reduction efforts, the federal government has also undertaken actions to address existing PFOA and PFOS contamination. For example, since 2017, EPA has listed five sites on the NPL based in part on the presence of PFOA or PFOS, 89 Fed. Reg. at 39177 n.72, and it has already "treated PFOA and PFOS as pollutants and contaminants at multiple Superfund sites," *id.* at 39173. The U.S. Department of Defense obligated nearly $2.5 billion through Fiscal Year 2023 to address its PFAS releases and, as of March 2023, had used its delegated

[5] For a detailed summary of other federal and state actions aimed at reducing and mitigating PFOA- and PFOS-related harms, see pages 71 through 112 of EPA's RIA, EPA-HQ-OLEM-2019-0341-0835, JA452–493.

authority under CERCLA to investigate and respond to PFOA and PFOS contamination at 425 of its facilities. RIA 86, JA467. Similar efforts to inventory and address PFAS, including PFOA and PFOS, contamination are also underway at the U.S. Departments of Energy and Homeland Security. *Id.* at 89, JA470.

C. Agency proceedings

1. EPA identifies hazard and fate and transport as the primary factors for determining whether a substance "may present substantial danger."

Against this backdrop, EPA proposed and finalized the rule challenged here, designating PFOA and PFOS as hazardous substances under Section 9602. *See* 87 Fed. Reg. at 54415 (proposed rule); 89 Fed. Reg. at 39124 (final rule). Section 9602 "delegates to EPA the authority to identify and weigh the scientific, technical, and other factual information relevant to determining whether a substance 'may present a substantial danger.'" 89 Fed. Reg. at 39141 (quoting 42 U.S.C. § 9602(a)). EPA identified "two primary factors" to guide this inquiry: the "hazard" posed by a substance, and the substance's "environmental fate and transport." *Id.* "Hazard" refers to the nature and severity of "potential harm to humans or the environment from exposure to the substance." *Id.* For example, a substance might be hazardous because it poses a risk of bodily injury due its "combustibility, flammability, reactivity, or corrosiveness." *Id.* Or it might be hazardous because of its "toxicity," a term encompassing "carcinogenicity, neurotoxicity, developmental toxicity,

reproductive toxicity," and other properties leading to "adverse health effects." *Id.* "Fate and transport" refer to a substance's persistence and mobility following release, including whether and how it degrades over time, and how easily that substance migrates through various media (air, water, soil, etc.). *Id.*

Along with hazard and fate and transport, EPA noted that it would also consider "additional information that could inform the degree of danger a substance may pose when released." *Id.* The agency identified information on the "frequency, nature, and geographic scope of releases" (i.e., "prevalence"), "likelihood of human exposure," and "accident history or other release data" as probative. *Id.*

EPA explained that it would qualitatively weigh hazard and fate and transport in making a designation determination. *Id.* And it interpreted the phrase "may present substantial danger," 42 U.S.C. § 9602(a), to require a showing that, "at a minimum, there is a possibility," but not a "certainty," that the release of a substance will present a substantial danger, 89 Fed. Reg. at 39141.

2. EPA concludes that releases of PFOA and PFOS may present substantial danger.

Applying this mode of analysis, EPA found at the proposed and final rule stages that releases of PFOA and PFOS "may present substantial danger." 87 Fed. Reg. at 54417; 89 Fed. Reg. at 39125.

On hazard, the agency drew on five "peer-reviewed Federal government documents," each of which "presents comprehensive, systematic reviews of

relevant, peer-reviewed literature." 89 Fed. Reg. at 39144. That "robust body of epidemiological and toxicological studies," *id.* at 39173, "support[s] a finding that PFOA and PFOS exposure can lead to" a variety of adverse health effects, *id.* at 39143. Among them, cancer: both PFOA and PFOS are "[l]ikely to [b]e [c]arcinogenic to [h]umans," with PFOA exposure linked to testicular and kidney cancers, and PFOS exposure associated with liver cancer. *Id.* at 39143.[6] PFOA and PFOS exposure are also associated with harms to pregnant women, including pregnancy-induced hypertension and preeclampsia. *Id.* at 39146. And because both substances pass from woman to fetus, PFOA and PFOS exposures are associated with adverse health effects for newborns as well, including lower birth weight and length, and smaller head circumference. *Id.* at 39144; *see also id.* (noting animal studies demonstrating "that the developing fetus is particularly sensitive to PFOA- and PFOS-induced toxicity"). Older children are susceptible to harm too. "Evidence indicates that exposure to PFOS and PFOA is associated with immunosuppression" in the form of decreased response to vaccines, and with "increased low-density lipoprotein cholesterol." *Id.* at 39145. And in adults, exposure to PFOA and PFOS

[6] EPA classified PFOA and PFOS as "[l]ikely to [b]e [c]arcinogenic" by weighing available evidence according to the agency's peer-reviewed Guidelines for Carcinogen Risk Assessment. *Id.* at 39125. The International Agency for Research on Cancer, a part of the Word Health Organization, also reviewed the literature using its own evaluative criteria and concluded that PFOA is "carcinogenic to humans," and PFOS is "possibly" so. *Id.* at 39143.

is linked to, *inter alia*, increases in the levels of enzymes that indicate liver damage, and decreases in bone-mineral density. *Id.* at 39145–46.

More still, "[t]here is no evidence that humans or animals are able to break down" PFOA and PFOS, and it takes years to excrete or otherwise eliminate those substances. *Id.* at 39144. This means that PFOA and PFOS "bioaccumulat[e]," and "[c]ontinued exposures to PFOA and PFOS" can thus "lead to significantly elevated concentrations in the human body," compounding the risk of harm from these substances. *Id.* For all these reasons and more, EPA concluded that PFOA and PFOS "may pose a hazard." *Id.* at 39143.

On environmental fate and transport, EPA noted that PFOA and PFOS are "surfactants," a property that makes them useful in industrial applications and consumer products but also allows them to "move between environmental media more easily." *Id.* at 39147. And because of their "strong carbon-fluorine bonds," they are "extremely resistant to degradation," and "remain in the environment for long periods of time." *Id.* Thus, "potential for human exposure continues long after a release" of PFOA and PFOS. *Id.*

The record bears this out. Levels of PFOA and PFOS generally increase with depth in soil samples taken at industrial facilities, "suggesting a downward movement of the contaminants and the potential to contaminate groundwater." *Id.* at 39148. Indeed, PFOA and PFOS have "been detected in groundwater" and in

"rivers, lakes, and streams" throughout the country. *Id.* at 39147–48. They have been found at high levels in "private drinking water wells" and in significant levels in "public water systems" serving a combined population of roughly 10.4 million people across 28 states, tribal areas, and U.S. territories. *Id.* at 39147. And both substances have been detected in "produce analyzed by the U.S. Food and Drug Administration," in fish and game, and in livestock. *Id.* at 39148.

In sum, "[n]umerous health studies support a finding that PFOA and PFOS exposure can lead to" serious adverse human health effects. *Id.* at 39143. Because of their persistence and mobility, major PFOA and PFOS releases threaten to spread to "an ever-expanding area of contamination" unless they are contained or cleaned up. *Id.* at 39148. And the spread of PFOA and PFOS from the point of release "create[s] more opportunities for exposure . . . thereby increasing the likelihood of adverse health effects and . . . ecological burdens stemming from the toxicity of these compounds." *Id.* EPA therefore concluded in both its proposed and final rule that releases into the environment of PFOA and PFOS "may present substantial danger." 87 Fed. Reg. at 54415; 89 Fed. Reg. at 39125

3. EPA takes comment on whether and how to consider costs when it proposes to designate PFOA and PFOS.

At proposal, EPA interpreted Section 9602 to preclude broader consideration of costs and benefits of designation. 87 Fed. Reg. at 54421. But it discussed those costs and benefits in the Economic Assessment ("EA") that accompanied the Notice

of Proposed Rulemaking. There, EPA provided estimated quantified costs and discussed qualitative benefits of release notification requirements. EA 39–44, JA138–43. It also noted that by enabling CERCLA cost-recovery and enforcement actions, designation would likely shift "costs of potential response activities from the public to polluters"—"an important indirect impact" that it considered a "transfer," not a net societal cost. *Id.* at 48, JA147. And it explained that designation could also indirectly increase "the total number of response actions," yielding public health benefits and "health care cost savings," while also increasing expenditures on cleanups. *Id.* at 10, JA109; *see also id.* at 45–48, JA144–47; *accord* 87 Fed. Reg. at 54423.

In the proposal, EPA also acknowledged "[s]ignificant uncertaint[ies]" that posed "barriers to developing a robust quantitative analysis of the indirect costs, benefits, and potential transfers" associated with future PFOA- or PFOS-related cleanup actions. EA 49, JA148. These included uncertainties regarding: "the number of sites that may require response actions to address past PFOA or PFOS releases," *id.* at 50, JA149; the incremental cost of addressing PFOA and PFOS at sites that also contain other hazardous substances, *id.*; the possibility that future rulemakings would set new cleanup standards, *id.* at 51, JA150; the potential for new treatment and disposal technologies to impact response costs, *id.* at 52, JA151; and

the challenge of predicting response actions, which "are contingent, discretionary, and site-specific," *id.* at 39, JA138.

EPA sought comment on all of this. In its Notice of Proposed Rulemaking, it asked for the public's views on:

> (1) Whether [Section 9602(a)] precludes, allows, or requires consideration of cost . . . , (2) which costs and benefits of those discussed in the EA should be considered, (3) whether additional benefits and costs not identified in the EA should be considered, (4) if indirect benefits and costs are considered, how they should be assessed in light of the discretion and uncertainties [about the location and cost of future response actions], (5) how benefits and costs could be incorporated into the designation decision, and (6) whether designation would be justified if costs were to be considered in the Agency's designation decision.

87 Fed. Reg. at 54423. The Notice also directed readers to the EA, which included 13 more requests for input on, *inter alia*, the "uncertainties regarding the unquantifiability of indirect cost, benefit, and transfer impacts," and any "information . . . that may allow EPA to estimate incremental indirect costs associated with this rule." EA 19, JA118.

4. In the final action, EPA concludes that designation is appropriate even if costs are considered.

In the final rule, EPA did not definitively resolve whether Section 9602 precluded or mandated consideration of costs. 89 Fed. Reg. at 39143. But based in part on the comments it received, EPA elected to consider direct and indirect costs

and benefits of designation, and it concluded, based on that analysis, that "designation is appropriate under either construction." *Id.*

EPA considered costs as part of a "totality-of-the-circumstances" analysis in which it weighed advantages and disadvantages of designating PFOA and PFOS. *Id.* at 39143. In doing so, the agency gave "considerable weight" to scientific evidence linking PFOA and PFOS exposure "to a wide range of adverse human health and environmental effects," and showing that "[i]f not addressed," existing PFOA and PFOS contamination "will continue to migrate, further exacerbating exposure risk and potential cleanup costs." *Id.* at 39149.

Given the gravity of that risk, EPA determined that even if it did not designate PFOA and PFOS, it would eventually respond to many releases of those substances by using its authority to address pollutants or contaminants. In particular, the EPA estimated that, independent of designation, it would spend around $10.3-to-$51.7 million per year from the Superfund to implement PFOA- or PFOS-related remedies at non-federal NPL sites. *Id.* at 39153. It also assumed that federal agencies would use their delegated authority under CERCLA to respond to PFOA and PFOS contamination at sites within their jurisdiction or control. *Id.* at 39128 n.11. But EPA found that designation would confer notable advantages over this baseline scenario. *Id.* at 39154.

For starters, designation would trigger notification requirements, which are "critical to ensuring that new releases are identified, evaluated, and addressed to the extent necessary." *Id.* at 39128. This early warning was "particularly important for persistent and mobile substances like PFOA and PFOS" that can "migrate away from the release." *Id.*

More broadly, by bringing PFOA and PFOS within the enforcement and liability provisions of Sections 9606 and 9607, designation would allow EPA and others to shift burdens of contamination from society at-large to those most responsible for the contamination, the PRPs. *Id.* at 39152. EPA considered this to be an advantage because Congress enacted CERCLA to ensure that the "costs of . . . cleanup efforts" at hazardous waste sites "were borne by those responsible for the contamination," *Burlington N. & Santa Fe Ry. Co.*, 556 U.S. at 602, and designation furthered that statutory purpose, 89 Fed. Reg. at 39164.

Shifting cleanup responsibility to PRPs would also expand the pace and scope of cleanup activity. *Id.* at 39153–54. Because PRPs know better than EPA "the location and extent of potential contamination" and can undertake work without "secur[ing] access orders," PRP-led cleanups tend to be "faster" and more "efficient." *Id.* at 39151. And with PRP-led actions relieving burdens on the Superfund, EPA could redirect taxpayer dollars to address other priority releases, *id.* at 39153, including releases at sites with no viable PRP, *id.* at 39151. The result,

EPA found, is that designating PFOA and PFOS would allow for response actions "earlier in time" and at "more sites." *Id.* at 39158. For example, EPA estimated that following designation, it would bring enforcement actions to compel PRP-led cleanups at roughly 67 sites not currently listed on the NPL, leading to $327,000-to-$18,100,000 in additional cleanup expenditures, per year. *Id.* at 39164; RIA 160, JA541. Such increased activity would "mitigate[] or eliminate[]" PFOA and PFOS "exposure pathways" and thus hasten improvements in health, reductions in healthcare expenditures, and increases in worker productivity and overall quality of life. 89 Fed. Reg. at 39154–58.

On the other hand, EPA noted that designation would impose new notification and disclosure-related costs. *Id.* at 39128. It also noted that, post-designation, PRPs could bear increased costs of litigating liability under Section 9607. *Id.* at 39162. And it acknowledged that in CERCLA's strict-liability regime, some litigation burdens might fall on parties with little responsibility for PFOA and PFOS contamination. *Id.* at 39160–62. But for several reasons, EPA concluded that these disadvantages of designation did not tip the scales against action. *Id.* at 39163–65.

Quantifiable notification costs would be minor, just $2,658 per reportable release—well worth the potential "value notification provides to impacted communities and regulatory agencies." *Id.* at 39128. And while EPA lacked data sufficient to quantify litigation costs or predict where litigation burdens would fall,

it noted that CERCLA imposes several limitations that mitigate risks of run-away litigation. For one, would-be plaintiffs must incur response costs before suing for reimbursement of those costs under Section 9607. *Id.* at 39129. CERCLA also limits recoverable costs to those costs that are consistent with, or not inconsistent with, the procedural measures and substantive criteria of the NCP, 42 U.S.C. § 9607(a)(4)(A), (B), which guard against "excessive cleanup costs relative to the effectiveness of a remedy," 89 Fed. Reg. at 39164. And the Act further constrains cost recovery by providing liability exclusions and affirmative defenses. *Id*. at 39160–61. Statutory constraints aside, moreover, courts typically use "equitable factors" to allocate liability among PRPs and assign "only a small percentage of response costs, if any," to those parties that did not contribute significantly to contamination. *Id.* at 39162.

Collectively, these safeguards have allowed "CERCLA's liability scheme [to] function[] in a rational way" for 40 years, *id.* at 39161, "generally protecting those that have played little to no role in significant environmental contamination from liability," *id.* at 39162, while transferring cleanup costs to parties that were "primarily responsible for" contamination, *id.* at 39164.

EPA determined that liability for PFOA and PFOS would function no differently. Several other hazardous substances have "a similar fate and transport to PFOA and PFOS and are similarly ubiquitous." *Id.* at 39161. For instance, EPA

estimated that PFOA and PFOS are likely present at around 400 NPL sites, *id.* at 39178, roughly the same number of sites with polychlorinated biphenyls, which, like PFOA and PFOS, are "ubiquitous and continuously circulating in the global environment," *id.* at 39170 (internal quotation marks omitted).

Other hazardous substances are present at still more NPL sites: mercury, trichloro- and tetrachloroethene, and arsenic, have been found at over 600, 800, and 1100 sites, respectively. *Id.* at 39161. Like PFOA and PFOS, those substances can be found in soil, groundwater, and industrial wastewater discharges. *Id.* at 39161–62. And like PFOA and PFOS, those substances are used in both industrial applications and consumer products, such as cleaners, glue, paint remover, and lightbulbs, so "[p]roperty owners . . . handle" them "as a result of home renovations," "gardening," or other "normal activities." *Id.* at 39161–62.

EPA's long experience addressing these substances under CERCLA gave the agency confidence that designating PFOA and PFOS would not entail substantial unintended negative consequences that might outweigh the foreseeable advantages of designation. *Id.* at 39164. EPA therefore concluded that action was appropriate. *Id.*

Throughout its analysis, EPA acknowledged that it could not precisely forecast costs of future CERCLA response actions, in part because it could not predict the number or extent of PFOA- and PFOS-contaminated sites that might be

subject to action under CERCLA. *Id.* at 39152. And for the (as-yet-unknown) sites that would be subject to a CERCLA response action, the nature of any such action—"including the response activities required and the amount of time it may take to implement them"—would be "difficult to estimate absent a preliminary assessment of the scope of contamination at a specific site." *Id.*

EPA faced similar challenges when calculating the benefits of future response actions. And the benefits that EPA was able to quantify "account[ed] for only a portion of the overall benefits from the designation of PFOA and PFOS," namely, those benefits that could be "monetized" at the level of a "unit reduction of PFOA and PFOS" and then only for reductions in private water supplies. *Id.* at 39155.[7]

For these reasons, EPA concluded, as it had at proposal, that "significant uncertainty" about the nature and scope of future actions precluded "a robust quantitative analysis of the potential indirect costs, benefits, and transfers associated with response to PFOA and PFOS contamination under CERCLA." RIA 211, JA592. The agency stressed, however, that future CERCLA response actions would be based on NCP-prescribed assessments of site-specific relative risk and assessments of the cost and cost-effectiveness of various alternative remedies. 89 Fed. Reg. at 39164; *see also id.* at 39169, 39179–80.

---

[7] EPA determined that benefits associated with PFOA- and PFOS-removal from public water supplies would be properly attributable to the National Primary Drinking Water Regulations promulgated under the Safe Drinking Water Act. *Id.*

SUMMARY OF ARGUMENT

1. EPA found, based on an extensive body of evidence, that PFOA and PFOS are toxic, likely carcinogenic, extremely persistent, and highly mobile. The agency therefore concluded that releases of both substances "may present substantial danger to public health or welfare or the environment." 42 U.S.C. § 9602(a). That conclusion was at least reasonable and well within the scope of EPA's statutory authority. Petitioners do not challenge EPA's scientific findings or its bottom-line conclusion, but they object to how EPA reached that conclusion. EPA's error, they say, was that it designated PFOA and PFOS without first defining the statutory phrase "may present substantial danger" by reference to an exacting and fixed boundary. But the bright-line substantial-danger threshold that Petitioners demand is unmoored from Section 9602's text and is inconsistent with broader statutory context and purpose.

2. Before acting, EPA carefully considered the advantages and disadvantages of designating PFOA and PFOS. That assessment was qualitative by necessity: inherent uncertainties about the number, location, nature, and cost of future PFOA- and PFOS-related CERCLA actions prevented a robust quantitative analysis. But the agency found, based on available information, that designation would shift the financial burdens of cleanup to those more directly responsible for contamination thereby increasing the amount and pace of cleanup activity and

reducing substantial risks of ongoing exposure from existing contamination. EPA considered these impacts in light of CERCLA's text and purpose and reasonably concluded that advantages of designating PFOA and PFOS outweighed reasonably foreseeable disadvantages, like increased litigation costs.

A. As a threshold matter, Petitioners say that uncertainty about future response actions precluded EPA from acting at all. In their view, EPA could designate PFOA and PFOS only if the agency first cataloged the sites and costs of future PFOA- and PFOS-related cleanups. But that degree of certainty about future events is not a prerequisite for agency action generally, and this Court has long recognized that it is up to agencies to decide in the first instance when regulation in the face of uncertainty is warranted. Action was warranted here, EPA explained, because CERCLA imposes procedural and substantive safeguards that channel cleanup activity to those sites that pose the greatest threat to public and environmental health, that mandate cost-effective remedies, and that allocate responsibility for cleanup to those entities most responsible for contamination. Thus, while EPA could not foresee the precise locations and costs of future PFOA- and PFOS-related response actions, it could reasonably conclude that designation would not result in unintended, inequitable outcomes.

B. Petitioners next contend that EPA violated procedural requirements of the Administrative Procedure Act ("APA") by not taking public comment on certain

cost estimates that the agency included in the RIA and referenced in the Final Rule. But, at proposal, EPA included an extensive request for comment on whether and how it should estimate costs of future PFOA- and PFOS-related cleanup activity. Petitioners commented on those issues. And the limited, illustrative cost estimates in the RIA and Final Rule required no additional, separate round of public comment. Petitioners' procedural challenge therefore fails.

C. Their substantive, record-based arguments fail too. Petitioners attack EPA's forecasts about the extent of future PFOA- and PFOS-related cleanup activity that would have occurred independent of designation and that would occur because of designation. But EPA's predictive judgments fell well within the bounds of reasoned analysis. Petitioners accuse EPA of ignoring costs of managing PFAS-contaminated waste or environmental media in various industrial sectors. But the costs that Petitioners identify are not fairly attributable to any CERCLA cleanup action and so fall outside the scope of this rulemaking. And Petitioners claim that EPA misclassified costs as benefits. But EPA's assessment of benefits reflected a common-sense understanding of statutory text and purpose.

Finally, Petitioners argue that EPA violated the Regulatory Flexibility Act ("RFA"). But EPA's approach was consistent with the RFA's text as interpreted by this Court and with longstanding agency guidance.

3. The Court should deny the petitions for review. But if it grants them in any respect, it should remand EPA's action without vacatur.

STANDARD OF REVIEW

The APA supplies the standard of review. EPA action under CERCLA may be set aside only if it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2); *see Carus Chem. Co. v. EPA*, 395 F.3d 434, 441 (D.C. Cir. 2005). Because this Court "shall decide all relevant questions of law," 5 U.S.C. § 706, it must determine the "best" reading of CERCLA by "applying all relevant interpretive tools." *Loper Bright Enter. v. Raimondo*, 603 U.S. 369, 373 (2024). Though in "a case involving an agency, of course, the statute's meaning may well be that the agency is authorized to exercise a degree of discretion." *Id.* at 394.

Review under the APA's standard is otherwise narrow and highly deferential. Courts cannot substitute their policy judgment for that of an agency. *Bluewater Network v. EPA*, 370 F.3d 1, 11 (D.C. Cir. 2004). Rather, "the role of the courts in reviewing arbitrary and capricious challenges is to simply ensur[e] that the agency has acted within a zone of reasonableness." *Biden v. Missouri*, 595 U.S. 87, 96 (2022). And where an agency has considered the relevant factors and articulated a rational connection between the facts found and the choices made, its decisions must

be upheld. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Judicial review is "particularly deferential in matters implicating predictive judgments," requiring only that "the agency acknowledge factual uncertainties and identify the considerations it found persuasive." *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105, 1108 (D.C. Cir. 2009). And this Court gives an "extreme degree of deference" to EPA's "evaluation of scientific data within its technical expertise." *Miss. Comm'n on Env't Quality v. EPA*, 790 F.3d 138, 150 (D.C. Cir. 2015).

ARGUMENT

I. EPA acted within the bounds of its statutory authority.

A. Section 9602 expressly authorizes EPA to designate substances like PFOA and PFOS as hazardous substances.

Section 9602 allows EPA to "promulgate and revise as may be appropriate, regulations designating as hazardous" those substances that "may present substantial danger to the public health or welfare or the environment." 42 U.S.C. § 9602(a). That explicit grant of authority comes with an unambiguously precautionary standard. The word "may" "express[es] possibility." Random House Dictionary of the English Language 1189 (2d unabr. ed. 1987). So too does "danger," which is "liability or exposure to"—but not the occurrence of—"harm or injury." *Id.* at 505; *cf. Ethyl Corp. v. EPA*, 541 F.2d 1, 13 (D.C. Cir. 1976) ("Case law and dictionary definition agree that endanger means something less than actual harm."). Section

9602 thus requires a possibility, but not a certainty, of substantial harm or injury. That is the best, and indeed only possible, reading of the statutory text.

Section 9602's precautionary nature was no accident. Congress defined "hazardous substance" under CERCLA to include every substance designated under five other statutory provisions. *See* 42 U.S.C. § 9601(14). When CERCLA was being drafted, there were already several hundred such substances. S. Rep. No. 96–848 (1980), at 24–27. But to ensure that the list of CERCLA hazardous substances could accommodate future scientific developments, Congress enacted Section 9602(a) "to afford the President broad discretion" to designate additional substances by applying "a lower threshold for designation than that currently in place" under existing laws. S. Rep. No. 96–848 at 28.

EPA reasonably exercised that express authority here. The two factors that the agency selected to guide its analysis—hazard, and environmental fate and transport—inform its review under every statute that is cross-listed in CERCLA's definition of "hazardous substance," all of which require some consideration of toxicity, persistence, and mobility. *See* 89 Fed. Reg. at 39142–43 (listing statutes). Both factors also guide EPA's review of whether specific releases "may present an imminent and substantial endangerment" under Section 9606(a). *See id.*at 39142 (discussing guidance). And the relevance of these factors under Section 9602 is undisputed; although Petitioners broadly attack EPA's mode of substantial-danger

analysis, they do not argue that EPA erred in looking to evidence of hazard or environmental fate and transport when determining whether PFOA and PFOS "may present substantial danger."

In assessing hazard, EPA found strong links between PFOA and PFOS exposure and a myriad of serious adverse health effects, including several cancers, pregnancy complications, and harms to fetuses and children. *See* Section C.3, *supra*. It also found that both substances bioaccumulate, compounding risks of chronic exposure. *See id.* In assessing environmental fate and transport, EPA found that PFOA and PFOS move easily through soil and water, pollute drinking water, and enter the food chain, making exposure more likely. *See id.* On the basis of those and other findings, the agency concluded that PFOA and PFOS satisfied Section 9602's precautionary standard for hazardous-substance designation. *See id.*

Rightly so. Releases of toxic, likely carcinogenic, bioaccumlative, extremely persistent, and highly mobile chemicals "may present substantial danger" on any ordinary understanding of that phrase. Reading CERCLA's designation standard with "a practical understanding of legislative intent" only bolsters that conclusion. *W. Virginia v. EPA*, 597 U.S. 697, 721, 723 (2022). CERCLA was a "response to the serious environmental and health risks posed by industrial pollution." *United States v. Bestfoods*, 524 U.S. 51, 55 (1998). PFOA and PFOS are industrial

pollutants that pose serious environmental health risks; by designating them, EPA acted within the heartland of its statutory authority.

B. Petitioners' statutory and constitutional arguments fail.

Petitioners do not contest EPA's scientific and technical findings. Nor do they directly dispute the straight-forward legal conclusion that EPA drew from those findings. Instead, they argue that EPA could not designate PFOA and PFOS without first defining the phrase "may present substantial danger" by reference to "fixed boundaries." Pet'rs' Br. 30–37. Not so.

1. Section 9602 contains no demand for "fixed boundaries."

Petitioners' statutory construction is atextual. Section 9602 directs EPA to "promulgate . . . regulations designating . . . hazardous substances." 42 U.S.C. § 9602(a). It does not, as Petitioners would have it, call for regulations setting generally applicable "standards," "limits," or "thresholds." Pet'rs' Br. 37. Had Congress wanted EPA to engage in that sort of standard-setting, it would have said "so explicitly, as demonstrated by other sections" of the Act. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452–53 (2002). In calling for the NCP, for example, Congress required EPA to "establish procedures and standards for responding to releases of hazardous substances," and it required that those standards and procedures include, "at a minimum," "methods and criteria" described in ten enumerated sub-paragraphs. 42 U.S.C. § 9605(a)(1)–(10). The lack of any remotely

comparable mandate in Section 9602 is strong indication that Congress conferred on EPA the authority to evaluate "substantial danger" by weighing relevant factors as the agency did here.

By employing a factor-based approach, EPA did not assert authority to designate "any substance" based only on evidence demonstrating a mere "possibility of harm." Pet'rs' Br. 32–33. In fact, the agency identified environmental fate and transport as a "central factor" in its designation inquiry precisely because it did not think that evidence of possible harm—*i.e.*, hazard—would be sufficient, considered in isolation, to establish eligibility for designation. *See* 89 Fed. Reg. at 39142. Petitioners thus fail to acknowledge the constraints inherent in EPA's approach.

Even setting that aside, EPA has not, and could not, amend Section 9602's standard for designation. Petitioners may prefer a less precautionary standard, but the phrase "may present substantial danger" hardly gives EPA a "blank check." Pet'rs' Br. 32. Courts are routinely asked to determine whether solid or hazardous waste "may present an imminent and substantial endangerment." *See, e.g.*, *Liebhart v. SPX Corp.*, 917 F.3d 952, 957–61 (7th Cir. 2019); *see also Maine People's All. & Nat. Res. Def. Council v. Mallinckrodt, Inc.*, 471 F.3d 277, 281–92 (1st Cir. 2006). And if Petitioners thought that PFOA and PFOS did not pose a potential substantial danger within the meaning of CERCLA, then they could have made that argument; tellingly, they did not.

2. Petitioners cannot use inferences drawn from statutory structure to eviscerate statutory text.

Instead, Petitioners invoke what they say is a "deliberate statutory hierarchy" between "hazardous substances" and "pollutants or contaminants." Pet'rs' Br. 35–36. And proceeding from this premise, they argue that "statutory structure" compelled EPA to set a standard for hazardous-substance designation that is a "harder standard to satisfy" than the "standard" in the statutory definition of "pollutant or contaminant." *Id.* at 36. This unusual claim does not withstand scrutiny.

As Petitioners note, the definition of "pollutant or contaminant" encompasses any substance that "'will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions . . . or physical deformations.'" *Id.* (quoting 42 U.S.C. § 9601(33)). If EPA had to set a "higher bar" for designation of a hazardous substance, as Petitioners claim, *id.* at 35, then it's hard to see how any substance would clear it. The "hierarchy" that Petitioners conjure from "statutory structure" (without support in text or legislative history), *id.*, would eviscerate Section 9602's express grant of authority to designate as hazardous those substances that "may present substantial danger," 42 U.S.C. § 9602(a). That cannot be right. *See Citizens Bank of Maryland v. Strumpf*, 516 U.S. 16, 20 (1995) ("It is an elementary rule of construction that the act cannot be held to destroy itself." (internal quotation marks omitted)).

"Statutory interpretation must begin with, and ultimately heed, what a statute actually says." *Groff v. DeJoy*, 600 U.S. 447, 468 (2023) (cleaned up). CERCLA's definition of "pollutant or contaminant" is a non-exclusive catchall provision: the term "*shall include but not be limited to*" substances that "will or may reasonably be expected to cause" the serious harms listed above. 42 U.S.C. § 9601(33) (emphasis added). Because that open-ended definition fairly describes every substance that "may present substantial danger to public health or welfare or the environment," *id.* § 9602(a), it is not plausibly construed as an implied constraint on EPA's designation authority, as Petitioners urge.

3. Petitioners' constitutional-avoidance argument is meritless.

Petitioners argue that if Section 9602 does not contain the atextual constraints that they read into it, then it would violate the nondelegation and void-for-vagueness doctrines. Pet'rs' Br. 34–35. Petitioners are wrong.

The Constitution vests all legislative power with Congress but does not "deny[] to the Congress the necessary resources of flexibility and practicality [that enable it] to perform its function[s]." *Gundy v. United States*, 588 U.S. 128, 135 (2019) (plurality) (internal quotation marks omitted). Since 1935, the Supreme Court has "upheld . . . without deviation, Congress' ability to delegate power under broad standards," *Mistretta v. United States*, 488 U.S. 361, 373 (1989), so long as Congress "lay[s] down by legislative act an intelligible principle to which the person

or body authorized to act is directed to conform," *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001) (cleaned up).

Applying that test, the Supreme Court has found intelligible principles in, among many other places, "various statutes authorizing regulation in the 'public interest.'" *Id.* at 474; *see id.* at 474–75 (collecting cases). Section 9602's "may present substantial danger" standard—interpreted in light of CERCLA's purpose and comprehensive scheme—falls well within the outer bounds established by these "intelligible principle" precedents.

The nature of EPA's designation authority further insulates Section 9602 from Petitioners' nondelegation charge. The "degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred," *id.* at 475, and the powers conferred under Section 9602 are modest: hazardous-substance designation's only direct effects are certain notification requirements and specific disclosure and regulatory obligations for federal agencies. To be sure, delegation's potential indirect effects are broader because the release of a hazardous substance might—contingent on subsequent, independent discretionary actions—trigger enforcement or cost-recovery actions under other provisions of CERCLA. But it was Congress, not EPA, that defined the nature and scope of that liability. And "once Congress prescribes the rule governing private conduct, it may make the application of that rule depend on executive fact-finding"—here, designation—

without implicating separation-of-powers concerns. *Gundy*, 588 U.S. at 158 (Gorsuch, J., dissenting). For all these reasons, Petitioners' invocation of the nondelegation doctrine falls flat.

Their invocation of the void-for-vagueness doctrine is likewise unavailing. That doctrine "guarantees that ordinary people have fair notice of the conduct a statute proscribes." *Sessions v. Dimaya*, 584 U.S. 148, 156 (2018) (internal quotation marks omitted). But "the law is full of instances where a man's fate depends on his estimating rightly some matter of degree." *Id.* at 159. And Section 9602 is no different from the "[m]any perfectly constitutional statutes" that "use imprecise terms like 'serious potential risk' . . . or 'substantial risk.'" *Id.* at 159 (cleaned up). More still, void-for-vagueness doctrine is applied on a sliding scale, with the "degree of vagueness that the Constitution tolerates" depending "in part on the nature of the enactment." *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 498 (1982). The Supreme Court has "expressed a greater tolerance of enactments" that impose "civil rather than criminal penalties" and that let the regulated public "clarify" a law's meaning "by resort to an administrative process." *Id.* at 498–99. Section 9602—which imposes no direct liability and is implemented only through rulemaking after public notice and comment—easily passes constitutional muster.

C. EPA reasonably chose a factor-based approach over a bright-line test for hazardous-substance designation.

What Petitioners are left with, then, is a policy preference for bright-line limits and thresholds. But EPA permissibly elected not to adopt rigid standards when acting under a statute that does not require them. Under arbitrary-and-capricious review, EPA's manner of implementing the statute is entitled to deference.

True, as Petitioners note, Pet'rs' Br. 38, EPA uses quantitative thresholds of health risk when considering sites for the NPL or selecting remedies. But to do so, the agency relies on site-specific information about contamination levels and exposure pathways. *See generally* 40 C.F.R. Pt. 300 App. A. That's not feasible at the designation stage, when EPA must assess potential substantial danger posed not by specific releases but by releases in general. *See* 42 U.S.C. § 9602(a). In that context, a risk threshold would need to, among other things: account for variation in the adverse health effects associated with different levels of exposure; address the differing risks from "acute, sub-chronic, and chronic exposure"; and standardize "carcinogenic and non-carcinogenic risk," which "are calculated separately." 89 Fed. Reg. at 39166. Establishing such a one-size-fits-all risk threshold would be impracticable, EPA concluded. *Id.*

And risk to human health is only part of EPA's designation inquiry. To determine whether designation is warranted, EPA "account[s] for all" of a substance's relevant characteristics. *Id.* That means looking not just at health risk,

but also at environmental harm, and at persistence and mobility. *See id.* Those interrelated considerations are not readily reducible to a generally applicable "bright-line test," and so EPA reasonably declined to adopt one. *Id.*; *see also Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 223 (D.C. Cir. 2007) (upholding EPA's determination that "a national risk threshold . . . could not address unique site-specific considerations" relevant to the regulation of hazardous-waste combustion).

Nothing in EPA's 1983 advance notice of proposed rulemaking ("Advance Notice"), Pet'rs' Br. 37–38, casts doubt on that decision. There, EPA "contemplate[ed]" applying a threshold to a list (or lists) of candidate substances and then designating en masse all substances that exceeded the chosen threshold. 48 Fed. Reg. 23602, 23603 (May 25, 1983). But the agency noted various drawbacks with this approach, including the possibility that "there would be no general agreement in the scientific community on how rating factors are to be combined to form an acceptable hazard index for a broad listing of chemicals." *Id.* at 23603–05.

EPA also made clear in 1983 that it was considering "[t]he option of designating no new hazardous substances." *Id.* at 23605. It ultimately chose that path; none of the approaches in the Advance Notice made it to a proposal, let alone a final rule. Petitioners' reliance on the Advance Notice is thus misplaced. So too is their reliance on *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009). Pet'rs' Br. 37 n.12. The oft-cited holding from that case—that an agency must "display

awareness that it is changing position"—presupposes some "prior policy" in place at the time. 556 U.S. at 515. The Advance Notice was not a policy, and EPA was not required to explain why it departed from a course that it had chosen not to take decades ago.

II. EPA reasonably concluded that designating PFOA and PFOS was appropriate.

Section 9602 authorizes EPA to "promulgate and revise, as may be appropriate" regulations designating hazardous substances. 42 U.S.C. § 9602(a). "Appropriate" is "the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors." *Michigan v. EPA*, 576 U.S. 743, 752 (2015). And while there "are undoubtedly settings in which" that term "does not encompass cost" as a relevant factor, *id.*, EPA assumed (without conceding) at the final-rule stage that Section 9602 was not one of those settings, *see* Section C.3, *supra*. In this case, then, there is no live dispute about whether Section 9602 requires consideration of costs. The only question is whether EPA's assessment of costs was arbitrary and capricious. It was not.

A. EPA reasonably weighed advantages and disadvantages of hazardous-substance designation.

"Reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan*, 576 U.S. at 753. But the unadorned word "appropriate" does not compel "a formal cost-benefit analysis in

which each advantage and disadvantage is assigned a monetary value." *Id*. at 759. Rather, it is "up to" agencies "to decide"—"within the limits of reasonable interpretation"—"how to account for cost." *Id.*

EPA did so here by assessing designation's advantages and disadvantages on a largely qualitative basis. And for good reason: any future CERCLA response actions will depend on "contingent, discretionary, and site-specific" assessments of risk and cost that are impossible to accurately predict at the threshold step of designation. 89 Fed. Reg. at 39169. EPA was able to generate quantitative estimates for only a subset of costs and benefits associated with certain cleanup activities, and these estimates it offered "to provide some context." RIA 27, JA408. But unavoidable uncertainty about the number and nature of future response actions precluded "a robust quantitative analysis of the potential indirect costs, benefits, and transfers associated with response to PFOA and PFOS contamination under CERCLA." *Id.* at 211, JA592.

EPA knew, however, that designation would (among other things) enable cost-recovery and enforcement actions that would shift responsibility for cleanups to PRPs. That outcome would likely entail increased litigation costs for PRPs, possibly including entities with little direct responsibility for contamination. But when PRPs bear financial responsibility for cleanup, it is possible to address contamination at "more sites and to do so earlier in time." 89 Fed. Reg. at 39127.

And because PFOA and PFOS are toxic, likely carcinogenic, highly mobile, and extremely persistent substances, the reasonably foreseeable alternative to a PFOA or PFOS cleanup action occurring "earlier in time," is likely to be a "more expensive, more expansive cleanup" occurring later in time, with potential serious harms from PFOA or PFOS exposure in the interim. *Id.* at 39151.

In determining how to weigh these and other considerations, EPA looked to CERCLA for guidance. Section 9602 makes public and environmental health the touchstones for regulatory decisionmaking and sets a precautionary standard for action. 42 U.S.C. § 9602(a). So EPA placed "considerable weight" on evidence documenting the threats of PFOA and PFOS exposure and on designation's potential to reduce exposures. 89 Fed. Reg. at 39149. CERCLA's cost-recovery and enforcement mechanisms exist because Congress wanted to "ensure that the costs of . . . cleanup efforts [are] borne by those responsible for the contamination." *Atl. Richfield Co. v. Christian*, 590 U.S. 1, 6 (2020) (internal quotation marks omitted). So EPA considered the burden-shifting consequences of designation to be an advantage of action. 89 Fed. Reg. at 39152. And CERCLA contains substantive and procedural safeguards that limit liability, ensure careful consideration of response-action costs, and direct response action to sites most in need of cleanup. See Section A.3–A.4, *supra*. So EPA concluded that the cost of litigating PFOA and PFOS liability—a disadvantage of designation—would not be anomalously high and

would be borne primarily by the entities most directly responsible for contamination. 89 Fed. Reg. at 39160–61, 39164. For these reasons and more, EPA concluded that the advantages of designation outweighed the disadvantages and action was therefore appropriate. *Id.* at 39164. That conclusion lay well "within the limits of reasonable interpretation." *Michigan*, 576 U.S. at 759.

A striking number of EPA's essential premises are uncontested here. Again, Petitioners do not dispute EPA's scientific judgments about the dangers that PFOA and PFOS pose to public health or the environment. They also do not dispute that designation will, through other CERCLA provisions, shift burdens of PFOA and PFOS contamination from society at-large to PRPs. And they do not dispute that this shift will lead to earlier and more PFOA and PFOS cleanup actions.[8]

Instead, Petitioners argue that EPA could not designate PFOA and PFOS before resolving "uncertainties" about the location, nature, and cost of future CERCLA response actions. Pet'rs' Br. 71–78. They argue that EPA needed to take comment on the quantitative estimates of costs and benefits that it included in the final rule. *Id.* at 44–51. They object to EPA's predictive judgments about the scope of PFOA- and PFOS-related cleanup activity that would have occurred independent of designation and that would occur following designation. *Id.* at 53–63. They

[8] By failing to develop any of these arguments in their opening brief, Petitioners have forfeited them. *See Herron v. Fannie Mae*, 861 F.3d 160, 165 (D.C. Cir. 2017).

accuse EPA of ignoring other purportedly relevant costs. *Id.* at 63–68. They insist that EPA misclassified costs as benefits. *Id.* at 68–69. And they claim that EPA violated the Regulatory Flexibility Act. *Id.* at 69–71. All these arguments fail.

B. EPA reasonably acted in the face of inevitable uncertainty about designation's indirect effects.

Petitioners argue that EPA could not designate PFOA and PFOS because the agency "lacks certainty" about where those substances are located, how parties will address contamination, and what the economic costs of cleanup will be. Pet'rs' Br. 73–75. Further study was needed, Petitioners say, to rule out "unintended consequences" that might flow from "unleash[ing] CERCLA onto substances" that are "everywhere." *Id.* at 72–73.

This reasoning fundamentally misconstrues CERCLA. Contamination does not, by itself, trigger any obligation to pay for cleanup. Among the Act's core features is a requirement that EPA "prioriti[ze] among releases" through progressively stringent, site-specific assessments of "relative risk." 42 U.S.C. § 9605(a)(8)(A). Thus, EPA conducts "preliminary assessment[s]" with an eye toward "[e]liminat[ing] from further consideration those sites that pose no threat to public health or the environment." 40 C.F.R. § 330.420(b)(1)(i), (2). Sites that make it over that initial hurdle may then be reviewed in greater depth to determine whether they should be added to the NPL. *Id.* §§ 300.420(c), 300.425. Most don't make the cut. Between Fiscal Years 2003 and 2022, "only about four percent of all

contaminated sites added to EPA's Active Site Inventory were placed on the NPL." 89 Fed. Reg. at 39128. And even then, "EPA's listing a site on the NPL . . . guarantees only more detailed study." *Daikin Applied Ams. Inc. v. EPA*, 39 F.4th 701, 705 (D.C. Cir. 2022).

Among those topics of study is "how parties will address contamination." Pet'rs' Br. 72; *see also* 40 C.F.R. § 300.430. Costs are an important consideration in that analysis. The NCP provides, among other things, that any CERCLA remedy "shall be cost-effective," meaning that its "overall effectiveness [is] proportional to its costs." 40 C.F.R. § 300.430(f)(1)(ii)(D); *see also id.* § 300.430(e)(7)(iii) ("Alternatives providing effectiveness and implementability similar to that of another alternative . . . but at greater cost, may be eliminated."). And CERCLA limits recovery under Section 9607 to the reimbursement of costs that a court concludes are "consistent with" (or "not inconsistent with") this cost-effectiveness requirement and other provisions of the NCP. 42 U.S.C. § 9607(a)(4)(A)–(B).

Petitioners' demand that EPA comprehensively assess future cleanup activity before designating PFOA and PFOS conflicts with CERCLA's deliberate, step-by-step decision-making process. It is also an impossible demand. As Petitioner Chamber of Commerce acknowledged in its comments to EPA, "estimating Superfund site cleanup costs is inherently uncertain." EPA-HQ-OLEM-2019-0341-0405_attachment_2 ("Chamber Report") 4, JA213.

That inherent uncertainty cannot be a barrier to designation, as Petitioners suggest. The APA does not demand "perfect empirical or statistical data," and the lack of such data is "not unusual in day-to-day agency decisionmaking." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021). Agency "action in the face of uncertainty" is often necessary. *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1090 (D.C. Cir. 2014) (internal quotation marks omitted). And it "is emphatically the province of EPA" to decide when action in the face of uncertainty is appropriate when implementing precautionary statutory provisions. *Id.*

EPA found that CERCLA's guardrails would channel action to those contaminated sites most in need of remediation. 89 Fed. Reg. at 39161. It found that CERCLA's limitations on liability and courts' equitable authority to allocate liability would channel cleanup burdens to those most directly responsible for contamination. *Id.* at 39160–61, 39164. And it concluded that those structural constraints would prevent or mitigate potential downsides of designating PFOA and PFOS. *Id.* at 39164. Action on the basis of those judgments was reasonable. Waiting for perfect data, by contrast, would have undermined Congress's purpose of protecting public health by driving timely cleanup of hazardous substances.

Petitioners offer no reason to believe that adding PFOA and PFOS to an already long list of similarly prevalent, persistent, and mobile substances will have major unintended consequences. Instead, they suggest that PFOA and PFOS

contamination "could . . . severely hamper real estate transactions." Pet'rs' Br. 76. But that bare statement of possibility does not compel EPA to choose inaction in the face of robust (and uncontested) evidence that PFOA and PFOS may present substantial danger to human health and the environment.

Petitioners' suggestion that designation "could" "slow down, rather than speed up" cleanup efforts at existing NPL sites is similarly unpersuasive. *Id.* at 75–76. Petitioners made the same arguments in comment letters. And as EPA explained then, "PFOA and PFOS are already considered CERCLA pollutants or contaminants," so designation "should not result in any change to the investigation, cleanup, and review processes for sites that are currently on the NPL." EPA's Response to Comments, ("RTC"), EPA-HQ-OLEM-2019-0341-0839 at 221–222, JA687–88; *accord id.* at 80–81, JA663–64. Petitioners fail to acknowledge, let alone rebut, that response.

C. EPA satisfied the APA's notice-and-comment requirements.

Petitioners' procedural argument—that EPA failed to provide adequate notice, Pet'rs' Br. 44–51—cannot be squared with this Court's precedents or the record. Notice under the APA must "fairly apprise interested persons of the subjects and issues involved in the rulemaking." *Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 6 (D.C. Cir. 1999) (internal quotations omitted). To meet its obligations, an agency must "disclose *critical* material, on which it relies." *Allina Health Servs. v.*

Sebelius, 746 F.3d 1102, 1110 (D.C. Cir. 2014). But that "requirement . . . does not extend to all data," *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 745 F.2d 677, 684 (D.C. Cir. 1984), and "an agency engaged in informal rulemaking is not obliged to consider only" those materials submitted for public comment, *Air Transp. Ass'n of Am.*, 169 F.3d at 7. Thus, the focus in this Court's "rulemaking cases is primarily on whether the final rule changes critically from the proposed rule rather than on whether the agency relies on supporting material not published for comment." *Id.*

The "public right to have a say" in agency rulemaking "is honored" when "affected parties should have anticipated" any changes in the final rule "in light of the notice." *Brennan v. Dickson*, 45 F.4th 48, 69 (D.C. Cir. 2022) (internal quotation marks omitted). That was certainly the case here. At proposal, EPA described what it saw as the reasonably foreseeable direct and indirect costs, benefits, and transfers associated with designation; it explained why it did not believe that most of those effects could be fully monetized; and it made a detailed request for comment on whether and how designation's direct and indirect costs should factor into its designation decision. *See* Section C.3, *supra*. Petitioners not only *should have* anticipated EPA's consideration of those issues, they *did*. The Chamber of Commerce, for example, submitted with its comments a 20-page report on how it believed EPA should account for indirect costs of future response actions at NPL

sites.[9] Chamber Report, JA213-29. Petitioners thus had—and took—the "opportunity to develop evidence in the record to support their objections to the rule." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 626 F.3d 84, 95 (D.C. Cir. 2010).

No matter, Petitioners say, because EPA did not take public comment on "new estimates of costs" and "benefits" that were contained in the RIA and Final Rule preamble and, according to Petitioners, were "crucial to quantitatively weighing costs and benefits." Pet'rs' Br. 46–47. The problem with this argument is that EPA did not need to, and did not in fact, justify its designation decision by quantitatively weighing costs and benefits. *See* Section II.A, *supra*; *see also Inv. Co. Inst. v. CFTC*, 720 F.3d 370, 379 (D.C. Cir. 2013) ("Where Congress has required rigorous, quantitative economic analysis, it has made that requirement clear in the agency's statute, but it imposed no such requirement here.")

Instead, EPA assessed advantages and disadvantages of designation on a qualitative basis. In doing so, the agency provided quantitative estimates only for "those categories of indirect costs, benefits, and transfers for which sufficient data were available." RIA 26, JA407. Those estimates rested on forecasts about future

---

[9] EPA responded at length, identifying "several unfounded or inaccurate assumptions" and explaining why the Chamber's approach to cost analysis was "based on an inaccurate application of the Superfund process for addressing contamination at NPL sites." RTC 221–22, JA687–88. Petitioners' brief provides no rebuttal.

activity that were themselves "highly uncertain." RIA 172, JA553. So EPA made clear in the RIA that its quantitative estimates were "illustrative." *Id.* at 27, JA408; *see also id*. at 160, JA541 ("Because it is not possible to attribute response activities to specific authorities, these estimates are illustrative and only in part attributable to this final rule."); *accord id.* at 157, 166, JA538, 547. And the agency also made clear in the Final Rule preamble that it would have acted "even without consideration of quantified benefits." 89 Fed. Reg. at 39155.

Owner-Operator Independent Drivers Association v. Federal Motor Carrier Safety Administration, 494 F.3d 188 (D.C. Cir. 2007), which Petitioners largely rely on, Pet'rs' Br. 47–48, is readily distinguishable. That case concerned action under a statutory provision that, unlike Section 9602, expressly required the agency to balance "the 'costs and benefits' of its safety regulations." *Owner-Operator*, 494 F.3d at 194 (quoting 49 U.S.C. § 31502(d)). Pursuant to that mandate, and unlike here, the agency treated as dispositive its conclusion that a regulatory action's estimated "economic costs to industry" "outweighed [its] safety benefits." *Id.* at 198; *see also id.* at 199–200. On those facts, this Court concluded that the quantitative model that underpinned the agency's cost-benefit assessment—and thus underpinned its substantive regulatory decision—was "unquestionably among the most critical factual material" in the record and had to be presented for public comment. *Id.* at 201 (internal quotation marks omitted).

Not so here. This Court has never held that the right to an "opportunity to participate in . . . rule making," 5 U.S.C. § 553(c), encompasses the right to comment on information that did not affect the outcome of a final rule. *See Pers. Watercraft Indus. Ass'n v. Dep't of Com.*, 48 F.3d 540, 544 (D.C. Cir. 1995) (study was not "material critical to an agency's decision" because the agency's decision was not "the product" of that study). The Court should decline Petitioners' invitation to vastly expand the "critical material doctrine." *Allina Health Servs.*, 746 F.3d at 1110.

It should look instead to those "logical outgrowth" cases in which an agency considered new information that "did no more than provide support for the same decision" that the agency "had proposed to take." *Bldg. Indus. Ass'n of Superior California v. Norton*, 247 F.3d 1241, 1246 (D.C. Cir. 2001); *see also, e.g.*, *Solite Corp. v. EPA*, 952 F.2d 473, 485 (D.C. Cir. 1991) (no comment required on "added data" that "was used to check or confirm prior assessments"). Here, as in those cases, EPA "advanced for comment a hypothesis," *Bldg. Indus. Ass'n*, 247 F.3d at 1246: that PFOA and PFOS should be designated as CERCLA hazardous substances. When it did so, EPA identified relevant direct and indirect costs and benefits of designation, and it asked for the public's views on whether and how those costs and benefits should inform its decision-making. *See* Section C.3, *supra*. Based on comments received, including comments from Petitioners, EPA tested its

hypothesis and generated new quantitative estimates of benefits and costs in the process. *See* Section C.4, *supra*. But the agency "did not reject or modify the hypothesis." *Bldg. Indus. Ass'n*, 247 F.3d at 1246. Instead, at the final-rule stage, EPA took the same action it had proposed. No opportunity for additional comment was required.

Even assuming for argument's sake that more procedure was required, Petitioners' argument would still fail because they cannot establish prejudice. Under the APA, "due account shall be taken of the rule of prejudicial error." 5 U.S.C. § 706. "Perhaps because of the possible tension between *Vermont Yankee* and [the] critical material doctrine," this Court has "more carefully examined whether a failure to disclose such material actually harmed a petitioner." *Allina Health Servs.*, 746 F.3d at 1110. It is Petitioners' burden to establish "enough uncertainty" as to the "possible effect" of their comments "on the agency's disposition." *Id.* (internal quotation marks omitted); *see also GPA Midstream Ass'n v. U.S. Dep't of Transp.*, 67 F.4th 1188, 1198 (D.C. Cir. 2023) ("To show prejudice, the petitioners must raise a credible argument about the merits of the rule."). Petitioners fail to carry that burden for three reasons.

First, their attacks on EPA's assessment of costs and benefits, Pet'rs' Br. 51–68, fail for the reasons discussed below. *See* Section II.D–F, *infra*. And Petitioners would not suffer prejudice from the denial of an opportunity to press losing

arguments. *See GPA Midstream Ass'n*, 67 F.4th at 1198 ("[W]e do not right wrongs that make no difference.").

Second, merits aside, many of the cost- and benefit-related arguments in Petitioners' brief are drawn directly from comment letters. That is true, for example, of everything in Section II.C.4 of their brief. Pet'rs' Br. 63–68. It is also true of Petitioners' arguments about the "Salvatore" study, which they cite no fewer than four times for the claim that there are 57,412 sites with PFOA or PFOS contamination. Pet'rs' Br. 12, 20, 58, 59. Commenters relied on that study for the same claim, and EPA explained why it disagreed with their assertions. RTC 289, JA715. Petitioners may quibble with EPA's responses to those comments, but they cannot argue that they were denied the opportunity to comment. *See Allina Health Servs.*, 746 F.3d at 1110 (noting that a party "would presumably be hoist on its own petard" if it commented on the very issues that it argues were insufficiently noticed).

Third, even if Petitioners had managed to cast doubt on EPA's illustrative quantitative estimates, that would not cast doubt on EPA's underlying action. None of Petitioners' arguments about costs disturb EPA's judgment that robust quantitative assessment of designation's indirect effects would be infeasible. Nor do they take aim at the central rationales on which EPA based its decision to designate. Any error in EPA's illustrative quantitative estimates would thus be harmless.

D. EPA made reasonable predictions about the scope of future PFOA- and PFOS-related response actions.

Petitioners challenge three of EPA's predictive judgments about the scope of certain future PFOA- and PFOS-related cleanup activities. Two concern the scope of cleanup activity that would have occurred independent of designation. First, in that baseline scenario, EPA predicted that federal agencies would address PFOA and PFOS contamination at sites within their jurisdiction. *See* Section C.4, *supra*. Second, EPA predicted that it would spend around $10.3-to-$51.7 million from the Superfund to remediate PFOA and PFOS contamination at non-federal NPL sites. *See id.* The third predictive judgment at issue concerns EPA's forecast that, following designation, it may undertake enforcement actions at around 67 sites not listed on the NPL. *Id.* Petitioners claim that EPA's predictions about baseline activity at federal sites and at non-federal NPL sites lack sufficient record support. And they quibble with the assumptions that EPA used to estimate cleanup costs at non-federal NPL sites and to estimate the number of non-NPL sites that may be subject to future enforcement actions. Neither line of argument succeeds.

1. EPA made reasonable forecasts about baseline PFOA and PFOS cleanup activity at non-federal NPL sites and at federal sites.

"In circumstances involving agency predictions of uncertain future events, complete factual support in the record . . . is not possible or required since a forecast of the direction in which future public interest lies necessarily involves deductions

based on the expert knowledge of the agency." *Rural Cellular*, 588 F.3d at 1105 (internal quotation marks omitted). This Court is thus "particularly deferential to agencies' predictive judgments, requiring only that the agency acknowledge factual uncertainties and identify the considerations it found persuasive." *Growth Energy v. EPA*, 5 F.4th 1, 15 (D.C. Cir. 2021) (internal quotation marks omitted).

"EPA cleared that modest bar." *Id.* For one thing, its forecasts of cleanup activity at non-federal NPL sites and federal sites in a no-designation baseline scenario comport with CERCLA. As EPA noted, it can list sites on the NPL and undertake response actions based on releases of pollutants or contaminants. *See* RIA 64–71, JA445–52; 89 Fed. Reg. at 39137–38; *see also* Section A.2–3, *supra*. To determine what actions may be appropriate, EPA assesses relative risk using NCP criteria that apply uniformly to all substances, whether designated or not. *See* 40 C.F.R. Pt. 300 App. A (hazard ranking system used to determine site eligibility for the NPL); *id.* § 300.425(d) (procedures for placing sites on the NPL); *id.* § 300.430(e)(2)(i) (factors and metrics that guide selection of remedial alternatives). And federal agencies must follow the same approach when exercising their delegated CERCLA authority to investigate and respond to pollutants or contaminants on sites within their jurisdiction. So while there remain "broad uncertainties[] regarding the extent of PFOA/PFOS contamination," RIA 20, JA401, there is every reason to believe that the robust evidence of PFOA- and PFOS-related

danger would inform EPA's and federal agencies' risk-based CERCLA decision-making and drive response actions even absent designation.

Indeed, it already had. Before designation, EPA had listed five non-federal sites on the NPL based in part on releases of PFOA or PFOS. *See* Section B, *supra*. And other federal agencies had invested billions to respond to PFOA and PFOS contamination at hundreds of facilities within their control. *See id.*

Petitioners demand more. To predict cleanup activity at federal facilities in a no-designation baseline, they say that EPA either needed to produce "federal facilities agreements" documenting planned remedies at particular sites or needed to identify a statutory "requirement" compelling agencies to act. Pet'rs' Br. 61–62. But in reviewing agency predictions, this Court "does not demand total assurances." *Melcher v. FCC*, 134 F.3d 1143, 1152 (D.C. Cir. 1998). Federal agencies had a record of addressing PFOA and PFOS before EPA designated those substances. With no evidence to the contrary—and Petitioners have offered none—EPA could reasonably conclude that those pre-designation trends would have continued apace in a no-designation baseline scenario.[10]

[10] While EPA assumed that federal agencies would address PFOA and PFOS contamination even absent designation, it did not "ignore[] cleanup costs at federal sites." Pet'rs' Br. 60. The agency discussed federal-site cleanup data at length in the RIA and also explained why it did not view those data as representative of non-federal sites. RIA 188–90, JA569–71.

The same goes for remedial action at non-federal NPL sites. True, as Petitioners note, Pet'rs' Br. 54, CERCLA remedies must be cost-effective, 40 C.F.R. § 300.430(f)(1)(ii)(D). And it is also true that EPA must support any response action aimed at pollutants or contaminants with a finding that contamination at a given site "'may present an *imminent* and substantial danger'" to public health or welfare. Pet'rs' Br. 53–54 (quoting 42 U.S.C. § 9604(a)(1)(B)). But neither requirement renders unreasonable EPA's prediction of PFOA- and PFOS-related remedial action at non-federal NPL sites independent of designation.

CERCLA and the NCP's cost-effectiveness mandate applies without exception to all remedies. 42 U.S.C. § 9621(a); 40 C.F.R. § 300.430(f)(1)(ii)(D). Having satisfied that requirement for every CERCLA remedy that it has ever selected, EPA could reasonably assume that it could do the same for remedies aimed at PFOA and PFOS. Indeed, Petitioners apparently reached the same conclusion. In lamenting "broad and harsh" liability for "remedial actions," Pet'rs' Br. 71, they presume that the costs of those actions would be recoverable from PRPs. But that presumption holds only to the extent that remedies are "consistent" or "not inconsistent" with the NCP, including its mandate for cost-effectiveness. *See* Section II.A, *supra*.

EPA could also reasonably presume its ability to make the imminent-and-substantial-danger finding necessary to take remedial action aimed at pollutants or

contaminants under Section 9604(a)(1)(B). Courts have long recognized that the analogous statutory phrase "may present an imminent and substantial endangerment" requires only that there be "a threat which is present now, although the impact of the threat may not be felt until later." *Meghrig v. KFC W., Inc.*, 516 U.S. 479, 485–86 (1996) (internal quotation marks omitted). And courts have "flatly rejected the proposition" that this language "was designed to control pollution only in emergency situations." *Maine People's All.*, 471 F.3d at 287. Superfund-led remedies are reserved for sites that are placed on the NPL. 40 C.F.R. § 300.425(b)(1). NPL sites pose the highest relative risk. *See* Section II.B, *supra*. And risk sufficient to justify NPL listing would also likely support an imminent-and-substantial-danger finding.

2. EPA's illustrative cost estimates were reasonable.

Petitioners object to certain inputs that EPA used to develop illustrative quantitative estimates of the costs associated with future PFOA- and PFOS-related remedial actions at non-federal NPL sites and with enforcement actions at non-NPL sites. As to the former, Petitioners say that EPA should have applied a higher "cost premium" to account for uncertainty about the costs of remedying PFOA and PFOS. Pet'rs' Br. 55–56. As to the latter, Petitioners say that EPA should have assumed enforcement actions at a greater number of sites. *Id.* at 58–59. As to both, Petitioners claim that EPA erred in using historic response-cost data to forecast costs

specific to PFOA and PFOS. Pet'rs' Br. 56, 59. Petitioners are wrong across the board.

This Court "accord[s] EPA discretion to arrive at a cost figure within a broad zone of reasonable estimate." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 563 (D.C. Cir. 2002). Petitioners' "burden to show error is high." *Id.* They do not carry it. EPA's predictions here fall well "within the limits of reason and rationality." *Melcher*, 134 F.3d at 1152. The APA demands nothing more, certainly not for calculations offered only "to provide some context." RIA 27, JA408.

a. In estimating costs of PFOA and PFOS-related remedial actions at non-federal NPL sites, EPA assumed that PFOA and PFOS would usually be commingled with other substances "that need to be addressed by a cleanup action because they [too] pose a potential threat to human health or the environment." 89 Fed. Reg. 39129 & n.14. That assumption has ample record support: there are an average of 19 such "[c]ontaminant[s] of [c]oncern" at non-federal NPL sites; 6.6% of those sites have more than 50 contaminants of concern; and only 5.5% are single-contaminant sites. RIA 128, JA509. Because remedies at NPL sites are designed to address all contaminants of concern, "some of the same treatment technologies for PFOA and PFOS contamination" would "likely be[] applied for other hazardous substances in many cases." RIA 173, JA554. Thus, the marginal cost of addressing PFOA or PFOS contamination at some non-federal NPL sites may well be zero. But

given the high degree of uncertainty around these projections, EPA made "the conservative assumption that," as a general matter, "there is a cost premium; that is, EPA assume[d] that addressing other" contaminants of concern would not always "simultaneously remedy PFOA and/or PFOS contamination." *Id.* at 172, JA553. To ballpark the potential average cost-premium of addressing PFOA and PFOS, the agency added 2–10% to historical remedial costs at non-federal NPL sites.

Petitioners argue that EPA should have applied a higher cost premium. Citing the cost study that the Chamber of Commerce submitted during the public comment period, they urge a 50–100% increase above historical costs. Pet'rs' Br. 55–56.[11] But EPA rejected the Chamber's analysis as unreliable because, among other things, it rested "on probability distributions that are based on discussions with industry rather than empirical data and . . . on 30-year-old data for a sample of 18 sites." RTC 222, JA688. Even setting that aside, a 2–10% across-the-board *average* cost premium allows for higher premiums at particular sites, including a 50–100% premium, where warranted. And in any case, Petitioners' disagreement with EPA's cost premium is no "more than an effort . . . to substitute its own analysis for the agency's." *New York v. U.S. Nuclear Regul. Comm'n*, 824 F.3d 1012, 1022 (D.C.

[11] Petitioners' reliance on materials submitted during the comment period further erodes their claim that inadequate notice deprived them of an opportunity to meaningfully comment on cost issues. *See* Section II.B, *supra*.

Cir. 2016). This is insufficient; EPA's predictive judgment is entitled to deference, not Petitioners'. *Id.* at 1023.

b. In estimating enforcement-related cleanup costs at non-NPL sites, EPA assumed that it would use its limited resources to bring enforcement actions at "sites where the likelihood of PFOA/PFOS contamination is highest." RIA 160, JA541. That common-sense proposition is also reflected in EPA's stated policy of "holding responsible entities who significantly contributed to the release of PFAS into the environment, including parties that manufactured PFAS or used PFAS in the manufacturing process." PFAS Enforcement Discretion and Settlement Policy Under CERCLA (April 19, 2024), https://www.epa.gov/system/files/documents/2024-04/pfas-enforcement-discretion-settlement-policy-cercla.pdf. Consistent with that understanding, EPA identified (only to estimate enforcement-related costs) 133 non-NPL sites that are "owned/operated by" major PFAS manufacturers and where reported releases of PFOA and PFOS have occurred. RIA 160, JA541. But because EPA is unlikely to take CERCLA enforcement action at all those sites, the agency assumed enforcement actions at 67 of them. *Id.* This was not designed to be a precise forecast—EPA described its methodology as "admittedly imperfect." *Id.* But these assumptions allowed EPA to develop a "central estimate" from which enforcement-related costs at non-NPL sites could be

calculated, despite the "highly uncertain" location and extent of those future actions. *Id.*

EPA's "admittedly imperfect" approach, *id.*, was far more reasonable than the one urged by Petitioners. They argue that EPA should have assumed some CERCLA action at "57,412 presumptively contaminated sites," a figure they draw from the Salvatore study. Pet'rs' Br. 59. But as EPA explained in response to comments raising similar arguments, the Salvatore study identified categories of sites with a "relatively high likelihood of containing PFAS," presumed an unspecified quantity of PFAS at every site in those categories, and failed to distinguish between PFAS generally—"a class of over 9,000 chemicals," RIA 211, JA592—and PFOA and PFOS in particular. RTC 289, JA715. All of which made the Salvatore study a poor foundation for cost estimate; EPA reasonably declined to treat it as one.

c. In assessing future PFOA- and PFOS-related cleanup costs, EPA relied on the best data available to it: historical cost data from response actions aimed at other substances. At proposal, EPA flagged the lack of robust data on PFOA- and PFOS-specific remedial costs, and it sought information and comment on this very topic. *See, e.g.*, EA 49, JA148 ("Given the lack of information and systemic analysis of remediation of PFOS and PFOA, we seek information and comment that may allow EPA to estimate incremental indirect costs associated with this rule."). But EPA did not receive any reliable PFOA- and PFOS-specific data in response, and so it used

available information, caveating its estimates accordingly. Nothing about that approach was arbitrary and capricious.

E. Other costs identified by Petitioners are beyond the scope of this action.

Apart from the costs of future CERCLA response actions, Petitioners present a grab-bag of other costs associated with changes in daily operations at landfills, water-treatment plants, paper mills, recycling plants, and construction sites—all aimed, they say, at managing PFAS-contaminated waste and environmental media. Petitioners argue that EPA had to consider these costs in determining whether to designate PFOA and PFOS as hazardous substances under CERCLA. But as EPA explained in response to comments raising the same arguments, none of the operational changes that Petitioners identify are fairly attributable to this action.[12]

Designation does "not impose specific waste management obligations pertaining to treatment, disposal, or storage of PFOA and PFOS contaminated wastes." RTC 121, JA680. Nor does it require facilities to proactively sample or treat for PFOA and PFOS. *See, e.g.*, *id.* at 5, 121, 145, JA661, 680, 682. In fact, day-to-day waste-management practices in the sectors that Petitioners reference are

---

[12] *See, e.g.*, RTC 84–85, 269, JA665–66, 706 (landfill leachate); *id.* at 224–31, JA690–97 (incinerating sludge from water treatment plants); *id.* at 94–102, JA667–75 (reusing paper-mill residuals); *id.* at 261–72, JA698–709 (managing recycling systems); *id.* at 284–90, JA710–16 (construction projects); *see also* 89 Fed. Reg. at 39178-79 (addressing comments pertaining to "PFOA and PFOS contaminated waste").

governed by laws other than CERCLA. These include the Safe Drinking Water Act, Clean Water Act, Toxic Substances Control Act, Resource Conservation and Recovery Act, and various state laws. Regulations aimed at PFOA and PFOS are already in place or in development under each of those federal statutes and under dozens of state statutes as well. *See* RIA 71–72, JA452–53 (detailing federal actions); RIA 89–90, JA470–71 (detailing state actions). The costs that Petitioners identify are thus attributable to non-CERCLA actions, placing them outside the scope of this rulemaking.

In response, Petitioners contend that because EPA relied on "the purported benefit of incentivizing better waste management practices of products that may contain PFOA or PFOS," it had to account for all costs associated with those practices. Pet'rs' Br. 64 (cleaned up). This argument makes a mountain out of a molehill. EPA's far more modest assertion was that designation "may" lead "some facilities" to adopt PFOA- and PFOS-related "best practices," "to the extent they have not done so already," 89 Fed. Reg. at 39159. That was so, the agency explained, because firms "may" elect to "incur [additional] costs" in order to avoid the $2,655 expense (and associated notoriety) of providing notifications in the event of releases of PFOA and PFOS at or above a reportable quantity. RIA 150 & n.226, JA531. In pointing this out, EPA did not claim as benefits of designation all "enhanced" PFOA- and PFOS-related "waste management practices," Pet'rs' Br. 68,

and thus did not render Petitioners' other "categories of cost" germane to this action, *id.* at 63.

Which is not to say that EPA ignored Petitioners' broader concerns about "liability exposure." *Id.* at 66. The agency acknowledged that some amount of litigation is "an expected and intended aspect of CERCLA" and a reasonably foreseeable consequence of designation. 89 Fed. Reg. at 39162. But EPA explained why it believed that CERCLA would "continue to function normally after the designation of PFOA and PFOS as it has for over forty years for the over 800 hazardous substances already designated under CERCLA." RTC 117, JA677. And Petitioners offer no reason why designation of PFOA and PFOS would suddenly "overburden," Pet'rs' Br. 64, or "significantly disrupt," *id.* at 66, industries that already manage other hazardous substances every day.

F. EPA reasonably assessed advantages of regulation.

Petitioners argue that EPA misclassified cleanup costs as an advantage of designation when those costs are borne by PRPs. Pet'rs' Br. 57, 68. Costs are costs, they insist, no matter "who ultimately pays the tab." *Id.* at 57. But "who ultimately pays" matters a great deal under CERCLA. The Act exists to "ensure that the costs of . . . cleanup efforts [are] borne by those responsible for the contamination." *Atl. Richfield Co.*, 590 U.S. at 6 (internal quotation marks omitted). CERCLA thus holds "[c]overed persons" liable for certain costs, 42 U.S.C. § 9607; authorizes EPA to

compel facility owners to undertake cleanups themselves, *id.* § 9606; and encourages EPA to use those authorities to pursue PRP-led cleanups by entering settlements "[w]henever" doing so is "practicable and in the public interest," *id.* § 9622(a). These provisions reflect Congress's policy judgment that when PRPs pay, the public benefits. Designation advances that legislative aim and EPA reasonably viewed this as an advantage.

More still, many costs borne by PRPs are costs that would otherwise have come from the Superfund. The transfer of these costs "leads to more total resources available for cleanups." 89 Fed. Reg. at 39153. And that in turn allows for earlier and more cleanup activity. *See* Section C.4, *supra*. It would be anomalous indeed if that was treated as a disadvantage under a statute that "seeks to promote timely cleanup." *Atl. Richfield Co.*, 590 U.S. at 6 (internal quotation marks omitted).

G. EPA's analysis is consistent with the requirements of the Regulatory Flexibility Act.

The RFA statute requires agencies to analyze impacts to small entities, unless the agency determines that the rule will not "have a significant economic impact on a substantial number of small entities." 5 U.S.C. § 605(b). An agency's compliance with the RFA is generally not judicially reviewable, but a rule's regulatory flexibility analysis "shall constitute part of the entire record of agency action." *Id.* § 611(b). Thus, this Court considers an RFA analysis "as part of its overall judgment [about]

whether a rule is reasonable." *Mid-Tex Elec. Coop., Inc. v. FERC*, 773 F.2d 327, 341 (D.C. Cir. 1985) (internal quotations omitted) ("*Mid-Tex*").

Petitioners' primary complaint is that EPA should have treated potential response costs as direct impacts of the rule. *See* Pet'rs' Br. 69–71. But such a determination would be inconsistent with the RFA. The RFA is limited to the "consideration of the economic impact of proposed rules to small entities that would be *directly regulated* by those rules." *Mid-Tex*, 773 F.2d at 341–42 (emphasis added). Agency guidance further provides that an entity is "directly regulated" if it "will have obligations imposed on [it] directly by the rule." RIA 61, JA442. The only direct obligation on small entities associated with designation is the requirement to report releases.[13] *Id.* That is so because if an entity releases PFOA and PFOS at or above the reportable quantity, then it must report the release as soon as it knows of the release. *Id.*; 42 U.S.C. § 9603(a). By contrast, neither a designation, nor CERCLA more generally, requires that any response action be taken to address a release. RIA 61, JA442; 89 Fed. Reg. at 39169.

[13] EPA also identified two other direct impacts of designation: costs to comply with the Hazardous Materials Transportation Act and federal-property transfers under 42 U.S.C. § 9620(h). EPA did not include these potential impacts in its analysis of impacts to small businesses; indeed, EPA concluded that costs associated with the Hazardous Materials Transportation Act were zero or negligible. RIA 220, JA601. Petitioners do not challenge this conclusion.

Petitioners cite *Mid-Tex* to support of their argument, Pet'rs' Br. 70, but that case reinforces the validity of EPA's approach. There, this Court determined that Congress intended agency review under the RFA to address "costs of compliance with uniform regulations to small businesses," not "every indirect effect that any regulation might have on small businesses in any stratum of the national economy." *Mid-Tex*, 773 F.2d at 343. Here, the site-specific nature of CERCLA response actions demonstrates that those actions impose no "uniform" "costs of compliance" to small entities. Rather, CERCLA response actions are indirect effects of designation because response actions "are not required" "and are discretionary and contingent upon a series of site-specific determinations." RIA 62, JA443. Nothing in the RFA or *Mid-Tex* undermines that conclusion.

Because EPA exhibited no clear error in judgment in its determinations under the RFA, Petitioners' claim fails. *See State Farm*, 463 U.S. at 43 (arbitrary-and-capricious review only allows a reviewing court to set aside a rule if "there has been a clear error in judgment").

III. Any remand to EPA should be without vacatur.

"Although vacatur is the normal remedy" under this Court's APA precedents, *Am. Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 518 (D.C. Cir. 2020), it "is simply not the law" that a court must vacate an agency action in violation of the

APA, *Sugar Cane Growers Coop. v. Veneman*, 289 F.3d 89, 98 (D.C. Cir. 2002).[14] Whether to remand with or without vacatur depends on "the seriousness of the action's deficiencies" and "the likely disruptive consequences of vacatur." *Am. Great Lakes Ports Ass'n*, 962 F.3d at 518.

On the first factor, many of Petitioners' arguments concern alleged errors in EPA's quantitative estimates for limited categories of costs, transfers, and benefits. These estimates were not statutorily required or central to EPA's designation decision. *See* Section II.A–II.B, *supra*. And if the Court were to declare them arbitrary and capricious, then EPA could readily correct any errors on remand. *See Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) (contrasting an "agency's failure to explain" an "otherwise permissible rule" with the kinds of "fatal flaw" that normally call for vacatur).

On the second factor, "as a general rule," this Court does "not vacate regulations when doing so would risk significant harm to the public health or the environment." *Wisconsin v. EPA*, 938 F.3d 303, 336 (D.C. Cir. 2019). And vacatur is less likely "when an agency cannot easily unravel a past transaction in order to impose a new outcome." *Am. Great Lakes Ports Ass'n*, 962 F.3d at 519. Both considerations weigh against vacatur here. The federal government is taking, and

[14] The position of the United States is that 5 U.S.C. § 706(2) does not authorize courts to vacate agency action. But the remedy analysis presented here follows controlling Circuit precedent.

will continue to take, response actions that presume PFOA's and PFOS's status as "hazardous substances." Were the Court to vacate, however, PFOA and PFOS would again be "pollutants or contaminants," and those response actions that agencies have undertaken since designation would be substantially delayed while those agencies documented the "imminent and substantial danger" determinations that are conditions precedent to any response action aimed at a pollutant or contaminant. *See* 42 U.S.C. § 9604(a). This process would require halting ongoing work that is addressing pressing public health risks.

Thus, should the Court find any error, it should remand the rule to EPA without vacatur.

CONCLUSION

For these reasons, the petitions should be denied.

Respectfully submitted,

ADAM R.F. GUSTAFSON
Principal Deputy Assistant Attorney General

/s/ *Jin Hyung Lee*
JIN HYUNG LEE
Trial Attorney
Environment and Natural Resources Division
U.S. Department of Justice

Of Counsel:

ELIZABETH G. BERG
NOEL M. JOHNSON
JEFFREY MANSBACH
Attorneys
U.S. Environmental Protection Agency

December 5, 2025

CERTIFICATES OF COMPLIANCE AND SERVICE

1. I certify that this brief complies with the type-volume limit of the Court's order of October 1, 2024 because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f), the brief contains 15,928 words.

2. I also certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Word for Microsoft Office 365 in 14-point Times New Roman font.

3. And I certify that on December 5, 2025, I filed the foregoing with the Court's CM/ECF system, which served copies of the brief on all ECF-registered counsel.

Dated: December 5, 2025

/s/ *Jin Hyung Lee*
JIN HYUNG LEE

Counsel for Respondents