Comments of the U.S. Chamber of Commerce
Coalition of Companies and Trade Associations on

Proposed Rule, Environmental Protection Agency; Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances; 87 Fed. Reg. 54,415 (Sept. 6, 2022), Docket ID No. EPA–HQ–OLEM–2019-0341(pp. 54415-54442)

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Executive Summary

The U.S. Chamber of Commerce Coalition of Companies and Trade Associations (the Coalition) supports accelerating appropriate cleanup of sites using existing regulatory tools to address the challenges presented by PFOA and PFOS to public health and the environment in communities across the United States. Businesses are actively collaborating with federal agencies and local and state government stakeholders to ensure an effective and balanced approach to addressing PFOA and PFOS-related concerns based on the best science and appropriate consideration of risk.

However, the Coalition opposes this rulemaking as it would have multiple negative, unintended consequences that would cause unnecessary impacts to companies and communities inconsistent with EPA's goal of safely and efficiently addressing sources of PFOA and PFOS in the environment that present risk. A CERCLA hazardous substance designation under 102(a) has never been promulgated by the Agency, and it is the wrong tool to address substances that EPA says are so widespread. Designating PFOA and PFOS as hazardous substances potentially could bring millions of landowners around the country under CERCLA jurisdiction and prompt a reopening of potentially a myriad of Superfund sites. While EPA insists it will use appropriate enforcement discretion, landowners with even small amounts of PFOA and PFOS could potentially be opened to liability by third parties. Accordingly, invoking CERCLA in this instance is not effective environmental policy.

Additionally, neither EPA, nor stakeholders have a full appreciation of the many consequences of this rule because EPA has refused to do a full regulatory impact analysis that evaluates all impacts, both direct and indirect, in accordance with Executive Order requirements and OMB guidance. Not fully weighing the costs versus the benefits of this rulemaking is an unacceptable omission that should be addressed before EPA continues with this rulemaking process.

Moreover, this rule is unnecessary, as EPA has ample existing authority to protect the public health and welfare and the environment from any potential risks posed by PFOA and PFOS without designating them as hazardous substances. EPA itself has recognized that even without this rulemaking it has numerous tools under CERCLA, SDWA, RCRA, CWA, and other laws to address sites containing PFOA or PFOS that could present a risk. The Coalition urges EPA to continue to consider how to utilize those tools as needed without resorting to this overbroad approach under Section 102(a).

Additionally, EPA should address numerous important issues prior to continuing this rulemaking, such as what levels of cleanup are feasible given the interim health advisories issued by EPA, how responsible parties would dispose of or destroy PFOA and PFOS in the remediation process, and how the waste that will be created from site cleanup would impact the passive receivers such as POTWs or landfills.

The comments presented herein describe the substantial shortcomings of the proposed rule, including: EPA's failure to describe the standard for listing a chemical as a hazardous substance; EPA's attempt to justify listing PFOA and PFOS as hazardous substances by merely

describing their characteristics rather than connecting those chemical properties to any risk of exposure; EPA's erroneous conclusion that Section 102(a) does not require or even allow consideration of costs; EPA's flawed and inappropriately limited economic analysis; EPA's failure to consider costs to small businesses; and the failure to explain how the rule would result in measurable protections to the public health and welfare or the environment. Without addressing these issues, the rule would be an invalid exercise of the agency's discretion and run contrary to administrative law.

The Coalition urges EPA to withdraw this proposed rule and use its existing authorities that are more appropriate for addressing any risks are that presented by PFOA and PFOS in the environment.

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I. Introduction

The U.S. Chamber of Commerce Coalition of Companies and Trade Associations (the Coalition) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA's) precedent-setting proposed rule[1] in which EPA proposes to define and exercise its authority for the first time under Section 102(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), also known as the Superfund statute, to designate the following substances as "hazardous substances:" perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers (hereinafter referred to as the "proposed rule" or "proposal"). This proposed rule is part of EPA's overall whole-of-government approach to addressing per- and polyfluoroalkyl substances (PFAS) as outlined in its 2021-2024 PFAS Strategic Roadmap.[2]

The Coalition represents downstream product manufacturers and users of PFOA and/or PFOS products, previous manufacturers and processors, and businesses in other areas of the value chain across the broad economy potentially impacted by the proposal.[3] The Coalition is composed of a wide cross-section of trade associations and industries, including aerospace, automotive, construction, electronics, energy, mining, health care, telecommunications, and textiles, and other community stakeholders, including first responder services, water and wastewater utilities, and waste management facilities. The Coalition also represents other businesses who could potentially be subject to CERCLA liability for PFOA and PFOS. The U.S. Chamber of Commerce is the largest business trade association in the world, representing more than 3 million companies of all sizes and sectors.

While EPA, in proposing the rule, has attempted to evaluate the potential impacts of the proposal, it has fallen short in this task. Among other things, EPA has failed altogether to assess the larger legal, economic, operational, and practical consequences looming from the proposed rule—that CERCLA's strict liability and cost recovery scheme would apply to potentially responsible businesses and landowners, including public entities, for any site in the country containing any level of PFOA and PFOS, which are some of the most pervasive contaminants known today.

The Coalition identified significant uncertainties[4] related to the proposal that would make implementation of, let alone commenting on, this proposed rule challenging.

EPA has ample existing authority to protect the public health, welfare, and the environment from potential risks posed by legacy PFOA and PFOS under current law, yet it has proposed to expand the use of CERCLA as an ill-suited regulatory tool to address challenges presented by PFOA and PFOS. This proposed reliance on EPA's CERCLA authorities is unlikely to accomplish EPA's stated goal of reducing exposures to PFOA and PFOS and

[1] 87 Fed. Reg. 54,415 (Sept. 6, 2022).
[2] EPA, PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024.
[3] Throughout these comments, when we refer to PFOA and PFOS, all references are meant to also include all their salts and their branched and linear structural isomers. This is consistent with EPA's approach in the proposed rule.
[4] *See* U.S. Chamber Coalition letter to Michael. S. Regan, EPA Administrator (Oct. 18, 2022) submitted to regulations.gov docket EPA–HQ–OLEM–2019-0341 (Nov. 7, 2002) tracking number la6-wbef-8e82.

accelerating cleanups without causing significant unintended consequences to the economy and chemical supply chain. Designating PFOA and PFOS as hazardous substances potentially would bring millions of new innocent landowners around the country under CERCLA jurisdiction and prompt a reopening of potentially a myriad of Superfund sites. Risks to the public health, welfare, and the environment potentially would increase caused by a stalled and disrupted federal site cleanup process, and a new wave of CERCLA litigation could be unleashed, not only between site owners and EPA, but among public and private potentially responsible parties (PRPs) attempting to allocate costs for cleanup. The proposed rule wholly ignores these significant consequences, with EPA maintaining that the only direct impact of the rule is limited to additional reporting of releases. That myopic approach is inadequate and legally flawed.

A CERCLA hazardous substance designation is the wrong regulatory tool to efficiently and effectively address sites that may contain PFOA and PFOS. If this rule is finalized as proposed, EPA would claim for itself the ability to activate authorities aimed at recovering its site cleanup costs and issuing orders compelling private parties to perform cleanup activities. Facilities would also be required to report to EPA on PFOA and PFOS releases that meet or exceed the proposed reportable quantity. EPA asserts that this will allow it to obtain information regarding the location and extent of releases of these substances.

In addition, the proposed rule fails to adequately articulate why PFOA and PFOS meet CERCLA Section 102(a)'s standard for designation as a hazardous substance, or even clearly describe what that standard is. EPA's stated rationale for proposing to designate PFOA and PFOS as hazardous substances does not include information about the level of risk to humans or the environment from exposures to PFOA and PFOS at or stemming from contaminated sites. In fact, EPA repeatedly claims that it is unable to fully assess the potential impacts of the proposed rule because of the uncertainties related to the scope and extent of sites that may have PFOA and PFOS, what cleanup standards are appropriate for remedial activities, and what technologies for responding to contamination should be used.[5]

EPA does not provide information about what potential risk it is trying to mitigate using its CERCLA authorities. In its approach EPA fails to factor in whether its authorities under CERCLA can appropriately address the exposures it believes warrant a federal response. EPA's flawed analysis seems to completely decouple its decision to list a substance as "hazardous" from the Superfund enforcement process that inevitably results from such a designation. EPA must recognize that the hazardous substance listing process and the implementation of CERCLA cleanup activities are inherently linked. Therefore, in designating hazardous substances, EPA must support its decision with data that there is risk to humans or the environment from PFOA and PFOS exposures from contaminated sites.

EPA must also consider the cost impacts from potential site cleanup enforcement. EPA tried to avoid this analysis by claiming that it can exercise enforcement discretion later in the process to factor in the financial means of candidate PRPs. By disregarding the significant costs that could be incurred by businesses pulled into Superfund cost recovery settlements (under the

[5] *See* EPA, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) as Hazardous Substances* (August 2022) at 12, https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0034.

guise that these are "indirect costs") and the impact of this action on associated property values, EPA demonstrates that it is viewing a hazardous substance designation separately from the overall CERCLA liability structure. EPA also justifies its failure to engage in this analysis by claiming that there are insufficient data and too many uncertainties to determine how many sites will be impacted by the proposed designation. As we discuss below, EPA's arguments do not justify these unprecedented regulatory actions, and its approach is inconsistent with CERCLA and with CERCLA's intended purposes.

The White House Office of Management and Budget (OMB) has designated the proposed rule as economically significant,[6] requiring the agency to prepare a regulatory cost-benefit analysis consistent with Executive Orders (EOs) 12866 and 13563. EPA apparently refuses to perform a complete Regulatory Impact Analysis (RIA) considering site cleanup costs.[7] It has also failed to demonstrate in the proposed rule that the benefits of the proposed listing of PFOA and PFOS as hazardous substances outweighs the potential costs associated with site remediation.

The Coalition urges EPA to withdraw this proposed rule and to use its existing authorities that are more appropriate for addressing PFAS exposures of concern. The use of existing authorities would maximize EPA's intended regulatory goals without creating unintended consequences across various industries. If EPA will not withdraw the rule, the Coalition recommends, at a minimum, that it take the following steps before continuing further with the rulemaking:

1. Consistent with its obligation under Section 102(a), assess the potential site cleanup costs (including costs associated with related investigations and litigation) to PRPs, as these are not "indirect costs" but are direct costs (with no intervening actors or mechanisms) stemming from liability imposed from the designations of PFOA and PFOS as hazardous substances;

2. Perform an RIA and issue a supplemental proposal once the RIA is completed that adequately considers the full costs of a hazardous substance designation, as required by EO 12866. This will allow regulated entities to have a fair opportunity to understand and comment on the potentially significant consequences of this precedent-setting rulemaking;

3. Engage with the Small Business Administration Office of Advocacy to assess the costs that the proposed rule would cause small entities to incur, including the completion of a regulatory flexibility analysis and a small business advocacy review panel to provide comments on the rulemaking;

[6] "Economically significant" rules are those expected to impose costs of $100 million or more annually.
[7] EPA's September 7, 2022, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as Hazardous Substances* describes many "uncertainties" regarding indirect impacts of the rule, including the number of potential sites affected, cleanup standards, cleanup technologies, and response activities. However, EPA has refused to develop a full RIA that would fully address impacts to the economy, consistent with OMB Circular A-4 and EO's 12866 and 13563.

4. Satisfy EPA's obligations under the Unfunded Mandate Reform Act (UMRA);

5. Explain why existing statutory authorities are insufficient to accomplish EPA's and relevant industries' common cleanup goals for PFOA and PFOS;

6. Provide a sufficient justification for its interpretation of its authority under Section 102(a) to designate hazardous substances that "may present a substantial danger" to the public health and welfare and the environment that is consistent with CERCLA and its purposes; and

7. Provide a sufficient explanation for why PFOA and PFOS, including their salts and structural isomers, meet this substantial danger standard for their exposures to humans and the environment. Additionally, EPA must explain how CERCLA, which is intended to be used for site remediation and does not address broader issues concerning the widespread presence of substances, is the appropriate tool to address these cleanups.

II. The Coalition Supports Accelerating the Responsible Cleanup and Remediation of PFOA and PFOS

While we oppose this unnecessary rulemaking, the business community continues to support accelerating cleanups using existing tools to address the challenges presented by PFOA and PFOS to public health and the environment in communities across the United States. Businesses are actively collaborating with federal agencies and local and state government stakeholders to ensure an effective and balanced approach to addressing PFOA- and PFOS-related concerns based on the best science and appropriate consideration of risk. PFOA and PFOS remediation is widely supported by businesses and communities, and more investment and research, some of which is already underway, is necessary to optimize cleanup processes and identify suitable and effective remediation, disposal, and destruction technologies. Ongoing PFAS remediation research can lead to more targeted approaches with smaller environmental footprints. As discussed below, EPA has other existing authorities that are better equipped than CERCLA to address PFOA and PFOS exposures. The public would be better served if EPA focused its resources on these other authorities.

III. Using CERCLA Section 102(a) as the Mechanism to Address PFOA and PFOS in the Environment Raises Multiple Policy Concerns and Will Slow the Responsible Cleanup and Remediation of PFOA and PFOS

A. CERCLA Section 102(a) Is Not an Appropriate Tool to Address the Challenges of Cleaning Up PFOA and PFOS

A significant problem with the proposed listing of PFOA and PFOS as CERCLA hazardous substances is that they are believed to be widespread, but the specific locations and concentrations are not known. CERCLA is one of the broadest liability statutes in federal law. It was not enacted, nor has it evolved, to address substances that EPA claims are so widespread that they are found in most water bodies, typically at very low levels. No amount of EPA enforcement discretion is available to cure CERCLA's expansive definitions and strict liability scheme. Instead of accelerating cleanups, the proposed hazardous substance designation will

result in cleanup delays and extensive litigation and substantial transaction costs, costing American businesses, the communities where they operate, and the federal government tremendous time and resources. CERCLA's blunt liability scheme is an ill-suited solution in this instance, particularly when far more precise legal tools are readily available. If existing data suggest that PFOA and PFOS are widely present at levels of concern throughout the country, EPA must consider whether subjecting millions of new sites to CERCLA is the best policy approach in light of CERCLA's broad legal liability for PRPs, as well as the increasing scarcity of water resources in the U.S. Declaring scarce water resources "contaminated" by a "hazardous" yet ubiquitous chemical runs counter to the science-driven need to protect human health and the environment.

1. CERCLA Coverage Will Institute a Liability Regime That EPA Cannot Effectively Tailor to Address the Unique Challenges of PFOA and PFOS

The strict, joint-and-several liability scheme created under CERCLA renders the statute unable to be properly tailored to effectively address the unique challenges of highly pervasive substances such as PFOA and PFOS. CERCLA was passed by Congress in 1980 as a drastic remedy to address emergency situations, and, unlike all the other major federal environmental laws that came before it, CERCLA was a liability, as opposed to a regulatory, statute.

Establishing liability under CERCLA requires only a showing that: (1) there has been a release or threatened release of a hazardous substance (2) at a facility, (3) causing the incurrence of response costs, and (4) that a party is among the four classes of potentially responsible parties (PRPs) under Section 107(a) of CERCLA.[8] Specifically, CERCLA imposes liability, regardless of fault, on the following four classes of PRPs (subject to the limited defenses set forth in Section 107(b)):

1) the owner and operator of a vessel or a facility,[9]

2) any person who at the time of disposal of any hazardous substance owned or operated any facility at which such hazardous substances were disposed of,

3) any person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances . . . at any facility . . ., and

4) any person who accepts or accepted any hazardous substances for transport to disposal or treatment facilities, incineration vessels or sites selected by such person, from which there is a release,[10] or a threatened

[8] 42 U.S.C. § 9607.
[9] The term "facility" is defined in part as "any site or area where a hazardous substance has been deposited, stored, disposed of, or placed, or otherwise come to be located." CERCLA § 101(9); 42 U.S.C. § 9601(9).
[10] CERCLA Section 101(22) defines "release" to mean "any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the

> release which causes the incurrence of response costs, of a hazardous substance . . ..[11]

CERCLA authorizes EPA to take action itself to address contamination or to settle with or require PRPs to do so. Alternatively, private parties may conduct CERCLA response actions under CERCLA preemptively, without any prodding or compulsion by the government to do so.

Thus, it is conceivable that a PRP might voluntarily engage in response actions to deal with on-site contamination, and, if such actions were conducted consistent with the National Contingency Plan (NCP), the PRP could take advantage of some of the same cost recovery authorities that are typically associated with EPA. Under Section 107(a) of CERCLA, EPA (or the preemptive PRP taking on remediation) can seek to recover all costs it incurs conducting response actions addressing the release or threatened release of a hazardous substance from any PRP. Costs for response actions that are found not inconsistent with (for EPA or a state) or consistent with (for private parties) the NCP are potentially recoverable.

Based on CERCLA's strict, retroactive, and generally joint and several liability scheme (discussed below), CERCLA enforcement by any party represents a potentially major environmental and financial exposure for businesses, government, and individuals. A defining distinction of CERCLA is that enforcement is carried out by both the federal government and private parties, based on the latter's ability to directly file private contribution and cost recovery actions. Regardless of the party instituting it, CERCLA enforcement is expensive and often counter-productive. Notably, PRPs "faced with disproportionate liability litigate tenaciously, prolonging or postponing remediation of contaminated sites, and increasing dramatically the costs of remediation."[12]

As a result of EPA's enforcement-first approach, its enforcement efforts for PFOA and PFOS are expected to occur throughout the CERCLA response action process. [13] Notably, upon PFOA and PFOS being listed, EPA's powerful Section 106 and 107 enforcement authorities would automatically be activated. These authorities are available only for releases or threatened releases of hazardous substances, but not for "pollutants or contaminants."[14] Although EPA can undertake response actions under Section 104 of CERCLA for pollutants or contaminants "which may present an imminent and substantial danger to the public health or welfare," EPA does not seek to recover costs incurred in undertaking those actions, nor can it order parties to undertake them. A CERCLA hazardous substance designation dramatically changes the approach to response and cost recovery for PFOA and PFOS.

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abandonment or discarding of barrels, containers, and other closed receptacles containing any hazardous substance or pollutant or contaminant)." 42 U.S.C. § 9601(22).

[11] 42 U.S.C. § 9607(a).

[12] *United States v. A & N Cleaners & Launderers, Inc.*, 854 F. Supp. 229, 241 (S.D.N.Y. 1994).

[13] *See* 87 Fed. Reg. at 54,436-37 (discussing 16 cases where EPA has addressed PFAS "using a variety of enforcement tools under the [SDWA], TSCA, RCRA, and CERCLA, as well as overseeing PFAS response actions by Federal agencies at National Priorities List sites.").

[14] *See* CERCLA §§ 106(a), 107(a), 42 U.S.C. §§ 9606(a), 9607(a) (discusses "hazardous substance," omits reference to "pollutant or contaminant"); *compare* CERCLA § 104(a), 42 U.S.C. § 9604(a) (providing for removal and remedial action for a "hazardous substance, pollutant, or contaminant" that meets the statutory criteria).

a. CERCLA Liability Is Strict and Typically Joint and Several

CERCLA imposes strict liability, meaning that a party – no matter how small – can be held liable, regardless of whether the conduct of that person was negligent, consistent with best practices, or reflected an intent to minimize or eliminate contamination. A party's potential liability under CERCLA generally is joint and several, meaning that any one PRP may be held liable under Section 107(a) for the entire cost of a site cleanup, regardless of the number of other PRPs that contributed to the site's contamination or the share of hazardous substances that each individual PRP contributed, unless that PRP can establish that the harm at a site is divisible.[15]

However, "[n]ot all harms are capable of apportionment … and CERCLA defendants seeking to avoid joint and several liability bear the burden of proving that a reasonable basis for apportionment exists."[16] And, "[w]hen two or more causes produce a single, indivisible harm, 'courts have refused to make an arbitrary apportionment for its own sake, and each of the causes is charged with responsibility for the entire harm.'"[17] The "[e]vidence supporting divisibility must be concrete and specific,"[18] and circumstantial evidence coupled with a "chain of possible inferences" will rarely support an apportionment.[19] Accordingly, "courts lacking a reasonable basis for dividing causation should avoid apportionment altogether by imposing joint and several liability."[20] Case law reflects the heavy burden that PRPs face when attempting to avoid joint and several liability under CERCLA, and proving divisibility continues to be an elusive undertaking.[21] At sites where hazardous substances are commingled, proving divisibility has been nearly impossible.[22] Further, when candidate PRPs go out of business, file for bankruptcy, or become otherwise incapable of reimbursing for past contributions to a PFOA or PFOS CERCLA site (such as is often the case for small businesses), remaining PRPs are statutorily left with the full burden of an overestimated share of the liability, even if they were minor contributors.

In stark contrast to CERCLA's expansive liability scheme, the statute contains only a small set of limited defenses. These defenses are narrow and "generally difficult to satisfy."[23] The statutory defenses to liability under Section 107(b) of CERCLA require the release or threatened release of a hazardous substance to have been caused solely by:

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[15] *See Burlington Northern and Santa Fe Ry. Co. v. United States*, 556 U.S. 599 (2009).
[16] *Burlington Northern,* 556 U.S. at 614.
[17] *Id.*
[18] *See United States v. Hercules, Inc*., 247 F.3d 706, 718 (8th Cir. 2001).
[19] *See Chem-Nuclear Systems, Inc. v. Bush*, 292 F.3d 254, 260-61 (D.C. Cir. 2002).
[20] *United States v. Township of Brighton*, 153 F.3d 307, 319 (6th Cir. 1998)).
[21] *See e.g., United States v. NCR Corp.*, 688 F.3d 833, 838 (7th Cir. 2012); *see also Ashley II of Charleston, LLC v. PCS Nitrogen, Inc.,* 791 F. Supp. 2d 431, 482 (D.S.C. 2011).
[22] *See e.g., Ashley II of Charleston, LLC*, 791 F. Supp. 2d at 482 (D.S.C. 2011) (proving divisibility of harm at a CERCLA site in accordance with the Restatement approach can be difficult because of "the commingling of wastes, the migration of contamination over time, and other complex fact patterns") *aff'd,* 714 F.3d 161 (4th Cir. 2013); *United States v. Davis*, 261 F.3d 1, 43 (1st Cir. 2001) (upholding lower court finding that that '"[s]ince the hazardous waste deposited at the Davis site has been commingled into an essentially homogeneous 'witches' brew,' it is impossible to allocate discrete portions of the cleanup cost to any particular type of waste or any particular party"').
[23] *Acushnet Co. v. Mohasco Corp.,* 191 F.3d 69, 74 (1st Cir. 1999).

1) an act of God;

2) an act of war;

3) an act or omission of a third party other than an employee or agent of the defendant, or than one whose act or omission occurs in connection with a contractual relationship, existing directly or indirectly, with the defendant . . . , if the defendant establishes by a preponderance of the evidence that (a) he exercised due care with respect to the hazardous substance concerned, taking into consideration the characteristics of such hazardous substance, in light of all relevant facts and circumstances, and (b) he took precautions against foreseeable acts or omissions of any such third party and the consequences that could foreseeably result from such acts or omissions; or

4) any combination of the foregoing paragraphs.[24]

CERCLA also contains exemptions and exclusions from certain liabilities for qualifying de micromis persons,[25] municipal solid waste generators,[26] applications of registered pesticides,[27] contiguous property owners,[28] bona fide prospective purchasers,[29] service station dealers sending used oil for recycling,[30] lenders under certain circumstances,[31] and state and local governments under certain circumstances.[32]

The existence of the Section 107(b) defenses has led courts to conclude that a CERCLA plaintiff need not establish a direct causal connection between the defendant's hazardous substances and the release or the plaintiff's incurrence of response costs.[33] Courts have also concluded that, because CERCLA establishes no minimum threshold to create liability, trace levels of a hazardous substance (down to a single molecule) found on or to have been released from a facility is enough to establish PRP status.[34] In the context of PFOA and PFOS, the likely scenario is that the vast majority of cases will involve very low or almost non-detectable amounts.

[24] 42 U.S.C. § 9607(b).
[25] 42 U.S.C. § 9607(o).
[26] 42 U.S.C. § 9607(p).
[27] 42 U.S.C. § 9607(i).
[28] 42 U.S.C. § 9607(q).
[29] 42 U.S.C. §§ 9601(40), 9607(r).
[30] 42 U.S.C. § 9614(c).
[31] 42 U.S.C. § 9601(20)(F).
[32] 42 U.S.C. § 9601(20)(D).
[33] *See U.S. v. Alcan Aluminum Corp.,* 964 F.2d 252 (3d Cir. 1992) (noting that requiring a showing of causation would render the defenses in CERCLA Section 107(b) superfluous and saddle plaintiffs with the difficult burden of tracing fault in multi-defendant cases).
[34] *See, e.g., A & W Smelter & Refiners v. Clinton*, 146 F.3d 1107, 1110 (9th Cir. 1989).

2. This Rule Could Unnecessarily Subject Numerous New and Reopened Sites to Liability

CERCLA's liability scheme could result in drawing in thousands of new and reopened sites. However, EPA does not provide information on the potential scope of the number of sites that would be created or reopened with its proposed listing of PFOA and PFOS as hazardous substances. The proposed rule suggests that Superfund cleanup and response decisions are difficult to quantify due to numerous uncertainties in the scope of PFOA and PFOS site contamination. EPA lists the following uncertainties:

> (1) How many sites have PFOA or PFOS contamination at a level that warrants a cleanup action; (2) the extent and type of PFOA and PFOS contamination at/near sites; (3) the extent and type of other contamination at/near sites; (4) the incremental cost of assessing and remediating the PFOA and/or PFOS contamination at/near these sites; and (5) the cleanup level required for these substances.[35]

EPA's economic assessment of the proposed rule also details significant uncertainty about the extent of existing PFOA and PFOS use and contamination, evolving assessment and response technologies, and the health science.[36] EPA identifies entities that have historically used PFOA and PFOS such as fire departments, military installations, and airports, but it notes that "the specific sites contaminated with these chemicals is unknown."[37] EPA also discusses the significant uncertainty surrounding additional and future impacts associated with development of and changes in federal cleanup standards to reflect changes to toxicity values for PFOA and PFOS.[38]

In pointing to these uncertainties, EPA has not attempted to assess existing data from available sources on PFOA and PFOS exposures from sites to provide stakeholders with information on the scope of the potential number of sites that would be created or reopened by designating PFOA and PFOS as hazardous substances. EPA's use of CERCLA authorities to address these exposures without providing stakeholders with this critical information would cause not only significant costs for affected businesses and property owners, but also uncertainties concerning how to predict which sites will be impacted, what kinds of exposures would trigger remediation, and how to remediate a site properly. Thus, the very stakeholder community that would likely be captured in some capacity under this proposal is not provided the necessary tools from the agency to properly assess its impact and related costs. EPA cannot lawfully finalize this rule without providing a basic understanding and explanation of the scope and scale of sites that will need to be investigated and potentially covered by this action (as discussed below).

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[35] 87 Fed. Reg. at 54,423.
[36] *See* EPA, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) as Hazardous Substances* (Aug. 2022) at 29, https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0034.
[37] *Id*. at 30 and Chamber non-federal cleanup cost modeling information.
[38] *Id*. at 31.

There are available data on potential PFOA and PFOS exposures that EPA could have utilized in understanding the scope of this rulemaking in terms of potential number of impacted sites. First, one of the best sources of information on nationwide occurrence of PFAS (including PFOA and PFOS) is in the analytical results from EPA's Third Unregulated Contaminant Monitoring Rule (UCMR3), carried out between 2013-2015. As part of the UCMR program, drinking water suppliers must collect finished drinking water samples and submit them for analysis for a limited number of unregulated contaminants. Due in part to its additional costs, UCMR3 testing was mandatory only for public water systems (PWSs) serving more than 10,000 people and was conducted on 800 representative PWSs serving 10,000 or fewer people.[39] Due to technical difficulties in reliably detecting low contaminant concentrations at the time, the reporting limits for PFOA and PFOS under UCMR3 were 20 and 40 ppt, respectively.[40] The data from the UCMR3 testing have been bolstered by additional testing, either voluntarily by PWSs or as required piecemeal by state water agencies. Although these data are valuable for understanding the nationwide occurrence of PFOA and PFOS, the true number of locations with levels of PFOA and PFOS detectable using more sensitive methods remains unknown.

Second, Congress included a provision in the FY2020 National Defense Authorization Act[41] requiring that sampling under the Fifth Unregulated Contaminant Monitoring Rule (UCMR5) should include 29 members of the class of compounds known as PFAS. EPA established a minimum reporting level (MRL) of 4 ppt for PFOA and PFOS.[42] This means that, when the testing and analysis under UCMR5 are complete, EPA will have nationwide data on PFOA and PFOS occurrence for PWSs that underwent UCMR5 testing and were found to have 4 ppt or more PFOA and/or PFOS in their drinking water.

Third, the U.S. Department of Defense (DoD) has undertaken assessments of military installations and National Guard facilities for PFAS (including PFOA and PFOS) use and releases. This is part of DoD's efforts to proactively address PFOA and PFOS under existing authorities and (consistent with CERCLA) to investigate potential releases of these chemicals and determine if cleanup actions are warranted. DoD has identified 700 installations where it believes PFAS may have been used or potentially released.[43] DoD expects to complete its assessments for all these installations by FY 2023. In its assessments, DoD conducts sampling of drinking water and publicly discloses PFAS sampling results[44] in accordance with the

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[39] EPA, "The Third Unregulated Contaminant Monitoring Rule (UCMR 3); Searching for Emerging Contaminants in Drinking Water" (May 2012), available at https://www.epa.gov/sites/default/files/2015-10/documents/ucmr3_factsheet_general.pdf.

[40] EPA, "The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Fact Sheet for Assessment Monitoring (List 1 Contaminants)" (May 2016), available at https://www.epa.gov/sites/default/files/2016-05/documents/ucmr3-factsheet-list1.pdf.

[41] Pub. Law No. 116-92.

[42] 86 Fed. Reg. 73,131 (Dec. 27, 2021).

[43] David Vergun, "DoD's PFAS Public Outreach Focuses on Cleanup Progress, PFAS-Free Firefighting Solutions, Officials Say," U.S. Department of Defense News (Oct. 21, 2021), available at https://www.defense.gov/News/News-Stories/Article/Article/2818535/dods-pfas-public-outreach-focuses-on-cleanup-progress-pfas-free-firefighting-so/. *See also* DoD, PFAS Progress as of March 31, 2022, https://media.defense.gov/2022/Jun/06/2003012511/-1/-1/1/PFAS-PROGRESS-AS-OF-MARCH-31-2022.PDF.

[44] Deputy Assistant Secretary of Defense for Construction, Memorandum for Assistant Secretary of the Army (Installations, Energy and Environment), "Public Disclosure of Department of Defense Testing Results of Per-and-Polyfluoroalkyl Substances in Drinking Water Within a Covered Area" (Apr. 26, 2022), available at

requirements of Section 345 of the 2022 National Defense Authorization Act (NDAA). DoD's sampling results can be found based on installation site (organized by state) here. These extensive sampling data are a potential source that EPA should have considered to assess the potential scope of PFAS site contamination.

Fourth, states across the country have collected PFAS testing data for drinking water and have provided the results publicly. For example, the Minnesota Department of Health released a dashboard showing PFAS (including PFOA and PFOS) monitoring results from community public water systems in June of 2022.[45] This statewide testing effort completed an assessment of over 400 public systems in the state that serve about 75 percent of Minnesotans who get their drinking water from these systems. The State of Michigan has performed a statewide survey of PFAS in public water utilities and has published sampling results.[46] The State of Illinois is conducting a statewide investigation into the prevalence of PFAS in finished water at 1,456 entry points to the distribution system representing 1,749 community water supplies across Illinois.[47] The state has released a PFAS Investigation Interactive Dashboard and Map[48] that displays sampling results by public water supplier. The State of South Carolina has released PFOA and PFOS sampling results for community drinking water systems based on 113 community water systems sampled.[49] Several states have similar programs and sampling data that are publicly available to inform EPA's deliberations concerning which areas of the country have, or are likely to have, PFOA and PFOS exposures from drinking water sources.

So, while robust collection of relevant data has already occurred and is continuing due to many efforts, EPA has not tried to connect how the existing (and soon to be collected) relevant data inform potential future CERCLA actions and has not adequately considered these data in proposing this rule.

3. EPA Has Not Identified Adequate and Cost-Effective Treatment or Destruction Methods for PFOA and PFOS

Additionally, PFOA and PFOS may not be addressed using traditional methods, and EPA has not clarified in the proposed rule existing and developing treatment or destruction methods at scale. EPA's own Office of Research and Development (ORD) has been developing data on the treatment of PFAS for various media[50] including drinking water, remediation media (such as water and soils), waste streams, and residual streams from above treatments. ORD has

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https://media.defense.gov/2022/Apr/27/2002985404/-1/-1/0/MEMO-PUBLIC-DISCLOSURE-POLICY-SECN-345-OF-FY22-NDAA.PDF.

[45] *See* Minnesota Department of Health, PFAS Testing of Minnesota Community Water Systems, https://mdh.maps.arcgis.com/apps/MapSeries/index.html?appid=63515695237f425ea7120d1aac1fd09a.

[46] *See* State of Michigan, Statewide PFAS Survey of Public Water Supplies, https://www.michigan.gov/pfasresponse/drinking-water/statewide-survey.

[47] *See* Illinois Environmental Protection Agency, PFAS Statewide Investigation Network: Community Water Supply Sampling, https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-statewide-investigation-network.aspx.

[48] *Id.*

[49] *See* South Carolina Department of Health and Environmental Control, "PFAS Sampling Results," https://scdhec.gov/BOW/pfas-sampling-results.

[50] *See* EPA's Office of Research and Development, presentation "Overview: PFAS Treatment and Destruction Research" (Sep. 29-30, 2021), https://www.epa.gov/system/files/documents/2021-09/cq3_treatment-and-destruction-overview_sayles.pdf.

researched the treatment and destruction technologies for PFAS (including PFOA and PFOS) for water treatment processes and their residual streams.[51] It has also looked into water treatment technologies and identified effective treatment technologies for PFOA and PFOS in drinking water, such as anion exchange resin, granular activated carbon (GAC), and membrane separation (reverse osmosis (RO) or nanofiltration).[52] Although EPA has previously indicated that PFAS found in spent media can be regenerated, landfilled, or incinerated with unknown quantities of PFAS bound to spent media, EPA has failed to explain what impact designating PFOA and PFOS as CERCLA hazardous substances might have on these critical end-of-life issues.[53] Complicating matters are the ongoing hazardous waste incinerator backlog[54] and landfill capacity challenges[55] in various regions of the country.

EPA has also not provided any treatment or destruction methods for RO concentrate streams or regenerant solutions, whether containing PFOA and PFOS or not.[56] For wastewater treatment, EPA has stated in the past that the fate of PFAS through wastewater treatment plants is not well characterized, with pretreatment practices likely proving to be more effective than central treatment. EPA is also researching thermal treatments of PFAS, including wastewater sludge incineration, pyrolysis of biosolids, GAC reactivation, and cement kiln incineration; and EPA is researching non-thermal destruction methods such as supercritical water oxidation (SCWO) and electrochemical oxidation.

As this research continues, EPA should refrain from designating PFOA and PFOS as hazardous substances under CERCLA until it can identify the treatment and destruction methods that are appropriate to use in properly remediating PFOA and PFOS on contaminated sites for purposes of CERCLA site cleanup.

4. EPA Has Not Addressed What Cleanup Targets Are Foreseeable

EPA's proposal fails to even discuss what specific targets or limits for either contaminant that, if present at a given location, would trigger remedial activities to remove them. While there is scientific uncertainty regarding the extent and significance of the hazards posed by PFOA and PFOS in different media,[57] EPA's choice to omit any considerations about actual site cleanup as

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[51] *See* Speth, T., P. Jordan, M. Krause, Jonathan D. Krug, T. Lee, M. Mills, M. Nadagouda, P. Potter, J. Ryan, E. Sahle-Demessie, E. Shields, E. Thoma, T. Tolaymat, and Rick Wilkin, EPA's Office of Research and Development, presentation "PFAS Destruction: Overview on EPA-ORD's Recent Activities" (Aug. 4, 2022), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=545152&Lab=CESER.
[52] *Id*.
[53] *Id*.
[54] *See* EPA, "Regulatory Options for Addressing the Temporary Backlog of Containerized Hazardous Waste Needing Incineration" (Aug. 10, 2021), *available at* https://rcrapublic.epa.gov/files/14939.pdf; EPA, *Hazardous Waste Generators*, (last visited Oct. 27, 2022), *at* https://www.epa.gov/hwgenerators (noting as of August 2022 that the memorandum "continues to be in effect").
[55] *See* MSW Consultants, "Massachusetts Materials Management Capacity Study," (Feb. 11, 2019), available at https://www.mass.gov/doc/massachusetts-materials-management-capacity-study-february-2019/download.
[56] *Id*.
[57] *See* Interstate Technology Regulatory Council, "PFAS Technical and Regulatory Guidance Document," §§ 10.1.2 ("PFAS are often detected at low levels in samples from locations without any apparent or nearby sources. In those instances, there may be a need to evaluate the site-specific anthropogenic ambient background concentrations and determine their contribution to PFAS concentrations in environmental media at a site."), 10.4.3.3 ("When evaluating

"indirect" and outside the scope of the rulemaking leaves property owners and other regulated parties without any way to assess, even in general terms, what EPA might choose to demand in the future for PFOA and PFOS. Accordingly, commenters are left with no reasonable way to ascertain the costs and impacts of this proposed rule.

When establishing the degree of cleanup required for a hazardous substance, Section 121 of CERCLA requires consideration of several applicable or relevant and appropriate standards, requirements, criteria, and limitations under TSCA, SDWA, the CAA, the CWA, the Ocean Dumping Act, RCRA, and certain state environmental and facility siting laws that are more stringent than their federal counterparts.[58] The statute also indicates that, for contaminants subject to SDWA primary drinking water regulations, absent EPA setting a different level, remedial actions could be required to attain the Maximum Contaminant Level Goal (MCLG).[59] EPA has yet to announce proposed Maximum Contaminant Levels (MCLs) or MCLGs for PFOA and PFOS, but the proposal was recently submitted to OMB for interagency review and is expected relatively soon.[60] Once those MCLs and MCLGs have been finalized, EPA should be able to provide clarity, in a supplemental notice of proposed rulemaking, on what the cleanup standards might be or what costs will be incurred in reaching them. This consideration alone provides a compelling reason for EPA to withdraw the proposal and/or delay finalization of this rulemaking until the national primary drinking water regulation for PFOA and PFOS is complete.

For now, all that EPA has made available for consideration is its interim health advisories for PFOA and PFOS, but it has provided no information on how those levels might relate to cleanup target levels at CERCLA sites.[61] While EPA states that these interim health advisories are not legally enforceable, they have real effect now; among other things, they represent EPA's current view on potential health risks associated with exposure to these substances, which would likely influence future cleanup standards.[62]

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fate and transport of PFAS in a groundwater plume, including time frame for remediation of PFAS, matrix diffusion may be an important process to consider…. As such, the potential impacts of diffusion on PFAS persistence in natural soils are a topic of ongoing research. Diffusion coefficients for PFAS are generally uncertain but are in development using measurements and models…."), 10.5 ("Source identification can be one of the challenges of PFAS investigations. The field of PFAS forensics is in its nascent stages. Researchers are still conducting studies to more fully understand the fate and transport of PFAS in the environment, and they continue to evaluate tools to investigate changes in PFAS composition for the purposes of source attribution. ") (internal citations omitted), *available at* https://pfas-1.itrcweb.org/10-site-characterization/).

[58] 42 U.S.C. § 9621(d)(2)(A) ("Such remedial action shall require a level or standard of control which at least attains Maximum Contaminant Level Goals established under the Safe Drinking Water Act [42 U.S.C. 300f et seq.] and water quality criteria established under section 304 or 303 of the Clean Water Act [33 U.S.C. 1314, 1313], where such goals or criteria are relevant and appropriate under the circumstances of the release or threatened release.")

[59] *Id.*

[60] EPA announced it anticipates finalizing the rule by end of 2023 to include a non-enforceable MCLG and an enforceable standard or MCL or Treatment Technique, https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.

[61] These interim health advisories have been challenged in federal court. See *ACC v. EPA*, No. 22-1177 (D.C. Cir. July 29, 2022).

[62] 87 Fed. Reg. 36,848 (June 21, 2022). Given EPA's position in litigation challenging other health advisories and its position in litigation over the PFOA and PFOS interim health advisories that the advisories are non-final agency actions, EPA may respond that, because its PFOA and PFOS health advisories explicitly state that they "should not

The trajectory for PFOA and PFOS health advisories has been increasingly more conservative since the West Virginia Department of Environmental Protection declared a risk-based human health protective screening level for PFOA of 150 parts per billion (ppb), equal to 150,000 ppt, in air, water, and soil in 2003.[63] In 2016, EPA announced a lifetime health advisory (HA) of 70 ppt for combined concentrations of PFOA and PFOS to provide the public, including the "most sensitive populations, with a margin of protection" from a lifetime of exposure to PFOA and PFOS from drinking water.[64] In June 2022, EPA issued revised "interim" health advisories for PFOA and PFOS at 0.004 and 0.020 ppt, equal to 4 and 20 parts per quadrillion (ppq).

If EPA's health advisory levels are an indicator of what future cleanup targets for PFOA and PFOS will be, then the levels could be extremely low. EPA's FAQ explains that "the health advisory levels for PFOA and PFOS are below the level of both detection. . ."[65]

If, based on current health advisories, EPA determines that, to be protective of public health and welfare and the environment, remedial activities at a site must continue until PFOA and PFOS can no longer be detected, that should be a factor for EPA to consider prior to finalization of this rulemaking as a potential foreseeable outcome. EPA should also describe potential scenarios for addressing the undetectable remainder of PFOA and PFOS at CERCLA sites, given that the health advisories refer to levels below detection. EPA should also address whether more sensitive detection methods developed in the future would trigger "reopener" provisions of settlement agreements for sites where remedial activities concluded prior to that technological capability.

While EPA has said that it would "weigh" hazards, environmental fate and transport, and the frequency, nature, and geographic scope of releases of the substances, EPA does not explain or indicate the level of contamination of PFOA and PFOS that "may present a substantial danger." Stakeholders are left with significant uncertainties because EPA has not even contemplated in this proposal what levels of PFOA and PFOS contamination warrant cleanup response. As discussed, EPA is still developing HALs for PFOA and PFOS and only recently issued interim health advisories for these substances in the parts per trillion level.[66] These interim health advisories are subject to legal challenges, including on the basis that they are not based on best available science.[67] EPA has yet to release for public comment its proposed rule to set

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be construed as legally enforceable Federal standards," they would not be a legally applicable "requirement, criteria, or limitation" that CERCLA Section 121(d)(2)(A) would require to be used to establish cleanup thresholds. We also note that EPA's position contradicts the World Health Organization's recent draft provisional drinking water guideline values for PFOA and PFOS, https://www.who.int/news/item/29-09-2022-rolling-revision-of-the-guidelines-for-drinking-water-quality.

[63] West Virginia Department of Environmental Protection, "Final Ammonium Perfluorooctanoate (C8) Assessment of Toxicity Team (CATT) Report" (Aug. 2002), available at https://dep.wv.gov/WWE/watershed/wqmonitoring/Documents/C-8/C-8_FINAL_CATT_REPORT_8-02.pdf.

[64] 81 Fed. Reg. 33,250 (May 25, 2016).

[65] "Questions and Answers: Drinking Water Health Advisories for PFOA, PFOS, GenX Chemicals and PFBS," U.S. EPA, available at: https://www.epa.gov/sdwa/questions-and-answers-drinking-water-health-advisories-pfoa-pfos-genx-chemicals-and-pfbs.

[66] 87 Fed. Reg. 36,848.

[67] See American Chemistry Council v. EPA, No. 22-1177 (D.C. Cir. 2022).

enforceable drinking water standards for PFOA and PFOS under the Safe Drinking Water Act.[68] EPA should finalize or revise this guidance according to the statutory deadlines before moving forward with this proposal. These interim proposals create significant regulatory uncertainty as to how EPA will set cleanup target levels at contaminated sites, particularly because the levels being contemplated are below the level of detection.

Until the science is improved, and applicable regulatory levels are finalized, stakeholders should not be required to guess at the range of potential levels of PFOA and PFOS that will be subject to assessment and remediation. EPA must complete a full RIA that incorporates reasonable assumptions for cleanup target levels, which is essential to understanding the true, direct, and foreseeable costs and impacts of this proposal.

Ultimately, this proposed rule and EPA's interim health advisories raise the specter of forcing site cleanup to levels beyond the detection ability of modern laboratory methods. This is a significant aspect of the problem of using CERCLA to address PFOA and PFOS that is not addressed by the proposed rule. In short, the normal CERCLA site assessment and remediation process does not provide the capacity to address the extraordinarily low levels of PFOA and PFOS that EPA has identified in the health advisories. If EPA has any persuasive rationale to the contrary, it must explain that in this rulemaking, not only to demonstrate that EPA understands the consequences of this action, but also to ensure that EPA's decision is rational and to comply with notice and comment requirements. Moreover, the Chamber also modeled the proposed treatment costs at various cleanup levels, including 4 ppt, and found that the closer levels are to zero, the costs rise significantly.

5. The Listing Would Put Essential "Passive Receiver" Sectors at Risk

Listing PFOA and PFOS as CERCLA hazardous substances would substantiate the fears and concerns of essential "passive receiver" sectors that neither manufacture nor use PFOA or PFOS, including the drinking water, wastewater utility, and solid waste sectors. These sectors provide essential public services to communities across the United States. Unfortunately, a hazardous substance designation would result in increased costs for these sectors by driving their customers, ratepayers, and stakeholders into an endless spiral of increasing costs and liability, at a particularly inopportune time of drought and water scarcity for a large part of the nation.

Although technologies for removing PFAS in liquids is still developing, the most common treatment method for removing PFOA and PFOS is filtration through granular activated carbon (GAC), which can be regenerated by releasing captured contaminants using thermal reactivation. Similarly, industrial-scale reverse osmosis/nanofiltration (RO) has been used effectively to remove PFOA and PFOS. However, even RO is only 90 percent effective[69], which does not eliminate all risk. With PFOA and PFOS being designated as CERCLA hazardous substances, concerns about aerial releases of PFOA and PFOS during the reactivation process

[68] This rulemaking is pending before OMB.
[69] *See* EPA website, Reducing PFAS in drinking water with treatment technologies, (Aug. 23, 2018). Available at https://www.epa.gov/sciencematters/reducing-pfas-drinking-water-treatment-technologies.

may lead to greater reliance on landfills to manage GAC, RO, and other media contaminated with PFOA and PFOS.

PWSs are already on the front lines dealing with PFOA and PFOS. Faced with public pressure to meet EPA's 70 ppt PFOA and PFOS health advisory from 2016, many PWSs spent millions of dollars to meet this unenforceable standard by installing treatment equipment that was recently rendered inadequate when EPA issued its interim PFOA and PFOS health advisories that moved the goalposts more than 1,000-fold lower than the current advisory level.

Wastewater utilities could face even greater threats of CERCLA liability if PFOA and PFOS are designated as CERCLA "hazardous substances." CERCLA provides limited exemptions for publicly owned treatment works (POTWs), which can become subject to liability under CERCLA if a hazardous substance is introduced into the sewer systems from industrial and sometimes residential customers. Although industrial inputs are generally required to have permits for any discharges to POTWs, such permits may not cover or account for unregulated contaminants like PFOA and PFOS. CERCLA provides limited exemptions for POTWs that dealt with hazardous substances sent to them by others before they were declared CERCLA hazardous substances (or perhaps before CERCLA itself was enacted). Municipalities in these circumstances may find themselves trapped for years in litigation, in which PRPs seek to work out how much each party owes for cleanup costs.

EPA's designation of PFOA and PFOS as hazardous substances under CERCLA also would have significant cost impacts on the solid waste sector, as well as broad unintended consequences on Administration priorities. Although EPA has recognized landfilling as one of the few effective options for managing and limiting PFAS in the environment,[70] this rulemaking would force the waste sector to reject certain waste streams containing PFOA and PFOS while increasing disposal costs for many wastes.

Landfills that rely on wastewater treatment plants for their discharge would need to undertake leachate pretreatment, significantly adding to the costs of landfill operation. The estimated capital cost to implement leachate pretreatment and PFAS treatment at a moderate-sized landfill (i.e., biological treatment of 30,000-40,000 gallons per day of leachate) to the extent necessary to minimize PFAS in leachate ranges from $2 million to $12 million, or potentially far more.[71] Included in this cost estimate is approximately $0.5 million to $1.5 million for PFAS removal technology, with additional costs anticipated for landfills where more stringent effluent levels are desired or mandated (e.g., Michigan). This does not include costs for PFAS residuals management, which is currently less well understood because most technologies have not been evaluated at full-scale. The combined *increased costs associated with PFAS management thus could total approximately $966 million to $8.187 billion per year for*

[70] See EPA, *Interim Guidance on the Destruction and Disposal of PFAS and Materials Containing PFAS* (Dec. 18, 2020), https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf.

[71] The standards that would govern a PFOA or PFOS cleanup action currently are unclear, complicated by a patchwork of state regulatory standards and EPA's interim drinking water health advisories for PFOA and PFOS. As such, the costs of PFAS treatment borne by landfills and their customers could far exceed these estimates.

municipal solid waste landfills alone. These costs typically cannot be absorbed by local governments with municipally operated landfills.

The resulting increased costs could curtail the ability of some facilities to continue operating, resulting in limited options for the long-term management of spent filters from PWSs and POTWs as well as impacted soils at DoD facilities. Moreover, because states have been restricting the availability of incineration and land application as viable disposal outlets, any impact to the landfilling of these materials could accelerate the looming challenges for biosolids management in the United States.[72] Customers and ratepayers ultimately would bear the burden of these cost increases, potentially resulting in disproportionate impacts on low-income households that rely on the affordability of services provided by the solid waste sector, leading to a "community pays" model of CERCLA, contradictory to the "polluter pays" structure that Congress originally intended.

Thus, designation of PFOA and PFOS as CERCLA hazardous substances could create significant challenges for passive receivers, the most obvious one being increased costs associated with handling wastes that contain PFOA and PFOS.

6. EPA Has Failed to Explain Why it Cannot Use its Existing Authority to Accomplish EPA's and Industries' Common Goal to Clean Up Sites

One of the key reasons why EPA has failed to establish the requisite need to designate PFOA and PFOS as CERCLA hazardous substances is that it has failed to explain why it cannot use its existing authority to adequately effectuate cleanups.

First of all, EPA has failed to explain why it could not take action under the less onerous standard of treating PFOA and PFOS as CERCLA "pollutants or contaminants."[73] EPA asserts that "CERCLA already provides significant authority to federal agencies to address PFOA and PFOS releases because these two chemicals are pollutants and contaminants."[74] CERCLA authorizes EPA cleanup of CERCLA "pollutants or contaminants," and EPA has used that authority to require their cleanup.

Before declaring PFOA and PFOS to be "hazardous substances" pursuant to CERCLA Section 102(a), EPA should establish whether they qualify as CERCLA "pollutants or contaminants" and, if so, should utilize the ample tools available in the statute to address them as such, such as CERCLA removal authority, for when "there is a release or substantial threat of

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[72] Maine, H.P. 1417 - L.D. 1911; Illinois, HB 3190; New York State, A10081.

[73] "The term 'pollutant or contaminant' shall include, but not be limited to, any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring." 42 U.S.C. § 9601(33).

[74] 87 Fed. Reg. at 54,420; *see also* 87 Fed. Reg. at 54,436 n.192 ("Where PFAS are commingled with CERCLA hazardous substances, EPA can require PRPs to address the PFAS. Additionally, CERCLA Section 120 federal facility agreements for federal facilities listed on the NPL require federal agencies to investigate and clean up hazardous substances, pollutants and contaminants which includes PFAS.").

release into the environment of any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare."[75] Additionally, PFOA and PFOS could be addressed under SDWA and RCRA authorities in a more targeted way, as EPA has done previously.

Despite EPA's insufficient showing to establish PFOA and PFOS as CERCLA pollutants or contaminants, it now seeks to designate PFOA and PFOS as CERCLA "hazardous substances" merely to obtain access to CERCLA's most powerful enforcement tools (such as Section 106 unilateral administrative orders to compel parties to act, Section 107(a) cost recovery action, and Section 113(f) contribution claims) without first establishing the insufficiency of other existing authorities.

Moreover, Congress very recently reinvigorated the CERCLA Superfund tax to provide EPA with a budget to pay for agency-funded cleanups.[76] Despite being dormant for years, the Superfund tax on chemical manufacturers was recently reintroduced by Congress, arguably to help pay for EPA to clean up unregulated contaminants like PFOA and PFOS. At many sites, PFOA and/or PFOS may be present but completely unrelated to site operations or releases and, therefore, be essentially an orphan contribution that should be addressed using the Superfund. Thus, EPA's justification for its proposed rule to designate PFOA and PFOS as hazardous substances pursuant to CERCLA Section 102(a) ignores that industry is now providing additional funding generated by the Superfund tax to reimburse EPA's costs, in addition to all the ongoing and effective cleanups at private parties' sites, and EPA has failed to adequately justify the need to foist the costs of this rule onto many of the same parties. The availability of this substantial new funding is an important aspect of the problem to which EPA must give due weight and consideration in making its decision.

In addition, EPA fails to explain in its proposal to establish PFOA and PFOS as CERCLA hazardous substances why its authorities under SDWA, RCRA, CWA, and other law, which it has used in the past to deal with PFOA and PFOS contamination, are now insufficient. We believe that EPA has power under these existing authorities to address PFOA and PFOS contamination that presents a danger to human health and the environment, as outlined below.

a. EPA's SDWA Authority

Section 1431 of the SDWA provides "emergency powers" to EPA to issue imminent and substantial endangerment (I&SE) orders to abate potential threats to public health from "a contaminant that is present in or is likely to enter a public water system or an underground source of drinking water" when the appropriate state and local authorities have failed to act to protect public health.[77] The SDWA's definition of "contaminant" is broad; it encompasses "any physical, chemical, biological, or radiological substance or matter in water." Under this

[75] 42 U.S.C. § 9604(a)(1)(B).
[76] Pub. Law No. 117-58.
[77] *See* 42 U.S.C. § 300i.

definition, EPA may address both regulated and unregulated contaminants based on the EPA Administrator's discretion to protect the health of potentially affected persons.[78]

In 2018, EPA extensively updated its Section 1431 guidance and provided a detailed description of the scope of EPA's authority, the application of the authority, and the recommended steps in an order issued under Section 1431.[79] EPA's guidance provided the agency's interpretations of "imminent" and "endangerment":

> An "endangerment" may include not only actual harm, but also a threatened or potential harm. No actual injury need ever occur. Therefore, while the threat or risk of harm must be "imminent" for EPA to act, the harm itself need not be. Public health may be endangered imminently and substantially "both by a lesser risk of a greater harm and by a greater risk of a lesser harm;" this will ultimately depend on the facts of each case.
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> An endangerment is "imminent" if conditions that give rise to it are present, even though the actual harm may not be realized. Courts have stated that an "imminent hazard" may be declared at any point in a chain of events that may ultimately result in harm to the public.

EPA routinely relies on its authority under SDWA Section 1431 to address releases that could potentially affect drinking water sources. EPA has issued 119 I&SE orders to deal with various sources of contamination, including corrosive conditions affecting water pipes, disease vectors in finished water storage, and exceedances of contaminant levels in drinking water.[80] In fact, EPA has used its emergency powers under SDWA Section 1431 to require responses to PFOA and/or PFOS releases and related contamination of drinking water supplies at four sites, three of which involved the DoD: [81]

- Warminster Naval Warfare Centre, Pennsylvania: In 2014, EPA issued an administrative enforcement order directing the U.S. Navy to address PFOS in three drinking water supply wells at and near this NPL site.[82]

- Former Pease Air Force Base, New Hampshire: In August 2015, EPA issued an administrative enforcement order to require the Air Force to design and construct a system to treat water systems contaminated from releases of PFOA and PFOS.[83]

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[78] 42 U.S.C. § 300f(6).
[79] *See* EPA Memorandum from the Office of Enforcement and Compliance Assurance to Regional Enforcement Directors, "Updated Guidance on Emergency Authority under Section 1431 of the Safe Drinking Water Act" (May 30, 2018), available at https://www.epa.gov/sites/default/files/2018-09/documents/updatedguidanceonemergencyauthorityundersection1431sdwa.pdf.
[80] *See* Congressional Research Service, "PFAS and Drinking Water: Selected EPA and Congressional Actions," R45793, at 12-13 (July 18, 2022) (available at https://crsreports.congress.gov/product/pdf/R/R45793)
[81] *Id.*
[82] *Id.*
[83] *Id.*

- Horsham Air Guard Station, Willow Grove, Pennsylvania: In 2015, EPA issued an order directing the Air Guard and Air Force to treat onsite drinking water wells and to provide treatment for private offsite wells.[84]

- Chemours Washington Works Facility, West Virginia, and Ohio: EPA issued three emergency orders to this facility requiring DuPont and Chemours to offer water treatment, connection to a public water system, or bottled water where PFOA concentrations exceeded 70 parts per trillion (ppt).[85]

The 2018 guidance recommends that EPA follow a process akin to that employed under CERCLA when using its SDWA authority, including issuance of orders for site investigation, risk assessment and cleanup feasibility assessment, and then remediation using the selected remedy.[86] EPA has pursued this approach for several SDWA orders involving PFOA and/or PFOS.

b. EPA's RCRA Authority

EPA can also potentially address releases and require cleanup of PFOA and PFOS through orders issued under Section 7003 of the Resource Conservation and Recovery Act (RCRA), through its "omnibus" authority at facilities requiring a RCRA permit, or via RCRA corrective action authorities.[87] RCRA provides EPA with the following authority to enforce against private parties that contributed to the "handling, storage, treatment, transportation or disposal" of certain wastes that may present an imminent and substantial endangerment:

> [U]pon receipt of evidence that the past or present handling, storage, treatment, transportation or disposal of *any solid waste* or hazardous waste may present an imminent and substantial endangerment to health or the environment, the Administrator may bring suit on behalf of the United States in the appropriate district court against any person (including any past or present generator, past or present transporter, or past or present owner or operator of a treatment, storage, or disposal facility) who has contributed or who is contributing to such handling, storage, treatment, transportation or disposal to restrain such person from such handling, storage, treatment, transportation, or disposal, to order such person to take such other action as may be necessary, or both.
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[84] *Id.*
[85] *Id.*
[86] EPA, Updated Guidance on Emergency Authority under Section 1431 of the Safe Drinking Water Act (May 30, 2018), available at https://www.epa.gov/sites/default/files/2018-09/documents/updatedguidanceonemergencyauthorityundersection1431sdwa.pdf.
[87] EPA has indicated it will be promulgating two rules: one to add PFOA, PFOS, PFBS, and GenX as RCRA hazardous constituents, which is a first step towards hazardous waste listing; and the second to clarify that EPA can require corrective action to address waste meeting the statutory definition of hazardous wastes. See EPA's regulatory agendas, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=2050-AH26 and https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=2050-AH27.

> The Administrator may also, after notice to the affected State, take other action under this section including, but not limited to, issuing such orders as may be necessary to protect public health and the environment.[88]

This section empowers EPA to address PFOA and PFOS that qualifies as "solid waste" under the statutory definition of the term, even if it has not been designated as hazardous, so long as the substances present substantial endangerment to health or the environment.[89]

States implementing RCRA permitting programs also have exercised authority to establish conditions in permits that protect human health and the environment under the "omnibus" authority, which has been used in the past to order cleanup of contamination beyond releases of RCRA hazardous constituents at permitted facilities. Currently, states are using their RCRA authority to address PFOA and PFOS releases. In Nebraska, state officials have required Offutt Air Force Base (AFB) environmental officials to take corrective action on PFOA, PFOS, and other PFAS under the installation's hazardous waste permit. Groundwater sampling for PFAS was planned site-wide and specifically includes a base firefighting training area. Offutt AFB and state officials performed a screening-level site inspection at several locations on Offutt where aqueous film-forming foams were historically used or stored. Similarly, in New Jersey, EPA is overseeing RCRA corrective action work at the Chemours Chambers Works complex located in Deepwater, New Jersey. The state and localities have required the company to sample off-site wells as part of its permitted corrective action program. These examples show that EPA, working with states, has relied on RCRA to address PFOA and PFOS releases.

Finally, RCRA gives EPA and authorized states ample power to require corrective action at facilities requiring a RCRA permit, power that EPA could readily extend to PFOA and PFOS. The RCRA regulations have always required permitted hazardous waste treatment, storage, and disposal facilities to meet a groundwater protection standard at RCRA-regulated units (e.g., surface impoundments) and to institute corrective action when that standard was exceeded.[90] The 1984 "HSWA" amendments to RCRA expanded that authority to enable EPA to require corrective action at "solid waste management units" (SWMUs), not just regulated units, at facilities holding or requiring a RCRA permit and to require such corrective action beyond the facility boundary where necessary to protect health or the environment.[91] These requirements can be imposed via RCRA permits or interim status corrective action orders.[92]

The corrective action authorities added by the HSWA amendments are not premised on the release of hazardous waste at a facility; rather, they authorize EPA to require corrective action "for all releases of hazardous waste *or constituents* from any solid waste management unit" at a RCRA facility.[93] Appendix VIII to Part 261 of the RCRA rules contains a list of over

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[88] 42 U.S.C. § 6973(a) (emphasis added).
[89] *See Connecticut Coastal Fishermen's Ass'n v. Remington Arms Co*., 989 F.2d 1305, 1316 (2d Cir. 1993) (finding the broader statutory definition of solid waste, as opposed to the narrow regulatory definition of that term, to apply to RCRA imminent hazard suits).
[90] *Id.* Part 264, Subpart F.
[91] *See* RCRA §§ 3004(u) and (v), 42 U.S.C. §§ 6924(u), (v), and 40 C.F.R. § 264.101.
[92] *See* 42 U.S.C. §§ 6925(c)(3), 6928(h).
[93] *Id.* § 6924(u) (emphasis added).

300 "hazardous constituents." Their main purpose is to support the listing of U-listed wastes,[94] but the list serves various other purposes under the RCRA program. In particular, the Appendix VIII constituents are the ones that EPA evaluates to determine whether to require corrective action at a SWMU and when to deem it completed.[95] Because Appendix VIII is contained in the Code of Federal Regulations, adding one or more PFAS to it would require rulemaking, but it would be simple for EPA to conduct this rulemaking, as the test is easily met: "Substances will be listed on appendix VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms."[96] Indeed, on October 26 of last year, EPA announced in response to a petition filed by New Mexico that it would initiate a rulemaking to list PFOA, PFOS, PFBS, and GenX as hazardous constituents.[97]

Adding PFOA and PFOS to the Appendix VIII list would thus give EPA all the corrective action authority over them that it possesses under Subtitle C of RCRA; i.e., it would allow EPA to require corrective action whenever it could show that PFAS were being released from a solid, not necessarily hazardous, waste management unit at a facility that requires or possesses a RCRA permit.

Importantly, unlike adding PFOA and PFOS as characteristic or listed hazardous wastes, an Appendix VIII listing would not automatically make either substance a CERCLA hazardous substance, thus avoiding the extraordinary potential for unforeseen consequences, and economic disruption, that a CERCLA listing would likely pose.

c. EPA's Clean Water Act Authority

EPA, and states with delegated authority to issue National Pollutant Discharge and Elimination System (NPDES) permits, could also use the Clean Water Act (CWA) to regulate PFOA and PFOS releases into the environment through NPDES permits. EPA and many states have already begun to require entities with NPDES permits to test effluent for PFOA, PFOS, and other contaminants. EPA could support states in managing their water quality by evaluating and developing ambient water quality criteria for PFOA and PFOS under CWA Section 304(a) to facilitate state efforts to limit additional discharges of PFOA and PFOS, assuming EPA has adequate data and appropriate justifications for doing so. In fact, EPA has released an advance notice of proposed rulemaking to support future potential rulemaking under the CWA relating to effluent limit guidelines for certain source categories to address discharges of PFAS.[98] EPA also has emergency powers under Section 504(a) of the CWA to address imminent and substantial endangerment caused by discharges from pollution sources.

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[94] *See* 40 C.F.R. § 261.11(a)(3).
[95] *See, e.g.,* OSWER Directive 9502.00-6D, *Interim Final RCRA Facility Investigation (RFI) Guidance*, Vol. I, pp. 3-16 to 3-17 (May 1989).
[96] 40 C.F.R. § 261.11(a)(3); *see, e.g.,* 70 Fed. Reg. 9138, 9142 (Feb. 24, 2005) (adding five chemicals to the Appendix VIII list of constituents "because scientific studies show the chemicals to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms").
[97] *See* https://www.epa.gov/newsreleases/epa-responds-new-mexico-governor-and-acts-address-pfas-under-hazardous-waste-law.
[98] 86 Fed. Reg. 14,560 (Mar, 17, 2021).

d. U.S. Department of Defense Responsibilities

As part of the NDAA for Fiscal Year 2021, Congress imposed several requirements and obligations on the DoD regarding PFOA and PFOS. For example, Section 335 required DoD to publicly disclose the results of any testing for PFOA, PFOS, and other PFAS conducted on military installations or formerly used defense sites, regardless of whether the testing was conducted by DoD, federal agencies, or any other public or private entities. Section 332 required the DoD, when conducting removal or remedial actions pursuant to CERCLA or the NDAA for Fiscal Year 2020 of PFOA and/or PFOS contamination from DoD or National Guard activities found in drinking water, or in groundwater that is not currently used for drinking water, to ensure that these actions result in PFOA and PFOS levels that meet or exceed the most stringent of any enforceable state and federal drinking, surface, or groundwater standards or health advisories issued pursuant to SDWA Section 1412(b)(1)(F).[99]

B. A Listing Under CERCLA Section 102(a) Would Have Significant Unintended Consequences

1. The Listing Would Slow Down, Not Speed Up, Site Cleanups

EPA asserts that "[d]esignating PFOA and PFOS as hazardous substances may have indirect, indeterminate impacts associated with potential increases in the speed of response activity and in the total number of response actions taken to address PFOA and PFOS releases."[100] Remediating Superfund sites is a multi-year, if not multi-decade, process (involving site assessment, remedial investigation and feasibility study, remedy decisions, remedial design and remedial action, post-construction, and more). PRPs that do not agree to comply must be compelled by further litigation, which can also take many years. The process of allocating responsibility among PRPs can be time-consuming, with delays in figuring out the allocation of financial responsibility among the PRPs. Contrary to EPA's position, this entire process takes time and will, in fact, slow down the site cleanup process.

The data on the lack of progress EPA has made in its cleanup of Superfund sites demonstrate that the program is already lagging. For example, at the end of FY 2019, only 424 of the 1,757 sites that had been added to the NPL since 1980 have been deleted, meaning that all cleanup goals at these sites were achieved.[101] In reviewing the NPL list as of August 17, 2022, there are 329 sites.[102] Approximately 75 percent of the NPL is more than 20 years old.

Additionally, discovery of PFOA and PFOS contamination during the five-year reviews of facilities where CERCLA remediation was previously completed would clearly slow down the rate of sites deemed remediated and "closed." Even sites that underwent cleanup of groundwater contaminated with PFOA and/or PFOS to EPA's previous health advisory of 70 ppt would face

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[99] NDAA FY2021 Section 332(c) is a "savings clause" that expressly states that the section does not affect the application of CERCLA in general, which would presumably include EPA's discretion to establish ARARs pursuant to CERCLA Section 121.

[100] 87 Fed. Reg. at 54,439.

[101] *See* https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0216.

[102] *See* https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0213.

risk that prior remedial efforts would not comply with future MCLs or MCLGs for PFOA and PFOS. Allowing EPA's remedial efforts to be driven by the presence of PFOA and PFOS may needlessly shift the focus away from the sites that pose the greatest risks to public health, welfare, and the environment and the sites where targeted cleanups may provide the greatest results, particularly without clear technical guidance on the identification of relevant PFOA/PFOS contamination sources, evaluation of background concentrations, and analytical methods for all environmental media.

In addition to causing government enforcement actions, a hazardous substance designation for PFOA and PFOS would likely spawn a significant rise in disruptive private-party CERCLA litigation. Under Section 113 of CERCLA, there are multiple circumstances where CERCLA contribution rights are triggered for private parties, based on certain legal actions and administrative and judicial settlements.[103] Additionally, cost recovery for voluntary cleanups is also available to private parties under Section 107 of CERCLA.[104] Coupled with CERCLA's extraordinarily broad liability structure, these private rights of action encourage litigation. Private CERCLA claims are not legally bound by any EPA enforcement guidance that could be crafted to try to blunt the unfairness of CERCLA's expansive liability structure.

For example, CERCLA litigation in New Jersey involving cleanup of hazardous substances in the Passaic River resulted in a settlement with industrial parties. Those parties then brought contribution actions against 261 third-party defendants, including 70 municipalities and other public entities, contending they bore site cleanup responsibility, resulting in litigation spanning eight years and culminating in a second settlement of $35.4 million.

Moreover, at sites that are the subject of private party litigation, EPA may be unwilling or unable to dedicate the necessary resources to attempt to negotiate settlements providing small contributors with contribution protection from other PRPs. Previous allocation litigation will not have included facts related to the contribution of PFOA or PFOS. These entirely different "waste" (or product manufacturing) streams that could not have been present in past negotiations would now need to be researched and considered, which could vastly change the CERCLA contribution allocation landscape, particularly for complicated multi-party sites like landfills. In any event, EPA cannot force such re-evaluations or settlements.

2. The Listing Would Affect Every Real Estate Transaction for Properties Where PFOA and PFOS Are Potentially Present

Designating PFOA and PFOS as hazardous substances under CERCLA Section 102(a) would likely cause the inventory of so-called "brownfield" sites to increase, given the widespread anthropogenic use of these chemicals in hundreds of consumer products and processes. In 2002, Congress sought to deal with a backlog of properties across the country, the "reuse of which may be complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant."[105] The purpose of this "Brownfield Program" was to facilitate property transactions that private parties, banks, and other financial institutions might

[103] 42 U.S.C. § 9613(f)(1) and (3)(B).
[104] *See U.S. v. Atlantic Research Corp.*, 551 U.S. 128 (2007).
[105] 42 U.S.C. § 9601(39).

refuse to participate in due to fears of assuming liability for cleaning up hazardous substances, especially where EPA's limited resources precluded assessing each property and releasing it from CERCLA jurisdiction. Congress created the "de minimis" settlement authority and "de micromis" exemption to facilitate this process, but qualifying for these protections involves satisfying complicated, stringent requirements. Thus, these tools are likely inadequate to address the broad concerns over PFOA and PFOS sites.

The widespread presence of PFOA and PFOS in the United States may present significant and potentially insurmountable challenges for anyone attempting to qualify for CERCLA's limited exemptions, exclusions, and defenses.[106] Many purchasers of property would at least have reason to know that the property was or could be contaminated with PFOA and PFOS. If this is taken to the extreme, it would preclude anyone from qualifying for the protections that Congress added to limit the potential for needless CERCLA liability for small parties. EPA's designation of PFOA and PFOS as hazardous substances pursuant to CERCLA Section 102(a) could unnecessarily complicate these issues.

3. There Will Likely Be a Lack of Adequate Disposal Capacity Nationwide

According to CERCLA Section 104(c)(9)(A), EPA cannot require remedial actions for either CERCLA "pollutants or contaminants" or "hazardous substances" unless certain conditions are met:

> unless the State in which the release occurs first enters into a contract or cooperative agreement with the President providing assurances deemed adequate by the President that the State will assure the availability of hazardous waste treatment or disposal facilities which… have adequate capacity for the destruction, treatment, or secure disposition of all hazardous wastes that are reasonably expected to be generated within the State during the 20-year period following the date of such contract or cooperative agreement and to be disposed of, treated, or destroyed….

As discussed, EPA has announced that it intends to designate PFOA and PFOS as RCRA hazardous constituents. The potential of CERCLA liability is pushing waste management facilities to reject receipt of non-hazardous waste PFOA/PFOS-containing materials and manage these only as RCRA hazardous wastes. EPA's justification for designating PFOA and PFOS as CERCLA hazardous substances fails to address whether states have adequate capacity to destroy, treat, or securely dispose of all the materials contaminated with PFOA and PFOS in the next 20

[106] For example, regarding the de micromis exemption, the person must have transported or arranged for the disposal of some of the hazardous substance at a given facility on the National Priorities List before April 1, 2001. *See* 42 U.S.C. § 9607(o)(1)(B). Regarding the contiguous properties exemption, the person cannot have caused, contributed to, or consented to the disposal of the hazardous substances on the person's property and is not potentially liable for response costs at another facility. *See* 42 U.S.C. § 9607(q)(1)(A)(i), (ii)(I). Regarding the bona fide prospective purchaser exemption, the person must prove that no disposal of hazard substances at the facility occurred after the person acquired the facility. *See* 42 U.S.C. § 9601(40)(B)(i). Regarding the limited exclusion for State and local governments, they cannot have caused or contributed to the release or threatened release of a hazardous substance from the facility. *See* 42 U.S.C. § 9601(20)(D).

years and beyond. Because EPA does not plan to release its Interim Guidance on Destroying and Disposing of Certain PFAS until Fall 2023,[107] EPA has provided no final indication that existing hazardous waste disposal capacity can handle the increased disposal volumes for wastes containing PFOA and PFOS. EPA's 2019 Assessment of National Capacity for Hazardous Waste Management stated "that adequate national capacity for the treatment and disposal of hazardous waste exists… through the year 2044," which means that EPA may not be able to satisfy CERCLA's mandatory 20-year period of sufficient capacity for hazardous wastes beginning in 2025.[108] Because that Assessment did not consider how the volume of hazardous wastes will increase dramatically if PFOA and PFOS are designated as CERCLA hazardous substances, EPA cannot guarantee it can satisfy CERCLA's mandatory 20-year period of sufficient capacity for hazardous wastes from today. EPA has acknowledged that it has required PFOA and PFOS cleanup at sites already by asserting that they are CERCLA pollutants or contaminants. However, it has not described disposal methods for contaminated soils or other media from the new sites that would be created if this rule is finalized.

Additionally, EPA has not disclosed any agreement with any state to ensure that the state has adequate capacity to destroy, treat, or securely dispose of all the materials contaminated with PFOA and PFOS in any period in the future.[109] There are currently an incineration capacity challenges that would certainly be exacerbated by this proposal. Biosolids may contain some amount of PFOA and PFOS, are generated nationally at a rate of approximately 4.5-6 million metric short tons annually and may necessitate specialized disposal solutions in some cases. EPA has failed to establish the adequacy of states' existing capacity to destroy, treat, or securely dispose of quantities of materials contaminated with PFOA and PFOS. In fact, to the extent that certain waste streams with elevated levels of PFOA and PFOS require management at a RCRA Subtitle C hazardous waste facility, all indications suggest that existing capacity would prove decidedly inadequate in short order and that waste streams from DoD facilities alone might be close to or even exceed capacity, with only a small amount remaining for any private requirements. EPA must finalize the Interim Guidance on Destroying and Disposing of Certain PFAS and estimate available waste disposal capacity before this proposed rule is finalized.

4. The Listing Will Impact Public Safety

When confronted with fire emergencies, airports, oil and gas facilities, the industrial sector, the shipping industry, and the U.S. military (including DoD, Navy, and Air Force) are among the many sectors that have historically used PFOA- and PFOS-containing aqueous film forming foams (AFFF) because they are proven effective at protecting life and critical infrastructure. The proposed rule fails to acknowledge how and why PFAS-containing AFFF are used, particularly that they are deployed at highly diluted concentrations in emergency firefighting situations. In the event of an emergency involving a hydrocarbon fire, firefighting

[107] *See* EPA, "PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024" at 17, *available at* https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.
[108] *See* EPA, "National Capacity Assessment Report, Pursuant to CERCLA Section 104(c)(9),"
[109] We are aware that some states and local governments are currently shipping or considering shipping PFAS-containing material to Subtitle C disposal facilities many hundreds of miles away to other states.

foams that allow swift and definitive extinguishing power are required to protect the lives of first responders, workers, and the public, as well as the environment.

The proposed rule also fails to acknowledge that firefighting capacity is critical to ensuring stable operation for the entire oil and gas industry, which, as part of the energy sector, is designated critical infrastructure by the Cybersecurity and Infrastructure Security Agency (CISA) under Presidential Policy Directive 21 (PPD-21).[110] Critical infrastructure is those "assets, systems, and networks, whether physical or virtual, … considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof."[111]

EPA must allow for an adequate period of time to elapse for any transition to fluorine-free firefighting foams: a minimum 3 to 5 years is necessary. EPA should also consider either appropriate exclusions for life-saving firefighting operations or modifying the listing in another manner such that reporting obligations and liability related to the use of fluorine foams are not imposed before users of these foams have an adequate time to make the transition.

C. EPA Cannot Appropriately Manage the Overbreadth of a CERCLA Section 102(a) Listing by Using Enforcement Discretion

Following the publication of this proposed rule, EPA made assurances to the regulated community that it plans to exercise its enforcement discretion and other approaches to ensure "fairness for minor parties who may have been inadvertently impacted by [PFOA and PFOS] contamination."[112] EPA has offered these remarks to assuage equity concerns expressed by small entities and certain industries and sectors, including public water utilities, municipal airports, and entities that use biosolids.[113] EPA asserts that it will also resolve issues on a "site-specific basis," and that it will seek to address potential liability on "equitable considerations" to protect certain parties from litigation by those "principally responsible for PFOA and PFOS contamination, and minimize transaction costs."[114]

While we appreciate EPA's awareness of potential equity issues that can arise with certain PRPs in the context of CERCLA enforcement, promises of enforcement discretion on a

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[110] In 2015 the Department of Homeland Security stated: "The Energy Sector consists of widely-diverse and geographically-dispersed critical assets and systems that are often interdependent of one another. This critical infrastructure … include[s] the production, refining, storage, and distribution of oil, gas, and electric power…. The Energy Sector supplies fuels to the transportation industry, electricity to households and businesses, and other sources of energy that are integral to growth and production across the Nation." U.S. Department of Homeland Security, *Energy Sector-Specific Plan 2015,* https://www.cisa.gov/sites/default/files/publications/nipp-ssp-energy-2015-508.pdf.

[111] *See* https://www.cisa.gov/critical-infrastructure-sectors.

[112] *See* EPA news release "EPA Proposes Designation Certain PFAS Chemicals as Hazardous Substances Under Superfund to Protect People's Health" (Aug. 26, 2022) https://www.epa.gov/newsreleases/epa-proposes-designating-certain-pfas-chemicals-hazardous-substances-under-superfund.

[113] *See* EPA, presentation "Notice of Proposed Rulemaking: Designating PFOA and PFOS as CERCLA Hazardous Substances" (Aug. 2022), https://www.epa.gov/system/files/documents/2022-09/Overview%20Presentation_NPRM%20Designation%20of%20PFOA%20and%20PFOS%20as%20CERCLA%20Hazardous%20Substances.pdf.

[114] *Id*.

case-by-case basis are no substitute for explicit regulatory exclusions from liability, which EPA believes it does not have the authority to provide.[115] The possibility of enforcement discretion provides no comfort to small entities, public utilities, and waste management facilities, who are at the mercy of changes in EPA position as agency leadership and priorities evolve over time. These entities are still left without certainty or the ability to predict what this enforcement discretion will cover and in what circumstances they can expect to see relief.

Even as it stands today, EPA has a policy against providing definitive assurances outside of the context of a formal enforcement proceeding.[116] EPA takes the position that such "no action assurances" erode the credibility of EPA's enforcement program by creating real or perceived inequities in the treatment of the regulated community and may hamper future enforcement efforts against a party who relies on that assurance.[117] The only exception EPA provides is for "extremely unusual cases" in which a "no action assurance" policy is "clearly necessary to serve the public interest."[118] EPA has explicitly affirmed that its general policy concerning "no action assurances" applies to sites subject to CERCLA.[119]

Given the number of new sites that may be reopened or investigated following EPA's listing of PFOA and PFOS as hazardous substances under CERCLA, it is questionable whether EPA will have the resources to properly handle the influx of new cases and new PRPs who will need specific case-by-case consideration for enforcement discretion.

IV. The Proposed Rule Fails to Provide Sufficient Explanation and Justification for EPA's Novel Proposed Use of its Authority

A. The Proposed Rule Does Not Explain EPA's Position on What Constitutes a "Substantial Danger," the Statutory Standard for Designating a Hazardous Substance

CERCLA Section 102(a) authorizes EPA to designate as "hazardous substances" substances that "when released into the environment may present substantial danger to the public health or welfare or the environment…."[120] The statute does not define this standard, and EPA has not previously provided an interpretation for this standard because it has never exercised this authority. Because EPA is exercising this authority for the first time, it must provide the public with a reasonable explanation of how the standard operates, any limiting principles that apply to its use, and the agency's reasoning as to why PFOA and PFOS meet this standard. It is axiomatic that EPA, as the agency charged with administering this section of the statute, has the burden to provide a reasoned explanation for its action and for its construction of the relevant provision, which in this case requires clearly explaining what criteria are to be used in determining that a

[115] *Id*. ("EPA does not have authority to exempt particular entities from liability.")
[116] Memorandum from Courtney M. Price, Assistant Administrator for enforcement and Compliance Monitoring to Assistant Administrators, Regional Administrators, General Counsel, and Inspector General, "Policy Against "No Action Assurances," November 16, 1984: https://www.epa.gov/enforcement/guidance-no-action-assurances-policy.
[117] *Id*.
[118] *Id*.
[119] Memorandum from Barry Breen, "Applicability of Policy Against 'No Action' Assurances to CERCLA," June 16, 2000: https://www.epa.gov/enforcement/guidance-applicability-policy-against-no-action-assurances-cercla.
[120] 42 U.S.C. § 9602(a).

substance "may present" a "substantial danger" for purposes of CERCLA.[121] The proposed rule makes little attempt to shed light on how EPA exercised its discretion in Section 102(a), leaving the regulated community unable to understand its reasoned basis for listing PFOA and PFOS.

EPA attempts to justify listing PFOA and PFOS as CERCLA hazardous substances by describing the characteristics of these substances, and then, without connecting those chemical properties to any risk of exposure, it simply labels these characteristics as creating "substantial danger." The logical gap between the descriptions and the conclusion must be filled by reasoning that is subjected to public comment. Moreover, EPA's approach (to the extent it can be discerned at all) appears to conflate two regulatory principles that it carefully distinguishes in other contexts, hazard and risk.[122] Many chemicals present a hazard to human health if ingested in sufficient amounts, but few present a potential level of exposure that warrants triggering new nationwide cleanup liability. EPA evades providing an interpretation of the statutory standard that would enable one to distinguish PFOA and PFOS from many other chemicals that, presumably, do not satisfy the standard. Additionally, EPA provides no discernable criteria that can be applied to other substances going forward. EPA must explain the statutory standard under CERCLA and then justify why PFOA and PFOS are appropriate candidates for listing based on that standard. Without providing a sufficient explanation of the standard, EPA's decision to list PFOA and PFOS is arbitrary and an invalid exercise of agency discretion.

It bears emphasis that EPA must fully explain its interpretation of Section 102(a) to afford stakeholders the opportunity to comment, including commenting on the criteria as applied to PFOA and PFOS. The failure to provide this opportunity violates the APA's public notice requirements. How EPA applies its criteria is not only highly consequential for these substances, but it is also precedent setting, as EPA has never wielded this authority in the more than 40 years since CERCLA's enactment. This proposed rulemaking would affect a broad set of stakeholders beyond those simply interested in PFOA and PFOS because it will affect EPA decisions on future hazardous substance listing decisions. EPA has already announced plans to release an advance notice of proposed rulemaking to add more PFAS as hazardous substances under Section 102(a). It must provide a reasoned explanation of how to apply this standard beyond a bare assertion that PFOA and PFOS may have human health effects, and that the chemicals may move through the environment.

1. EPA Fails to Provide its Interpretation of the "May Present a Substantial Danger" Standard Under CERCLA

In this proposed rule, EPA fails to provide clear parameters or guidance on the meaning of the "may present a substantial danger" standard under CERCLA Section 102(a). The only "considerations" EPA articulates for this standard are as follows:

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[121] *See Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984) (judicial review under APA requires assessment of appropriateness of agency's construction of statute); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 42 (1983) (presumption for judicial review is against agency changes in current policy that are not justified by the rulemaking record).

[122] Risk is a concept that integrates hazard and exposure. See, for example, EPA's procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,752 (Jul. 20, 2017), under which risk characterization requires integration of hazard and exposure.

> In assessing whether a substance, when released, may present "substantial danger," the EPA proposes to consider information such as the following: the potential harm to humans or the environment from exposure to the substance (*i.e.,* hazard), and how the substance moves and degrades when in the environment (*i.e.,* environmental fate and transport). To further inform its decision about whether the statutory factors have been met, the Agency proposes to also consider other information that may be relevant when evaluating releases of the substance, such as the frequency, nature, and geographic scope of releases of the substances. The Agency proposes to weigh this information to determine whether the substance, when released, may present a "substantial danger."[123]

The language of the "information" about the "statutory factors" that EPA will consider is all forward looking, indicating that EPA has not yet undertaken the task of applying the level of "harm to humans or the environment from exposure" or the "environmental fate and transport" to PFOA and PFOS. EPA also proposes to address the "frequency, nature, and geographic scope of releases of the substances" but gives no indication in the proposal that it has attempted any effort to characterize where and how PFOA and PFOS exist in the environment. This raises a host of questions and uncertainties that must be answered if EPA were to attempt to adopt a reasonably discernible standard. While the proposal, relying on EPA's Health Advisories, provides information on potential harm to humans, it offers little on estimated exposure from contaminated sites. There is no mapping of expected PFOA and PFOS releases or how those releases are a threat to public health, in what frequencies, at what level, in what medium, and over what period of time. EPA's rationale does not provide stakeholders with nearly enough information to begin to evaluate these questions. EPA's explanation is vague and sheds even less light on how this information will be "weighed" against the poorly defined list of considerations.

In interpreting the "may present a substantial danger" standard under CERCLA, EPA must consider how the hazardous substance listing warrants use of its full authorities under CERCLA to address the "substantial danger" to public health and welfare or the environment. As discussed, in the proposed rule, the only considerations EPA would "weigh" in deciding to list a substance under the "substantial danger" standard are hazard, environmental fate and transport, and the frequency, nature, and geographic scope of releases of the substances. However, EPA does not explain how each of these considerations affects the listing decision. Further, EPA does not explain why PFOA and PFOS present hazards at a frequency, nature, and scope that "may present a substantial danger" to the public or the environment in the context of CERCLA, meaning *from contaminated sites*. Indeed, it would be quite difficult for EPA to argue that raindrops, which could contain PFOA and PFOS,[124] present a "substantial danger."

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[123] 87 Fed. Reg. at 54,421.

[124] Ian T. Cousins, Jana H. Johansson, Matthew E. Salter, Bo Sha, and Martin Scheringer, *Environmental Science & Technology* 2022 56 (16), 11172-11179, https://doi.org/10.1021/acs.est.2c02765; Karen Y. Kwok, Sachi Taniyasu, Leo W. Y. Yeung, Margaret B. Murphy, Paul K. S. Lam, Yuichi Horii, Kurunthachalam Kannan, Gert Petrick, Ravindra K. Sinha, and Nobuyoshi Yamashita, *Environmental Science & Technology* 2010 44(18), 7043-7049, https://doi.org/10.1021/es101170c; Seung-Kyu Kim and Kurunthachalam Kannan, *Environmental Science & Technology* 2007 41(24), 8328-8334, https://doi.org/10.1021/es072107t.

2. The Proposed Rule Appears to Improperly Conflate Any Chemical with a Hazard Profile as a Chemical That Warrants a Hazardous Substance Listing Under CERCLA

In lieu of a reasoned explanation of the statutory standard for "may present a substantial danger," EPA merely summarizes the chemical and physical characteristics, toxicity and toxicokinetics, and environmental prevalence of PFOA and PFOS and concludes the summary with blanket statements that this information "demonstrates" that PFOA and PFOS should be designated as hazardous substances under CERCLA.[125] EPA makes conclusory statements that the "totality of the evidence" indicates that PFOA and PFOS may present substantial danger, and that "[t]his level of evidence is more than sufficient to satisfy the CERCLA section 102(a) standard. EPA believes that *this amount and type* of evidence exceeds the minimum required under CERCLA section 102(a)" (emphasis added).[126]

EPA has not given stakeholders any indication of what "amount and type of evidence" is required to "exceed the minimum required" under CERCLA. The agency identifies scientific evidence about PFOA and PFOS exposures (with the acknowledgement that the science is still evolving)[127] but fails to explain why and how this evidence "may present a substantial danger" to public health or the environment.

Thus, EPA appears to work backwards in the proposed rule by explaining what it believes are the characteristics and hazards of PFOA and PFOS and justifying their listing based on these characteristics specific to PFOA and PFOS, rather than first establishing the statutory standard with specific criteria and then determining if PFOA and PFOS meet these criteria for listing. The latter approach is consistent with good practices and sound public policy; the former approach – particularly in this context, where the standard is being applied for the first time – risks arbitrary outcomes and is legally insufficient.

EPA must interpret the "may present a substantial danger" standard based on the purpose and intent of hazardous substance designations under CERCLA and then evaluate whether PFOA and PFOS are appropriate for listing. The vague and broad nature of EPA's rationale would surely allow EPA to list a wide range of chemicals, including many persistent and bioaccumulative substances, as hazardous substances. Yet many of these same substances would never meet a reasonable definition of "substantial danger."

As EPA describes in the preamble, CERCLA was enacted to promote the timely cleanup of contaminated sites and provide the federal government with authority to respond to releases or threatened releases of hazardous substances in order to protect the public health and the environment.[128] Key to considering a chemical as a hazardous substance, which could trigger not only reporting requirements but also potential financial liability for property owners to perform remediation of PFOA and PFOS present on their property, is that the hazardous substance presents a "substantial danger" to public health and the environment within the context of

[125] 87 Fed. Reg. at 54,429.
[126] *Id*. at 54,416.
[127] *Id*. at 54,423.
[128] *Id*. at 54,420.

CERCLA's authority. In this context, Congress did not intend for CERCLA authority to address every chemical substance with a hazard profile. Otherwise, any chemical substance would be eligible for a CERCLA hazardous substance designation because virtually any substance could potentially pose a "hazard" to public health or the environment. EPA does not even describe how potential PFOA and PFOS exposure levels lead to risk levels sufficient to meet the standard. As drafted, the proposal has the potential to open and reopen numerous Superfund sites based on any presence whatsoever of PFOA and PFOS on the property, which could have originated from any number of sources.

Since EPA can use its authority under CERCLA to compel site cleanup (or cost recovery for site cleanup), EPA must explain why PFOA and PFOS may present a substantial danger to public health and the environment *from contaminated sites*. EPA acknowledges in the proposed rule that there are numerous uncertainties in how many sites could be impacted, including:

> (1) how many sites have PFOA or PFOS contamination at a level that warrants a cleanup action;
> (2) the extent and type of PFOA and PFOS contamination at/near sites;
> (3) the extent and type of other contamination at/near sites;
> (4) the incremental cost of assessing and remediating the PFOA and/or PFOS contamination at/near these sites; and
> (5) the cleanup level required for these substances.[129]

EPA claims that it cannot know how many sites could have PFOA and PFOS contamination, and therefore it cannot know to what extent the substances are present, which sites will require cleanup, and how much human or environmental exposure there is to these substances from these sites. Without a diligent attempt at answering these questions (including using quantification techniques as appropriate), EPA cannot demonstrate (how EPA interprets the statutory standard) that PFOA and PFOS "may present a substantial danger" to public health or the environment under CERCLA. EPA must attempt to evaluate existing data sources on known PFOA and PFOS exposures, including, as appropriate, the use of modeling efforts that are available to EPA to assess these questions, as the Chamber did for non-federal Superfund sites. EPA's decision to designate PFOA and PFOS as hazardous substances under CERCLA is arbitrary. EPA should withdraw this rulemaking until it completes a more comprehensive assessment of likely nationwide occurrences of PFOA and PFOS and address other uncertainties we raised in our October 18, 2022, letter. EPA should not guess for the purposes of this rulemaking about the extent of PFOA or PFOS pollution at contaminated sites; the stakes are too high.

3. The Proposed Rule Provides No Basis for Determining Which Chemicals Could Be Listed Under CERCLA Section 102(a)

Under the current CERCLA regime, which has been successful for many years without resorting to Section 102(a), stakeholders have a level of predictability because the hazardous substance definition incorporates lists of chemicals from other statutes that either adopt lists

[129] *Id*. at 54,423.

designated by statute or have more specific criteria for the types of hazards or risk that is contemplated:

- Any substance designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act [33 U.S.C. § 1321(b)(2)(A)];

- Any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act [42 U.S.C. 6921] (but not including any waste the regulation of which under the Solid Waste Disposal Act [42 U.S.C. § 6901 et seq.] has been suspended by Act of Congress);

- Any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act [33 U.S.C. § 1317(a)], (E) any hazardous air pollutant listed under section 112 of the Clean Air Act [42 U.S.C. § 7412];

- Any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act [15 U.S.C. § 2606]….[130]

Congress failed to supply as precise a definition in Section 102(a), but it did not grant unbridled discretion to EPA. EPA must, at a minimum, provide a similar level of predictability for future designations of hazardous substances by clearly defining the criteria in Section 102(a), recognizing where it differs from the other statutory mechanisms that are imported by CERCLA. Without a clear articulation of the Section 102(a) standard before making a Section 102(a) designation, potentially any chemical substance, including chemicals identified on a hazardous substance list or chemical of concern list generated by another state, federal, or international agency, could be designated as a CERCLA hazardous substance at any time. EPA could choose to consider only "the potential harm to humans or the environment *from exposure* to the substance (i.e., hazard)" (emphasis added) in making such a designation decision. Under an uncertain and unbounded standard, businesses, non-profits, and property owners across the country would face potentially significant liability and little certainty as to when and how liability could arise.

B. EPA's Definition of "Hazardous Substance" Must Be Informed by the Statute's Treatment of "Pollutants and Contaminants"

1. Congress Drafted CERCLA to Require "Hazardous Substances" to Be More Than Mere "Pollutants or Contaminants" Reasonably Anticipated to Cause Harm to Human Health

CERCLA authorizes EPA to clean up both "hazardous substances" and "pollutants or contaminants," but places heightened priority and legal liabilities for "hazardous substances." In defining the term "pollutant or contaminant," Congress did not adopt simpler definitions of pollutants or contaminants from other major federal environmental statutes, such as the CAA,

[130] 42 U.S.C. § 9601(14).

CWA, or SDWA.[131] Instead, Congress defined "pollutant or contaminant" in CERCLA, to encompass any substance that "will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction), or physical deformations, in [any] organisms" exposed to that substance after release into the environment, or to such organisms' offspring.[132]

The way that Congress chose to distinguish a "hazardous substance" from a "pollutant or contaminant" within CERCLA Section 104(a) informs the meaning of "hazardous substances" in CERCLA Section 102(a). Specifically, the language Congress used to describe what happens when "there is a release or substantial threat of release into the environment" of hazardous substances and of pollutants or contaminants reveals Congress' intent for dealing with three different kinds of situations:

1. If a CERCLA "pollutant or contaminant" does not "present an imminent and substantial danger to the public health or welfare," then EPA is not authorized to take any removal or remedial actions under CERCLA, even if the pollutant or contaminant being released is a substance that "may reasonably be anticipated to cause … physiological malfunctions…."[133]

2. If EPA shows that a CERCLA "pollutant or contaminant . . . may present an imminent and substantial danger to the public health or welfare," then EPA is authorized to take certain removal or remedial actions allowed under CERCLA but cannot recover its costs

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[131] *See* 42 U.S.C. § 7602(g) ("The term 'air pollutant' means any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive (including source material, special nuclear material, and byproduct material) substance or matter which is emitted into or otherwise enters the ambient air."); 33 U.S.C. § 1362(6) ("The term 'pollutant' means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water."); 42 U.S.C. § 300f(6) ("The term 'contaminant' means any physical, chemical, biological, or radiological substance or matter in water.").

[132] 42 U.S.C. § 9601(33) ("The term 'pollutant or contaminant' shall include, but not be limited to, any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring; except that the term 'pollutant or contaminant' shall not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under subparagraphs (A) through (F) of paragraph (14) and shall not include natural gas, liquefied natural gas, or synthetic gas of pipeline quality (or mixtures of natural gas and such synthetic gas)."). To date, EPA has not issued any regulations providing a different definition. As part of the National Contingency Plan (NCP), the EPA adopted a rule that defines "pollutant or contaminant" by repeating that phrase's definition in CERCLA § 101(33) and then adds that "when determining whether to add a facility to the NPL to mean a "pollutant or contaminant" that "presents an ***imminent*** and substantial danger to public health or welfare." 40 C.F.R. § 300.5. This definition does not support EPA's position here because the rule only defines a certain subset of pollutants or contaminants that "may present an imminent and substantial danger" without altering the statutory definition of "pollutant or contaminant" in CERCLA Section 101(33).

[133] *Compare* CERCLA § 101(33) (defining "pollutant or contaminant" as "any substance … which after release into the environment and upon exposure … may reasonably be anticipated to cause … physiological malfunctions….") *with* § 104(a) (authorizing removal and/or remedial action for release of "any pollutant or contaminant" only if it "may present an imminent and substantial danger to the public health or welfare….").

of removal or remedial action from owners, operators, arrangers, or transporters associated with the pollutant or contaminant upon which the EPA is taking action.[134]

3. If EPA has made a "hazardous substance" designation, then it is authorized to take removal or remedial actions (or to issue Section 106 orders to PRPs) without making an imminent and substantial endangerment finding, and EPA can *also* recover its costs of those actions from owners, operators, arrangers, or transporters.[135]

Thus, the statute's structure reveals that a "hazardous substance" must present more of a "danger" than CERCLA "pollutants or contaminants." This reading is supported by CERCLA Section 104(i)(18). There, Congress expressly stated that, before a CERCLA "pollutant or contaminant" could be treated "as a hazardous substance" when assessing the need to take remedial actions under CERCLA Section 104, the Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR) must first make an administrative determination that such treatment "is appropriate…."[136]

2. If EPA Believes That PFOA and PFOS Are CERCLA "Pollutants or Contaminants," it Should Correctly Make the Showing Required to Support that Conclusion Prior to Considering Elevating Their Status to "Hazardous Substance"

To date, EPA has taken the position that PFOA and PFOS are CERCLA pollutants or contaminants and has required that they be addressed at several facilities. However, EPA's justification for its new rule summarily declares PFOA and PFOS to be pollutants and contaminants "because of their release into the environment and their resistance to degradation," which does not specifically address the elements required under the statute.[137] EPA should correctly make the showing required to establish PFOA and PFOS as CERCLA "pollutants or contaminants."

EPA's justification for designating PFOA and PFOS as CERCLA "hazardous substances" fails to suggest that they cause or are reasonably expected to cause death, disease, physiological malfunctions, or any other conditions in the definition of "pollutant or contaminant" in CERCLA Section 101(33). EPA states that "[h]uman studies have found ***associations*** between PFOA and/or PFOS exposure and effects on the immune system, the cardiovascular system, human development (e.g., decreased birth weight), and cancer," which fall short of the statutory standard of "will or may reasonably be anticipated to cause" such effects.[138] EPA's justification discusses the "Toxicity and Toxicokinetics" of PFOA and PFOS in

[134] *Compare* CERCLA § 104(a) (authorizing removal and/or remedial action for release of "any pollutant or contaminant" only if it "may present an imminent and substantial danger to the public health or welfare….") *with* § 107(a) (ascribing PRP liability for EPA's costs for "hazardous substances," not "pollutants or contaminants").
[135] *See id*.; CERCLA § 104(i)(18).
[136] *See* 42 U.S.C. § 9604(i)(18).
[137] 87 Fed. Reg. at 54,417; *see id*. at 54,428.
[138] 87 Fed. Reg. at 54,424 (emphasis added).

terms of the possible, not probable.[139] For example, EPA notes that "[e]pidemiology studies have generally found a positive ***association*** between increasing serum PFOA and total cholesterol levels in PFOA-exposed workers and residents of high-exposure communities" but fails to note that the increased cholesterol levels did not lead to increased incidence of heart disease.[140] Similarly, research found "***associations*** between increasing serum PFOA concentrations and elevations in serum levels" of certain enzymes but not any associated effects on liver function.[141] EPA acknowledges that "[e]vidence of an association between PFOS exposure and cancer is less conclusive" than even the mere "association" found between PFOA and cancer.[142] EPA also noted that the International Agency for Research on Cancer could conclude only that PFOA was "possibly carcinogenic to humans" because "[s]tudy findings are mixed."[143] Moreover, no "mutagenic mode of action" has ever been found for either PFOA or PFOS.[144] Notably, EPA said it had "preliminary data" indicating that "PFOA is likely carcinogenic to humans" but did not use this unapproved conclusion in its proposal to designate PFOA and PFOS as CERCLA hazardous substances.

3. EPA's Failure to Establish PFOA and PFOS as CERCLA "Pollutants or Contaminants" Should Preclude Their Designation as CERCLA "Hazardous Substances"

The language Congress chose to include in CERCLA establishes a hierarchy of substances, with the pinnacle being a "substantial danger" posed by threatened releases of "hazardous substances" (which, by nature of this designation, are presumed to form an imminent danger if their release is threatened). To give full and reasonable effect to the relevant CERCLA provisions, EPA should explain the standard that it proposes to use to distinguish the lower standard for pollutants and contaminants from the standard for hazardous substances, which carry the maximum level of liability that CERCLA provides.

EPA's failure to define what might make the release of a pollutant or contaminant an "imminent and substantial danger" should be addressed with respect to PFOA and PFOS. EPA's failure to explain what would elevate the danger posed by a release or threatened release of a CERCLA pollutant or contaminant from insignificant to significant exposes a crucial flaw in its proposal to designate PFOA and PFOS as CERCLA hazardous substances. EPA's inability to establish that PFOA and PFOS qualify as CERCLA "pollutants or contaminants" renders

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[139] 87 Fed. Reg. at 54,424 ("associated with a variety of adverse human health effects"), 54,425 ("observed associations between PFOA exposure," "An association" or "associations"), 54,426 ("an association," "capable of producing tumors," "correlation between PFOS exposure and the incidence of cancer are limited.").
[140] 87 Fed. Reg. at 54,426 (emphasis added); *see* ATSDR (2021), Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry at 145 ("The available occupational, community, and general population studies have not consistently found increases in the risk of heart disease or stroke that were associated with serum PFOA levels.").
[141] *Id.* at 54,425 (emphasis added).
[142] *Id*.
[143] *Id.* at 54,426.
[144] *Id*.

academic any further discussion about whether the danger their release might pose would be significant or insignificant.

The fact that EPA is choosing to exert authority it has never previously used to designate as CERCLA hazardous substances PFOA and PFOS, two substances it has not shown causes death or illness, suggests the inappropriateness of EPA's proposed designation here. Allowing EPA to designate PFOA and PFOS as CERCLA "hazardous substances" without first establishing that they are CERCLA "pollutants or contaminants" ignores the structure that Congress intentionally embedded in CERCLA.

CERCLA Section 107(a) assigns PRP liability only to owners, operators, arrangers, and transporters of "hazardous substances," not of "pollutants or contaminants," or even of "pollutants or contaminants which may present an imminent and substantial danger to the public health or welfare."[145] EPA should interpret the "substantial danger" standard in light of the fact that it is unlikely that Congress intended to grant it authority to assign PRP liability for a chemical that it has not yet explained thoroughly qualifies as a "pollutant or contaminant." EPA should not skip over these lower determinations and jump straight to declaring that PFOA and PFOS are "hazardous substances" under CERCLA Section 102(a).

C. Section 102(a) Requires Consideration of Costs in Making the Listing Decision

EPA's position that it may not, and need not, consider cost when adopting a rule designating PFOA and PFOS to be hazardous substances pursuant to CERCLA Section 102(a) is deeply flawed and contrary to the Supreme Court precedent it cites as justification for its position. Not only does CERCLA Section 102(a) *allow* costs to be considered, but it also *requires* that EPA do so. EPA's reading of the statutory text to preclude consideration of costs is in direct tension with cases, starting with *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co*., 463 U.S. 29 (1983), through *Michigan v. EPA*, 576 U.S. 743 (2015), that find that agencies should consider the costs and benefits of their actions absent statutory text to the contrary.[146] EPA's interpretation of CERCLA Section 102(a) is also belied by the alternative paths by which other substances may be designated as hazardous under CERCLA.

1. U.S. Supreme Court Precedent Establishes that EPA May Consider Costs Even When a Statute Is Silent and *Must* Consider Costs When Certain Broad Language Is Used by Congress

Three relatively recent and highly relevant U.S. Supreme Court cases have considered the direct question of whether EPA must consider costs when applying standards in other similar statutes: *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001); *Entergy Corp. v.*

[145] *See* 42 U.S.C. § 9607(a).

[146] "Indeed, we do not quibble with [Judge Kavanaugh's] general premise—and that of the many legal luminaries he cites—that an agency should generally weigh the costs of its action against its benefits." *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 723 (D.C. Cir. 2016) (responding to dissent, which argued that cost consideration was required).

Riverkeeper, Inc., 556 U.S. 208 (2009); and *Michigan v. EPA*, 576 U.S. 743 (2015).[147] In *American Trucking*, EPA was precluded from considering costs; in *Entergy Corp.*, EPA was permitted to consider costs; and in *Michigan*, EPA was compelled to consider costs.

The CAA requires that, for certain listed air pollutants, EPA must issue air quality criteria for them based on factors relating to how each pollutant's presence in the atmosphere might affect public health or welfare.[148] Moreover, when EPA prescribes national primary ambient air quality standards (NAAQS) for certain air pollutants, CAA Section 109(b)(1) describes what EPA must consider in their establishment:

> ***National primary ambient air quality standards***, prescribed under subsection (a) ***shall be ambient air quality standards*** the attainment and maintenance of which in the judgment of the Administrator, ***based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health***. Such primary standards may be revised in the same manner as promulgated.

The Supreme Court held in *American Trucking* that EPA could not consider costs when setting NAAQS because cost considerations (including any balancing of costs and benefits) are not a criterion or consideration relating to public health.[149]

Subsequently, in *Entergy Corp. v. Riverkeeper, Inc.*, the Supreme Court upheld EPA's interpretation that it could consider cost as a factor in setting standards under CWA Section 316(b) for the design and operation of power plant cooling water intake structures to minimize adverse impacts to aquatic life, even where the statute was completely silent as to cost consideration. The statutory provision said:

> Any standard established pursuant to section 1311 of this title or section 1316 of this title and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact.[150]

The Court reasoned "that [CWA] § 1326(b)'s silence [as to cost] is meant to convey nothing more than a refusal to tie the agency's hands as to whether cost-benefit analysis should be used, and if so to what degree."[151] The Court also found that *American Trucking* "stands for the rather unremarkable proposition that sometimes statutory silence, when viewed in context, is best interpreted as limiting agency discretion."[152]

Finally, the Supreme Court addressed in *Michigan v. EPA* what type of statutory language affirmatively implies that cost must be considered by the agency. All nine Justices in

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[147] For a broader discussion of cases where benefit-cost analysis was found to be integral to particular environmental statutes, see *Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process*, 85 Fed. Reg. 84,130, 84,131-35 (Dec. 23, 2020).
[148] *See* 42 U.S.C. § 7408(a)(2).
[149] *Am. Trucking Ass'ns*, 531 U.S. at 465.
[150] 33 U.S.C § 1326(b).
[151] *Entergy Corp.* 556 U.S. at 222; *see also id.* at 212, 219-20, 226.
[152] *Id*. at 223.

Michigan agreed that "[c]ost is almost always a relevant—and usually, a highly important—factor in regulation. Unless Congress provides otherwise, an agency acts unreasonably in establishing 'a standard-setting process that ignore[s] economic considerations.'"[153]

At issue was what the CAA authorized EPA to consider when adding power plants as a category of sources of hazardous air pollutants. The statutory provision at issue in *Michigan* uses the words "appropriate and necessary" and does not expressly reference cost in the list of factors the agency must consider.[154] In its Mercury and Air Toxics rulemaking, EPA had concluded that, when adopting regulations for emissions by electric utility steam generating units ("power plants"), EPA was not required to consider costs.[155] CAA Section 112(n)(1)(A) states:

> The Administrator shall perform a study of the hazards to public health reasonably anticipated to occur as a result of emissions by electric utility steam generating units of pollutants listed under subsection (b) after imposition of the requirements of this chapter. … The Administrator shall regulate electric utility steam generating units under this section, if the Administrator finds such regulation is ***appropriate and necessary*** after considering the results of the study required by this subparagraph.[156]

The Supreme Court reviewed EPA's interpretation under its *Chevron* standard and concluded that EPA's refusal to consider costs reflected an unreasonable interpretation of the statute.[157] Although EPA must consider study results of hazards to public health reasonably anticipated to occur from power plant emissions, "Congress instructed EPA to add power plants to the program if (but only if) the Agency finds regulation 'appropriate and necessary.' … In particular, 'appropriate' is 'the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors.'"[158]

Inclusion of "appropriate" in the statute "requires at least some attention to cost," and "an agency may not 'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate."[159] The Supreme Court made clear the distinction between the statute at issue in *Michigan* and the CAA provision it assessed fourteen years earlier:

> *American Trucking* thus establishes the modest principle that where the Clean Air expressly directs EPA to regulate on the basis of a factor that on its face does not include cost, the Act normally should not be read as implicitly allowing the Agency to consider cost anyway. That principle has no application here. "Appropriate and necessary" is a far more comprehensive criterion than "requisite

[153] *Michigan*, 576 U.S. at 769 (dissenting opinion of Justice Kagan).
[154] *Id.* at 751-53.
[155] *Id.* at 749.
[156] 42 U.S.C. § 7412(n)(1)(A) (emphasis added).
[157] *Michigan*, 576 U.S. at 751 (citing *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (2015)).
[158] *Id.* at 752 (quoting *White Stallion Energy Center, LLC v. EPA*, 748 F.3d 1222, 1266 (D.C. Cir. 2014) (opinion of Kavanaugh, J.)).
[159] *Id.* (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)).

to protect the public health"; read fairly and in context, as we have explained, the term plainly subsumes consideration of cost.[160]

2. The Analysis in *Michigan v. EPA* Governs CERCLA Section 102(a), Requiring EPA to Consider Cost When Adopting Rules Revising the CERCLA Hazardous Substances List

Given the specific language in CERCLA Section 102(a), which resembles CAA Section 112(n)(1)(A), the holding in *Michigan* compels EPA to consider costs when designating PFOA and PFOS as hazardous substances. Congress expanded EPA's discretion to revise the list of substances deemed to be hazardous substances by including "appropriate" in CERCLA Section 102(a):

> The Administrator shall ***promulgate and revise as may be appropriate***, regulations designating as hazardous substances, in addition to those referred to in section 9601(14) of this title, 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, and shall promulgate regulations establishing that quantity of any hazardous substance the release of which shall be reported pursuant to section 9603 of this title.[161]

Like the CAA provision assessed in *Michigan*, Congress authorized EPA to revise the list of hazardous substances "as may be appropriate," and EPA's obligation to consider a substance's potential for presenting "substantial danger to the public health or welfare or the environment" is similar to EPA's obligation under CAA Section 112(n)(1)(A) to consider a study of a given pollutant's hazard to public health reasonably anticipated to occur from power plant emissions. Moreover, the logic of *American Trucking* is inapplicable to CERCLA Section 102(a) because, unlike the relevant provision of CAA Section 109(b)(1), which was referenced by CAA Section 109(d) expressly,[162] CERCLA Section 102(a) does not limit the criteria EPA may consider in designating hazardous substance to only "such criteria … requisite to protect public health" or some similar term. Nor did Congress expressly preclude EPA from considering costs in making the determinations specified in CERCLA Section 102(a).

EPA's justification for ignoring cost considerations when deciding to designate PFOA and PFOS as CERCLA hazardous substances pursuant to CERCLA Section 102(a) ignores critical details in the statutes and cited court opinions, resulting in a legal assessment divorced

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[160] *Id.* at 755-56 (quoting *Am. Trucking*, 531 U.S. at 467).

[161] 42 U.S.C. § 9602(a) (emphasis added). The language in CERCLA Section 102(a) also mirrors that of CWA Section 311(b)(2)(A), and EPA's consideration of costs when designated substances to be hazardous under that statute predate the passage of CERCLA itself. *Compare* 33 U.S.C. § 1321(b)(2)(A); *see* 43 Fed. Reg. 10,474, 10,479 (March 13, 1978) (when EPA first published its proposed regulations for CWA § 311 hazardous wastes, EPA had already "determined that the economic impact of the designation of hazardous substances could not be separated from a consideration of removability, harmful quantities and rates of penalty.").

[162] "[T]he Administrator shall complete a thorough review of the criteria published under section 7408 of this title and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards ***as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section***." 42 U.S.C § 7409(d)(1)(emphasis added)

from applicable law. EPA cherry-picks language from *American Trucking* to create a false impression that whenever Congress authorizes EPA to consider public health and welfare while making regulatory decisions, cost should be precluded.[163] CAA Section 109(b)(1), quoted in context, unlike the edited quote in the proposal, illustrates the stark difference between that statute and CERCLA Section 102(a). As *American Trucking* observes:

> Section 109(b)(1) instructs the EPA to set primary ambient air quality standards "the attainment and maintenance of which… are requisite to protect the public health" with "an adequate margin of safety."[164]

EPA incorrectly suggests that CERCLA Section 102(a) is similar to the quite different statutory provision that was at issue in *American Trucking*. Far from employing even remotely similar language, CERCLA Section 102(a) does not identify any standards to which hazardous substances should be subject; EPA acknowledges that "determinations of *whether and how to address* something hazardous" occur later "in the context of response actions," in which EPA might consider costs.[165] Unlike CAA Section 109(b)(1), CERCLA Section 102(a) delegates to EPA the discretionary authority to designate a substance as a CERCLA hazardous substance, not a mandatory duty to establish numeric limits "requisite" to protect the public health. If, instead, CERCLA Section 102(a) created a nondiscretionary duty for EPA to designate as a "hazardous substance" ***all*** "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…," table salt might have to be listed under this section, because freshwater fish would certainly face "substantial danger" if an errant truckload of sodium chloride crashed into their pond.[166] EPA acknowledges the holding in *Michigan* that Congress' inclusion of the broad term "appropriate" requires "consideration of all the relevant factors," including "at least some attention to cost."[167] As for the presence of "appropriate" in CERCLA Section 102(a), EPA confusingly asserts that it "is not used in the context of what EPA should consider when assessing whether a substance is hazardous," but then says CERCLA Section 102(a) commands it to "promulgate and revise as may be appropriate regulations that accomplish the statutory goal of designating hazardous substances."[168] As the words are literally identical, this falls short of even the proverbial "distinction without a difference."[169]

EPA's final attempt to justify its decision to ignore cost considerations is by analogy to RCRA. In *Utility Solid Waste Activities Group v. EPA*, the D.C. Circuit held that

> Under any reasonable reading of RCRA, there is no textual commitment of authority to the EPA to consider costs in the open-dump standards. RCRA's statutory language instructs the EPA to classify a disposal site as a sanitary landfill and not an open dump only "if there is no reasonable probability of

[163] *See* 87 Fed. Reg. at 54,421(quoting *Am. Trucking*, 531 U.S. at 465).
[164] *Am. Trucking*, 531 U.S. at 465 (quoting 42 U.S.C. § 7409(b)(1)).
[165] 87 Fed. Reg. at 54,421 (emphasis in original).
[166] CERCLA § 102(a), 42 U.S.C. § 9601(a) (emphasis added).
[167] 87 Fed. Reg. at 54,421 (quoting *Michigan*, 576 U.S. at 752).
[168] 87 Fed. Reg. at 54,421.
[169] *Sessions v. Dimaya*, 584 U.S. __, 138 S. Ct. 1204, 1218 (2018).

> ***adverse effects on health or the environment*** from disposal of solid waste at such facility."[170]

Yet, in the following sentence, the D.C. Circuit distinguished *Michigan* because the RCRA statute lacked "any flexible language such as 'appropriate and necessary' that might allow the EPA to consider costs in its rulemaking."[171] As CERCLA Section 102(a) unquestionably states that EPA may designate substances as CERCLA "hazardous" substances "*as may be appropriate*," (emphasis added), CERCLA Section 102(a) is closer to the CAA provision in *Michigan* than to the RCRA provision in *Utility Solid Waste Activities Group*, which in turn reflects the same principle that was dispositive in *American Trucking*.

3. CERCLA "Hazardous Substances" Automatically Include Hazardous or Toxic Wastes and Pollutants Pursuant to Other Federal Environmental Regulatory Laws, the Designations of Which Sometimes Require Considerations of Cost

In addition to Congress' delegation of authority to EPA to add substances to the list of hazardous substances under CERCLA Section 102(a), CERCLA's definition of "hazardous substance" requires automatic inclusion of certain substances declared to be hazardous or toxic wastes or pollutants pursuant to other federal environmental regulatory laws.[172] At least one of these provisions clearly requires EPA to consider costs; it contains the same operative language as does CERCLA Section 102(a).

a. CWA Section 311(b)(2)(A) Requires EPA to Consider Costs

Congress appeared to model the statutory language in CERCLA Section 102(a) on CWA Section 311(b)(2)(A), which requires, in pertinent part, that EPA:

> [S]hall ***develop, promulgate, and revise as may be appropriate*** regulations designating as hazardous substances…, such elements and compounds which, when discharged in any quantity into or upon the navigable waters of the United States or adjoining shorelines… present an imminent and substantial danger to the public health or welfare, including but not limited to fish, shellfish, wildlife, shorelines, and beaches.[173]

Although Congress instructed EPA to assess whether substances may "present an imminent and substantial danger to the public health or welfare," the fact that Congress authorized EPA to "develop, promulgate and revise" this hazardous substances list "as may be appropriate," requires application of the analysis in *Michigan*, not *American Trucking*. Therefore, EPA must consider costs when revising the list of CWA Section 311(b)(2)(A) hazardous substances.[174]

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[170] 901 F.3d 414, 448-449 (D.C. Cir. 2018) (emphasis in original) (quoting 42 U.S.C. § 6944(a)).
[171] *Id.* at 449 (quoting *Michigan*, 576 U.S. at 756, 135 S. Ct. at 2709).
[172] 42 U.S.C. § 9601(14).
[173] 33 U.S.C. § 1321(b)(2)(A) (emphasis added).
[174] The same basic reasoning and analysis likewise apply to RCRA Section 3001(b). See RCRA § 3001(b)(1).

Indeed, EPA has considered costs when assessing substances for designation as CWA Section 311 hazardous substances since before the program was implemented. On December 30, 1975, when EPA first published its proposed regulations for CWA Section 311 hazardous wastes, EPA had already "determined that ***the economic impact of the designation of hazardous substances could not be separated from a consideration of removability, harmful quantities and rates of penalty***."[175] The fact that the "economic impact of the proposed regulations was not considered major" did not excuse EPA from conducting the economic analysis at all.[176]

Moreover, as part of EPA's initial designation of hazardous substances in 1978, EPA prioritized regulation of "materials of relatively low market price and relatively high toxicity, i.e., meeting the toxicological selection criteria" by considering the value of the product to be regulated.[177] For sufficiently toxic candidate substances with annual production of less than one billion pounds annually:

> the selling price of the substance at the first commercial market level was examined. Available evidence appeared to indicate that substances with relatively high selling prices had a smaller discharge frequency, since more expensive chemicals are generally packaged and shipped in smaller quantities, and with greater precautions. If a candidate substance had a high selling price relative to the majority of substances, it was not further considered for testing.[178]

In this way, the financial value of the substances subjected to regulation was deemed by EPA to be inversely proportional to the substances' need for regulation. For example, EPA maintained ammonium bicarbonate's designation as a hazardous substance because its "diverse industrial use," 16 million pound annual production, and "low selling price of $0.10 to $0.12 per pound" indicated "a reasonable discharge potential."[179] Conversely, EPA agreed to delete antimony pentafluoride from the designation list because its "annual production quantities of less than 5,000 pounds and a selling price of $15 per pound" for "limited application as a catalyst in organic synthesis" suggested "a low potential for discharge…."[180] There is no credible reason to conclude that "the economic impact of the designation of hazardous substances" were appropriately considered for designations pursuant to Section 311 but must be ignored for designations pursuant to CERCLA Section 102(a).

b. The Definition of Imminently Hazardous Substances in TSCA Section 7 Expressly Prohibits Consideration of Costs

CERCLA hazardous substances, by definition, include "any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of [TSCA]," which in turn currently defines "imminently hazardous chemical substance or mixture" to mean:

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[175] 43 Fed. Reg. 10,474, 10,479 (March 13, 1978) (emphasis added).
[176] *Id.*
[177] *See id.* at 10,475.
[178] *Id.*
[179] *Id.* at 10,477.
[180] *Id.*

> a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, ***without consideration of costs or other nonrisk factors***.[181]

It follows that EPA cannot consider costs when assessing whether to take action under TSCA Section 7 regarding a substance, an express prohibition conspicuously absent from CERCLA Section 102(a).

However, costs *were* relevant under TSCA Section 7 as it stood in 1980, the year when CERCLA was enacted, which long preceded the Lautenberg amendments of 2016. At that time, TSCA Section 7(f) defined an "imminently hazardous chemical substance or mixture" as one that "present[ed] an imminent and unreasonable risk of serious or widespread injury to health or the environment."[182] "Imminent" was further defined as "likely to result in injury to health or the environment before a final rule under section 6 [now 42 U.S.C. § 2605] of this title can protect against such risk."[183] Section 2605 was (and still is) the mechanism by which EPA can take action against substances posing "unreasonable risk." Thus, in 1980, for EPA to issue a rule concluding that a substance presented "unreasonable risk," EPA had to consider "the reasonably ascertainable economic consequences of the rule."[184] Therefore, CERCLA Section 102(a) should be read in a similar manner as the contemporaneously enacted provision, that EPA must consider the economic consequences of the rule when determining a substance is hazardous.

c. At a Minimum, CERCLA Section 102(a) Does Not Preclude EPA From Considering Costs

As we have explained, Section 102(a) *requires* the consideration of costs in designating a substance as hazardous under that provision. But we respectfully submit in the alternative that, at a minimum, EPA's assertion that it is forbidden from considering costs under CERCLA Section 102(a) is clearly erroneous and unreasonable. At the very least, EPA possesses discretion to consider costs under Section 102(a), as there is no textual indication that Congress precluded consideration of cost. It would be arbitrary and capricious for EPA to finalize such a designation without providing a rational explanation of how and why it exercised its discretion to reject cost consideration when courts have recognized repeatedly that cost is almost always a fundamental consideration in regulation. That is particularly the case where, as here, cost is a highly relevant and important factor in deciding whether it is "appropriate" to list PFOA and PFOS as hazardous substances, given the likely far-reaching legal and economic consequences, and now that these comments have raised the issue.[185]

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[181] Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. Law No. 114-182 § 7(f), 130 Stat. 470 (June 22, 2016) (codified as amended at 15 U.S.C. § 2606(f) (2020) (emphasis added).
[182] Toxic Substances Control Act, Pub. Law No. 94-469, § 7(f), 90 Stat. 2027 (Oct. 11, 1976) (codified at 15 U.S.C. § 2606(f) (1976)).
[183] *Id.*
[184] *Id.*, § 6(c)(1)(D), 90 Stat. 2022 (Oct. 11, 1976) (codified at 15 U.S.C. § 2605(c)(1)(D) (1976)).
[185] *See, e.g., Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016).

D. EPA's Economic Assessment Is Grossly Inadequate

As discussed earlier in these comments, EPA has taken the position that costs do not need to be considered when designating chemicals as CERCLA hazardous substances. While OMB has designated this rulemaking to be an economically significant action, EPA has not provided a complete regulatory impact analysis and instead has provided only an "Economic Assessment" of potential costs.[186] For a regulation of this importance, significance, and size, this is unacceptable and not consistent with EOs 12866 and 13563 and Circular A-4. EPA's requests for comment on the Economic Assessment do not negate the need for a far more robust analysis. In fact, comments that EPA receives on the proposed rule should be used to inform a proper RIA. Once EPA receives these comments, it should develop a complete RIA that is sufficient to show how the benefits of this rule outweigh the significant costs. This analysis should be released for public comment, along with a revised proposal that takes its findings into account. If the costs were appropriately considered, as discussed below, EPA would find that the decision to designate PFOA and PFOS as hazardous substances is not justified, especially as the outcomes of reduced exposure and accelerated cleanup can be achieved with alternative, less costly means.

1. A Robust Impact Analysis Can and Should Be Developed by EPA

EPA acknowledges that, if finalized, this regulation would indeed lead to increases in the number of CERCLA response actions and that the response costs are more likely to be borne by responsible parties. Yet EPA has taken a position that the uncertainties are too great to quantify, making quantitative estimates "impractical." EPA has provided only a minimal break-even analysis that solely considers the cost of reporting a release to EPA, when considering the impacts on small entities. EPA states that "the multiple, contingent, discretionary and site-specific steps between designation of a hazardous substance and the incurrence of cleanup costs contribute to the inability to quantify costs at the designation stage."[187]

We disagree with the proposition that the uncertainties are too great to conduct a robust analysis. In fact, experts have conducted such an analysis; and we provided it to EPA on June 8, 2022.[188] This analysis, *PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites* (referred to as the Cleanup Cost Analysis),[189] estimates that the costs of cleanup for potentially responsible parties (PRP) could total over ***$17.4 billion dollars*** for existing non-federal national priority sites alone.[190] Annualized private party cleanup costs at existing non-federal sites could

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[186] *See* EPA, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances*, EPA-HQ-OLEM-2019-0341-0035.
[187] 87 Fed. Reg. at 54442.
[188] This analysis, *PFOS and PFOA Private Cleanup Costs at Superfund Sites* was provided to EPA on June 8, 2022, and was also submitted to the regulations.gov docket EPA–HQ–OLEM–2019-0341 on Nov 7, 2022.
[189] The analysis, conducted by experts and prepared for the US Chamber of Commerce, is available at https://www.uschamber.com/environment/pfos-and-pfoa-private-cleanup-costs-at-non-federal-superfund-sites.
[190] Mean estimates for existing NPL sites alone are present value $17.4 billion (90 percent prediction interval equaling $10 billion to $27.2 billion) using a 3 percent discount rate and $9.8 billion (90 percent prediction interval equaling $5.9 billion to $15 billion) using a 7 percent discount rate.

cost $700-$900 million annually.[191] Despite any existing uncertainties, which are qualitatively and quantitatively discussed in the Cleanup Cost Analysis, these costs are simply too large for EPA to ignore.

Further, the DoD's ongoing remediation work provides example cost data that EPA could use to build estimates.[192] Recognizing that private parties are not the only parties impacted by this proposal, EPA should conduct additional economic modelling for federal facilities, municipalities responsible for community water systems, landfills, publicly owned treatment works, and potential state and local brownfield sites. While there are uncertainties in the Cleanup Cost Analysis, and there will be uncertainties in the additional analyses, none of these uncertainties are so great that they should preclude additional analysis. In fact, EPA has acknowledged cleanup cost uncertainties in the past and has still estimated these costs.[193]

2. EOs 12866 and 13563 and OMB Circular A-4 Require a Regulatory Impact Analysis

EOs 12866 and 13563 together establish the requirement that economically significant regulatory actions must be supported by a RIA that includes an assessment of the benefits and costs anticipated from the regulatory action, quantified to the extent feasible, as well as a similar assessment and quantification for identified potential alternatives.[194] EO 13563 further requires that these assessments "use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible."[195] The best available technique for quantifying the benefits of EPA regulations that are directed toward reducing risks is risk assessment. To implement these directives, agencies are instructed to follow OMB Circular A-4, which describes the elements that must be in the regulatory impact analysis of an economically significant regulation.[196] EPA's proposed rule and the associated Economic Assessment do not meet the most basic requirements of a regulatory impact analysis as required by EOs 12866 and 13563 and Circular A-4.

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[191] *See* EPA, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances*, EPA-HQ-OLEM-2019-0341-0035, at 4.

[192] *See* 217-2019 Remediation Market Survey (Sept. 7, 2022): https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0201.

[193] For example, EPA estimated the cost of cleanup at 456 non-federal NPL sites comprising 1,073 operable units (OUs) with planned remedial actions at between $15.5 and $23.3 billion in 2003 dollars (*see* EPA Office of Solid Waste and Emergency Response, Cleaning Up the Nation's Waste Sites: Markets and Technology Trends: 2004 Edition, EPA 542-R-04-015. 2005). In the same study, EPA uses a similar approach to the Chamber's model to project future CERCLA cleanup costs and derives a range from $23 billion to $50 billion. The study makes key assumptions in the absence of available data, for example, "[i]t was assumed that 50 percent of sites with RD underway have already incurred the RD costs, 50 percent of sites with study underway already have incurred RI/FS costs, and 45 percent of all sites will require LTRA."

[194] *See* EO 12866, § 6(a)(3)(C); EO 13565, § 1(b).

[195] *See* EO 13565, § 1(c). As then OIRA Administrator Cass Sunstein put it, EO 13563 "made an unprecedented commitment to quantification of both costs and benefits." Cass R. Sunstein, "The Stunning Triumph of Cost-Benefit Analysis, Bloomberg Opinion, Sept. 12, 2012. https://www.bloomberg.com/opinion/articles/2012-09-12/the-stunning-triumph-of-cost-benefit-analysis.

[196] OMB Circular A-4 is available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.

First, Circular A-4, consistent with EO 12866, requires a statement of need for the regulatory action. This statement should describe the problem that the agency seeks to address. In the Economic Assessment, while EPA has a section entitled "Need for Regulatory Action," EPA does not describe any problem or problems that need fixing.[197] EPA does state that the action would "further CERCLA's primary goal of protecting public health and welfare," but this is not a problem. EPA has not explained why CERCLA, as it currently exists, is not protecting public health and welfare. EPA notes that the designations of PFOA and PFOS as hazardous substances would improve information quality and improve our understanding of PFOA and PFOS releases. However, there is no discussion of a problem that exists due to poor quality information, nor is there a discussion of problems caused by an information insufficiency. The other actions proposed by EPA's Strategic Roadmap do not obviously require designation under CERCLA to achieve the key outcomes. Without identifying a problem, there is no justification for the proposed PFOA and PFOS designations.

Second, Circular A-4, consistent with EO 12866, requires an examination of alternative approaches that the agency considered. Neither the proposed rule nor the Economic Assessment provide any discussion of alternatives that EPA considered. The lack of consideration of even one viable alternative is an egregious error that must be corrected.

Third, Circular A-4, consistent with EOs 12866 and 13563, requires an evaluation of the benefits and costs, quantitative and qualitative, of the proposed action and the main alternatives identified by the analysis. Unfortunately, EPA quantifies only reporting costs and ignores the reasonably foreseeable and predominant quantifiable cleanup costs that would be associated with designating PFOA and PFOS as hazardous substances. Not only does EPA ignore costs to private parties, but it also ignores costs to states, tribes, municipalities, federal facilities, publicly owned treatment works, and landfills. Arguing that most impacts are "indirect effects" is not compelling, as Circular A-4 makes clear that the economic analysis "should look beyond the direct benefits and direct costs" of the rulemaking. Similarly, EPA's arguments that the information is too uncertain also fall flat. Uncertainty is not an acceptable excuse for providing a subpar analysis that ignores the costliest aspects of the proposal. Circular A-4 provides agencies with many options for quantitatively treating uncertainty, including but not limited to sensitivity analyses and probabilistic analyses. Finally, as we have noted previously, as no alternatives are presented, there is no analysis of alternatives.

3. EPA Ignores Indirect Costs of the Listing Decision Even as it Promotes the Potential Indirect Benefits Associated With Additional Site Cleanup

EPA's Economic Assessment estimates only the costs associated with reporting activity. All costs related to potential increases in response activities and increases in the speed of response activities are only qualitatively described. EPA refers to these costs as indirect costs. However, when EPA discusses the benefits of the proposed rule, all the reported benefits related

[197] EPA's *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) as Hazardous Substances* (August 2022) at 23, https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0034.

to health protection stem from these "indirect" effects.[198] This disconnect is particularly noticeable in Section VI (Effect of the Designation) of the proposed rule preamble. When discussing the effect of the designations in this section, EPA makes no mention of increases in response activities and the increases in the speed of response. EPA cannot have it both ways. It cannot, and should not, tout the alleged health benefits of a proposal and then simply ignore their costs. The costs associated with conducting response activities, including the significant costs associated with complex litigation that frequently occurs under CERCLA, is a direct impact of designating substances as CERCLA hazardous substances and must be considered in a regulatory impact analysis.

EPA states that "the multiple, contingent, discretionary and site-specific steps between designation of a hazardous substance and the incurrence of cleanup costs contribute to the inability to quantify costs at the designation stage."[199] This is not convincing. These costs are reasonably foreseeable, ascertainable, and capable of being estimated. As noted above, external experts were able to conduct such an analysis for costs to private parties. EPA has sufficient data from which they can extrapolate and conduct a bounding or sensitivity analysis. Indeed, the proposed rule preamble describes the available data on PFOA and PFOS prevalence, which EPA could easily use as a starting point for extrapolations to inform predictions of new sites that might be designated or additional sites that may require reopening for remediation. Similarly, EPA has a wealth of information to inform the frequency at which sites are placed on the NPL; data also exist to inform the costs of final cleanup decisions, as memorialized in public Records of Decisions (ROD). While these analyses may not be perfect, they would be far superior to simply ignoring costs which are an inevitable and direct result of the proposed rule.

4. EPA's Projected Costs Are Significantly Underestimated

As noted above, in the Economic Assessment provided by EPA, only the reporting costs are quantified. EPA claims that other costs are indirect and/or too uncertain to be quantified. Yet these costs are neither indirect nor too uncertain to be quantified.

Regarding indirect costs, EPA's Guidelines for Preparing Economic Analyses (2010) states: "Indirect costs are the costs incurred in related markets or experienced by consumers or government agencies not under the direct scope of the regulation. These indirect costs are usually transmitted through changes in the prices of the goods or services produced in the regulated sector."[200] Consistent with the direct liabilities that come with a CERCLA designation, impacts to the public, governments (federal, state, local, and tribal), municipalities, publicly owned treatment works, and landfills must be considered by EPA.[201] As discussed above, our external

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[198] See 87 Fed. Reg. at 54,418 ("A faster pace of cleanups would provide public health protection for affected communities sooner and could reduce the cost of individual cleanups (generally, the sooner contamination is addressed, the less it spreads and the smaller the area that needs to be cleaned).").

[199] 87 Fed Reg. at 54442.

[200] EPA's Guidelines for Preparing Economic Analyses are available at: https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses.

[201] CERCLA Section 107, 42 U.S.C. § 9607, in discussing liability, clearly defines persons covered by the statute and the direct coverage is quite inclusive:

> **(a) Covered persons; scope; recoverable costs and damages; interest rate; "comparable maturity" date**

analysis puts a subset of these costs at over ***$17.4 billion*** for existing non-federal national priority sites. This does not include federal, state, local, and tribal sites. It also does not include the costs related to reopening existing sites or adding additional sites to the NPL or costs due to disruptions at many ongoing remediation sites.

EPA's quantified cost upper end value of $370,000 is simply not representative of the direct liabilities that come with a PFOA and PFOS CERCLA designation, which are not only foreseeable but EPA's intended end goal of this rulemaking. EPA's qualitative discussion of direct costs is also insufficient, as it covers only costs associated with CERCLA Section 120(h) notifications. EPA's discussion of indirect qualitative costs is also insufficient. EPA must consider not only the costs associated with site cleanups, investigations, and associated litigation, but also the direct impacts that this rulemaking will have on slowing the speed of ongoing state cleanups and brownfield remediations. Agricultural impacts (due to impacts on biosolids) should also be considered, along with the increased waste management challenges that will be created by the soil that could be deemed to be a hazardous substance.

EPA also fails to consider the cost of "regulatory familiarization" in the economic analysis. Regulatory familiarization costs account for the value of time and effort that every potentially affected individual or business must undertake to determine if the regulation applies to their situation or not, and how their activities must adapt to comply. It is often the largest component of the initial year economic cost of any regulation. When an agency takes careful notice of the regulatory familiarization issue, it writes the rulemaking notice and accompanying public communications in a manner that makes it immediately clear to unaffected persons and entities that the new rule does not apply to them. This attention to communication detail minimizes the familiarization time. Neglecting this analysis can unintentionally impose an enormous familiarization cost burden on the general public. In this proposal, EPA has assumed

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> Notwithstanding any other provision or rule of law, and subject only to the defenses set forth in subsection (b) of this section—
> (1) the owner and operator of a vessel or a facility,
> (2) any person who at the time of disposal of any hazardous substance owned or operated any facility at which such hazardous substances were disposed of,
> (3) any person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person, by any other party or entity, at any facility or incineration vessel owned or operated by another party or entity and containing such hazardous substances, and
> (4) any person who accepts or accepted any hazardous substances for transport to disposal or treatment facilities, incineration vessels or sites selected by such person, from which there is a release, or a threatened release which causes the incurrence of response costs, of a hazardous substance, shall be liable for—
>
> (A) all costs of removal or remedial action incurred by the United States Government or a State or an Indian tribe not inconsistent with the national contingency plan;
> (B) any other necessary costs of response incurred by any other person consistent with the national contingency plan;
> (C) damages for injury to, destruction of, or loss of natural resources, including the reasonable costs of assessing such injury, destruction, or loss resulting from such a release; and
> (D) the costs of any health assessment or health effects study carried out under section 9604(i) of this title.

that there will be no incremental costs associated with rule familiarization.[202] This assumption is flawed.

As proposed, this rule could potentially impact 261,477,000 persons and 7.96 million business establishments.[203] Under the heading "Does this rule apply to me?" EPA states "any person … as soon as they have knowledge of any release … at or above the reportable quantity must immediately report such releases."[204] This imposes on every person a duty to be aware and to be alert. The initial year familiarization cost will most likely exceed the $100 million threshold of EO 12866's designation of an "economically significant" rulemaking and the $150 million threshold for designation of a "major" rule under the Congressional Review Act.[205]

The agency should withdraw the proposed rule, undertake the data collection and communication strategy work that needs to be done before issuing any proposed rule, and realistically consider familiarization cost burdens in its presentation of any future proposals. It should also consider ways in which individuals and business establishments could be exempted from the proposal in order to decrease the cost burdens of rule familiarization.

E. The Proposed Rule Does Not Appropriately Analyze Costs to Small Business and Creates Unfunded Mandates

EPA inappropriately certifies under the Regulatory Flexibility Act (RFA) that this proposed rule would not have a significant economic impact on a substantial number of small entities, and thus that it does not need to complete a regulatory flexibility analysis or initiate the Small Business Regulatory Enforcement Fairness Act (SBREFA) panel process.[206] EPA also mischaracterizes the rule as not containing an unfunded mandate of $100 million or more as described in the Unfunded Mandates Reform Act (UMRA) and does not significantly or uniquely affect small governments.[207] EPA's basis for these certifications is on its calculation of the nominal costs of reporting releases only. EPA does not consider the significant costs that a final rule would impose on small businesses as well as state, local, and tribal governments in

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[202] EPA, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) as Hazardous Substances* (Aug. 2022) at 40, https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0034.

[203] 261,477,000 is estimated U.S. civilian non-institutional population age 16 and older in 2021 (annual average) as reported by Bureau of Labor Statistics at https://www.bls.gov/news.release/empsit.a.htm; 7.96 million is estimated number of U.S. private business establishments in 2019 (latest available) published by U.S. Census at https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html.

[204] 87 Fed. Reg. at 54,416.

[205] The dollar values are simple multiplications of the population and business establishment totals by the hourly wage ($32.46 hourly wage for individuals per BLS at https://www.bls.gov/news.release/empsit.t19.htm and $59.31 per BLS hourly wage for business establishment managers at https://www.bls.gov/Oes/current/oes110000.htm. Using a *de minimis* one hour time frame to read EPA's public information materials, the cost to individual citizens would be $8.5 billion, and the cost to business establishments would be $466.1 million. Because the actual time burdens to read and understand the EPA public information materials and the regulatory text are likely much greater than the one hour parameters used in these hypothetical examples, and because the opportunity cost time values may also be greater, the actual familiarization cost burden of the proposed rule as published is likely much more than the $8.95 billion sum of the calculations shown above.

[206] 87 Fed. Reg. at 54,440.

[207] *Id*.

triggering CERCLA site cleanup response actions. The proposed rule fails to appropriately analyze what EPA describes as "indirect" costs in assessing whether its obligations under the RFA/SBREFA or the UMRA are triggered.

EPA must consider the potential impact that listing PFOA and PFOS as hazardous substances will have on small entities and small governments in terms of 1) the costs that small businesses could incur for cleanup of sites contaminated with potentially miniscule levels of PFOA and PFOS,[208] and 2) the costs that state and local governments, as well as the private sector, could incur from the rule, particularly local water and wastewater systems. If EPA were to properly consider these costs, it would conclude that the rule would have a significant economic impact on a substantial number of small entities, and thus that it is required to complete a regulatory flexibility analysis and to work with the Small Business Administration's Office of Advocacy to convene a SBREFA panel to ensure appropriate public engagement concerning the impacts on small entities from this proposed rule. EPA must adhere to the consultation requirements of SBREFA and the UMRA to comply with law and to ensure the rule will be cost-effective for small entities, including small businesses and small governments.

1. EPA Is Required to Perform a Regulatory Flexibility Analysis and Undergo the SBREFA Panel Process

The RFA[209] as amended by SBREFA[210] is intended to "fit regulatory requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to the regulation" by requiring that agencies determine a rule's economic impact on small entities.[211] Congress found that small businesses bear a disproportionate share of regulatory costs and burdens, and therefore that reforms were necessary to make agencies more responsive to small businesses, provide them with more resources, and hold agencies accountable for their enforcement actions.[212] In enacting SBREFA, Congress emphasized the importance of agencies undertaking this comprehensive review of the potential impacts of a rulemaking on small entities by subjecting an agency's certification that a rule does not have a significant economic impact on a substantial number of small entities to judicial review. Congress empowered courts to not only order an agency to take corrective action if it is found to violate the RFA, but also remand the rule, defer enforcement of the rule against small entities, or enter other relief, including staying the effective date of a rule.[213] Congress intended for agencies to take this obligation to assess impacts on small entities seriously, as a failure to do so could result in significant delays in implementing the rule or a remand of the rule.

Consistent with the intent of the RFA, EPA was required in this proposed rule to evaluate the costs and regulatory burdens that small entities would bear if PFOA and PFOS are designated

[208] EPA has announced near-zero interim health advisories, which recommend levels below available detection or treatment methods. 87 Fed. Reg. 36,848 (June 21, 2022).
[209] 5 U.S.C. § 601 et seq.
[210] Pub. L. No. 104-121.
[211] See EPA website, "Summary of the Regulatory Flexibility Act, as amended by [SBREFA]," https://www.epa.gov/laws-regulations/summary-regulatory-flexibility-act-amended-small-business-regulatory-enforcement.
[212] Pub. L. No. 104-121, Section 203 Purposes.
[213] 5 U.S.C. § 611(a)(4)-(5).

as hazardous substances. EPA's certification that the rule does not have a significant impact on a substantial number of small entities is flawed in that it considered only release reporting costs. EPA evades its obligation to do a full regulatory flexibility analysis and initiate the SBREFA panel process by pointing only to what it considers to be "direct" compliance costs of release reporting. EPA must also consider the potential burdens and costs that designating PFOA and PFOS as hazardous substances will have on small entities that are considered potential responsible parties.

In EPA RFA guidance, EPA indicates that the "simplest method" of screening economic impacts on small entities is a comparison of the compliance costs faced by small entities (estimated as the capital, operating, maintenance, administrative, and other direct compliance costs associated with the rule) to one or more financial statistics (e.g., sales, profits, operating expenditures) of the regulated small entities.[214] While EPA uses the term "direct" costs in this guidance, the costs for small businesses to contribute to site cleanup and remediation, and the cost of hiring expert consultants to negotiate settlements with EPA, go directly towards operating costs and impacts associated with the rulemaking. Small entities could face substantial remediation costs and incur legal and consulting fees in an attempt to disentangle themselves from CERCLA lawsuits.

EPA must satisfy its obligations under the RFA by assessing the potential costs of this rulemaking on small entities beyond only the release reporting requirements. EPA must evaluate the costs that small entities will incur who potentially have PFOA and PFOS on their sites (at any level) and who could become potentially responsible parties in costly and time-consuming CERCLA cleanup actions.

2. EPA Must Comply With the Requirements of the Unfunded Mandate Reform Act

The Unfunded Mandates Reform Act (UMRA)[215] is intended to avoid imposing unfunded federal mandates on state, local, and tribal governments (SLTG) or the private sector. The UMRA applies to proposed and final rules that are subject to notice and comment and include a federal mandate that may result in the expenditure of funds by SLTG in the aggregate, or by the private sector, of $100 million or more in any one year. If a rule is subject to the UMRA, the agency must prepare a written statement ("regulatory impact statement") that includes a cost-benefit assessment and a summary of SLTG concerns and how they were addressed. The agency must also consider regulatory alternatives and select the least costly, least burdensome, or most cost-effective option that achieves the objectives of the rule or explain why the agency did not make such a choice. The agency must also consult with elected officers of SLTG to provide input in the development of proposed rules containing significant federal intergovernmental mandates.

[214] EPA Office of Policy and Economics Innovation, "EPA's Action Development Process, Final Guidance for EPA Rulewriters: Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act" (Nov. 2006) at 20, available at https://www.epa.gov/sites/default/files/2015-06/documents/guidance-regflexact.pdf.
[215] 2 U.S.C. § 1531-1538.

EPA has once again sidestepped its statutory obligations to satisfy these requirements of the UMRA by considering only the costs to SLTGs and the private sector of reporting releases. EPA says in the proposed rule that the rule does not contain an unfunded mandate of $100 million or more and does not significantly or uniquely affect small governments: "This action is expected to result in reporting costs of $561 per release that meets or exceeds the RQ, and the estimated annual cost of the proposed rule is not expected to exceed $370,000 per year."[216] EPA ignores the costs that its designation of PFOA and PFOS as hazardous substances would have on SLTGs and the private sector from costs associated with site cleanup. Per EPA's own guidelines for preparing economic analyses, the UMRA requires that cost estimates take into account both indirect and implicit costs on state and local governments.[217]

Stakeholders from state and local governments have already warned EPA that the "direct and indirect economic consequences on local governments, landfills, and water/wastewater systems by this rulemaking warrant consultations required by statute and established practice" given the "reasonable prospect that the rule will impose new and significant economic burdens on local governments."[218] EPA must be cognizant of impacts that will be incurred by local governments and water and wastewater systems:

> Communities will likely bear significant legal fees, if not the cost of corrective action, if PFOA and PFOS are listed as hazardous substances under CERCLA. For context, there are almost 16,000 wastewater treatment works in the United States, which in keeping with EPA policy, historically and currently pursued beneficial uses for solids from their treatment processes. The nation's roughly 50,000 community water systems are similarly at risk of such expenses and liability due to their need to dispose of PFOA and PFOS that are removed from drinking water supplies during the water treatment process. Finally, municipal governments could incur liability due to other facilities they have operated where PFOA and PFOS contamination occurred, such as fire training facilities and landfills.[219]

In addition to these costs, designation of PFOA and PFOS as hazardous substances under CERCLA would increase costs for potentially responsible parties that are private entities, municipal utilities and waste management facilities, and governments, as CERCLA requires states to pay for 10 percent of remedial action costs and 100 percent of operating and maintenance costs at certain sites. EPA fails to explain why it precluded consideration of these costs in assessing the impacts on STLGs and the private sector.

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[216] 87 Fed. Reg. at 54,440.
[217] EPA, Guidelines for Preparing Economic Analyses (Dec. 17, 2010, updated May 2014) at 8-7, https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf.
[218] *See* U.S. Conference of Mayors, Association of Metropolitan Water Agencies, National League of Cities, California Association of Sanitation Agencies, National Association of County Officials, National Association of Clean Water Agencies, American Water Works Association, National Association of Water Companies, National Rural Water Association, and Water Environment Federation, letter to Barry Breen, OLEM (July 11, 2022), https://www.amwa.net/system/files/linked-files/2022%2007%2011%20Jt%20Association%20Letter%20CERCLA%20PFAS%20Not%20Locked.pdf.
[219] *Id*.

Without an explanation of why it did not consider these costs, EPA fails to satisfy its obligations under the UMRA to assess whether the proposed rule may result in the expenditure of funds by SLTG in the aggregate, or by the private sector, of $100 million or more in any one year. If it had, the likely result would be that EPA is required under the UMRA to consult with SLTGs and prepare a regulatory impact statement. EPA would also be required to consider regulatory alternatives and select the least costly, least burdensome, or most cost-effective option that achieves the objectives of the rule or explain why it did not make such a choice.

F. EPA Makes No Showing That its Designations Pursuant to CERCLA Section 102(a) Are Entitled to Retroactive Treatment

CERCLA has also been interpreted to create retroactive liability. The Act has been construed broadly in order to give effect to its purpose,[220] and even though retroactivity is not set out expressly in CERCLA's statutory text, every court of appeals to have considered the question has concluded that Congress intended CERCLA to apply retroactively to current and former owners, operators, arrangers, and transporters.[221] Nonetheless, it is well settled that federal laws and regulations are not construed to have retroactive effect unless there is a clear statement in the statute that indicates retroactive application.[222]

EPA's justification for designating PFOA and PFOS as hazardous substances fails to even address how EPA's exercise of the authority delegated by Congress in CERCLA Section 102(a) should be afforded retroactive effect. Congress did not delegate in CERCLA Section 102(a) the power to assign sweeping retroactive liability, which in the case of PFOA and PFOS would subject millions of unexpecting property owners to liability.

1. CERCLA Section 102(a) Does Not Authorize Application of EPA's "Hazardous Substances" Retroactively

The EPA's justification for designating PFOA and PFOS as "hazardous substances" pursuant to CERCLA Section 102(a) makes no attempt to explain why such a designation should enjoy the same retroactive treatment as is provided for other substances that Congress declared to be "hazardous substances" under CERCLA. As the U.S. Supreme Court explained in *Bowen v. Georgetown University Hospital*,

> Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result. By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms. Even where some substantial justification for

[220] *B.F. Goodrich Co. v. Betkoski*, 99 F.3d 505, 514 (2d Cir. 1996).
[221] *See, e.g., Commonwealth Edison Co. v. United States*, 271 F.3d 1327, 1350-51 (Fed. Cir. 2001); *United States v. Northeastern Pharm. & Chem Co.*, 810 F.2d 726, 734 (8th Cir. 1986); *United States v. Monsanto Co.*, 858 F.2d 160, 174 (4th Cir. 1988); *Franklin County Convention Facilities Auth. v. Am. Premier Underwriters, Inc.*, 240 F.3d 534, 551-52 (6th Cir. 2001).
[222] *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *Landgraf v. USI Film Prods.*, 511 U.S. 244, 270 (1994).

> retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.[223]

In this instance, EPA cannot skirt the question whether CERCLA Section 102, from which it derives the authority it seeks to exercise here, delegates to the Administrator power to create retroactive liability. In a single footnote, EPA acknowledges that Section 102(a) operates "prospectively" like other "traditional regulatory statute[s]" in certain respects, yet simultaneously suggests that the entirety of CERCLA is enough to imbue this rulemaking with retrospective effect.[224] This interpretation is not rationally explained because it is unreasonable.

It is true that the few courts of appeals that have considered whether CERCLA should be interpreted broadly enough to allow retroactive imposition of PRP liability have held that Congress intended the statute to be retroactive given its remedial nature.[225] But none of those prior opinions involved substances that EPA designated pursuant to CERCLA Section 102(a) to be "hazardous substances." This is a question of first impression, as EPA has never undertaken such a designation before. EPA's proposal to designate PFOA and PFOS as hazardous substances under CERCLA Section 102(a) represents the first time it has attempted to make such a designation.[226] EPA's failure to even attempt to explain why this designation is entitled to retroactive effect is grounds alone to limit PRP liability to the future and not the past.

2. CERCLA Section 102 Authorizes Only Prospective Regulatory Requirements

EPA's proposal to designate PFOA and PFOS as "hazardous substances" pursuant to CERCLA Section 102(a) occurs within an action to promulgate a new rule or regulation,[227] which is limited to prospective application. "It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."[228] Because retroactivity is disfavored, "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms."[229] One such example is found in the

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[223] *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988) (internal citations omitted); *cf. Landgraf v. USI Film Prods.*, 511 U.S. 244, 270 (1994) ("A statute does not operate 'retrospectively' merely because it is applied in a case arising from conduct antedating the statute's enactment, or upsets expectations based in prior law. Rather, the court must ask whether the new provision attaches new legal consequences to events completed before its enactment. … Since the early days of this Court, we have declined to give retroactive effect to statutes burdening private rights unless Congress had made its intent clear.").

[224] 87 Fed. Reg. at 54,420 ("Other than the reporting requirements in [§ 102], CERCLA is not a traditional regulatory statute that prospectively regulates behavior; rather it is remedial in nature, generally designed to address contamination on a site-specific basis.")

[225] *See, e.g., Commonwealth Edison Co. v. United States*, 271 F.3d 1327, 1350-51 (Fed. Cir. 2001); *United States v. Northeastern Pharm. & Chem Co*., 810 F.2d 726, 734 (8th Cir. 1986); *United States v. Monsanto Co*., 858 F.2d 160, 174 (4th Cir. 1988); *Franklin County Convention Facilities Auth. v. Am. Premier Underwriters, Inc*., 240 F.3d 534, 551-52 (6th Cir. 2001).

[226] *See* 87 Fed. Reg. at 54,421.

[227] *See* 87 Fed. Reg. 54,415 ("Action: Proposed rule."); CERCLA § 102(a) ("The Administrator ***shall promulgate*** and revise as may be appropriate, ***regulations*** designating as hazardous substances….") (emphasis added).

[228] *Bowen*, 488 U.S. at 208.

[229] *Id.*

Medicare Act, which delegated to the Secretary of Health and Human Services the "authority to promulgate cost-reimbursement regulations" that "provide for the making of suitable ***retroactive*** corrective adjustments where, for ***a provider*** of services ***for any fiscal period***, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive."[230] In *Bowen*, the Supreme Court explained that, although Congress' delegation expressly authorized regulations to be applied retroactively for a single hospital for any prior fiscal year, such a clear delegation was insufficient to authorize DHHS to promulgate a regulation that retroactively established cost reimbursements for all hospitals.[231]

In its justification for its proposed new rule, EPA concedes that Congress' delegation of authority in CERCLA Section 102 limits rules promulgated thereunder to have prospective, not retroactive, effect.[232] That subsection delegates to EPA the authority to promulgate and revise regulations designating substances to be "hazardous substances" "as may be appropriate" and also requires EPA to "promulgate regulations establishing that quantity of any hazardous substance the release of which shall be reported…."[233] EPA correctly notes that "the reporting requirements" in CERCLA Section 102(a) "prospectively regulate[] behavior…" because Section 102(a) lacks language indicating this duty to report hazardous substance releases should apply retroactively.[234] Given that Congress' delegation of authority to EPA to designate substances to the "hazardous substance" list contains no indication that such a designation should apply retroactively and is found in the same subsection as the prospective-only reporting requirement, any PRP liability involving PFOA and PFOS must look no further backwards in time than the day EPA's rule is finally adopted (if ever).[235]

At a more fundamental level, delegation of authority from Congress to a federal administrative agency is presumptively limited to the issuance of rules and regulations that act prospectively. The "basic structural legislation" that embodies the "general principles of administrative law" is the federal Administrative Procedure Act (APA).[236] The APA defines a rule to mean "the whole or a part of an agency statement of general or particular applicability ***and future effect*** designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency…."[237] Administrative law in general, and the APA specifically, distinguishes prospective rules from retroactive adjudications:

> Of particular importance is the fact that 'rule' includes agency statements not only of general applicability but also those of particular applicability applying either to

[230] *Id.* at 209 (quoting 42 U.S.C. § 1395x(v)(1)(A)) (emphasis added).
[231] *See id.* at 210, 213-14.
[232] CERCLA § 102(a), 42 U.S.C. § 9602(a).
[233] CERCLA § 102(a), 42 U.S.C. § 9602(a).
[234] 87 Fed. Reg. at 54,420.
[235] *See, e.g., Thermtron Prods. v. Hermansdorfer*, 423 U.S. 336, 345-46 (1976) (Provisions within the same statute "are *in pari materia* [and] are to be construed accordingly rather than as distinct enactments….") (quoting *Employers Reinsurance Corp. v. Bryant*, 299 U.S. 374, 380 (1937)).
[236] *See Bowen*, 488 U.S. at 216 (Scalia, J., concurring) (citing 5 U.S.C. §§ 551-552, 553-559, 701-706, 1305, 3105, 3344, 5372, 7521).
[237] *Id.* (quoting 5 U.S.C. § 551(4)) (emphasis added).

> a class or to a single person. In either case, they must be of ***future effect***, implementing or prescribing future law.
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> . . .
>
> [T]he entire Act is based upon a dichotomy between rule making and adjudication…. Rule making is agency action which regulates the future conduct of" person(s) and "is essentially legislative in nature, not only because it operates in the future but also because it is primarily concerned with policy considerations. … Conversely, adjudication is concerned with the determination of past and present rights and liabilities.[238]

Based on prior rulings of the courts of appeals regarding the retroactivity of CERCLA for "hazardous substances" so designated by Congress,[239] it would seem that Congress may create a "federal toxic tort liability scheme for past actions which were perfectly legal at the time."[240] Setting aside the constitutional question whether Congress is permitted to delegate to an administrative agency the power to change the law retroactively and attach new legal liabilities to past actions (which the proposal does not address, but which EPA would need to address prior to issuing a final rule),[241] Congress clearly did *not* do so here. To argue that Congress impliedly did so in Section 102(a) runs counter to Supreme Court doctrine requiring express delegation of such authority to an administrative agency, as well as the APA's presumption of prospective application of rules. EPA's purporting to decide what legal liability would attach to actions in the past, before giving fair notice by rule pointing to a clear statement of authority in the statute, fails even basic notions of notice required for rulemakings.

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[238] *Id.* at 218-19 (quoting the 1947 Attorney General's Manual on the Administrative Procedure Act (AG's Manual) at 13-14) (emphasis in original). Both the Attorney General's authoritative 1947 Manual on the Administrative Procedure Act and the APA's legislative history make clear that "[t]he phrase 'future effect' does not preclude agencies from considering and, so far as legally authorized, dealing with past transactions in prescribing rules for the future." *Id.* at 219 (quoting H.R. Rep. 1980, 79th Cong., 2d Sess., 49, n.1 (1946); citing AG's Manual at 37).

[239] *See, e.g., Commonwealth Edison Co. v. United States*, 271 F.3d 1327, 1350-51 (Fed. Cir. 2001); *United States v. Northeastern Pharm. & Chem Co*., 810 F.2d 726, 734 (8th Cir. 1986); *United States v. Monsanto Co*., 858 F.2d 160, 174 (4th Cir. 1988); *Franklin County Convention Facilities Auth. v. Am. Premier Underwriters, Inc*., 240 F.3d 534, 551-52 (6th Cir. 2001).

[240] *See A Legislative History of the Comprehensive Environmental Response, Compensation and Liability Act of 1980*, Senate Finance Committee, S. Doc. No. 97-14, 97th Cong., 2d Sess. 1983, Vol. 2, p. 237 (statement of Dr. Louis Fernandez, Chemical Mfrs. Ass'n).

[241] *See Bowen*, 488 U.S. at 220 ("But when the Secretary prescribed such a formula for costs reimbursable while the prior rule was in effect, she changed the ***law*** retroactively, a function not performable by a rule under the APA.") (Scalia, J., concurring). The Supreme Court has discussed the nondelegation doctrine in terms of delegating to an agency the authority to create potential legal liability after Congress enacts enabling legislation and the agency promulgates a rule. *Compare Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (opinion of Kagan, J., for four Justices) (agreeing that Court would "face a nondelegation question" if Congress had granted federal agency "plenary power to determine [an Act's] applicability to pre-Act" situations not unlawful at the time) *with id.* at 2144 (Gorsuch, J., dissenting) (concluding that Act gives agency "the authority to 'prescrib[e] the rules by which the duties and rights' of citizens are determined, a quintessentially legislative power. ... If the separation of powers means anything, it must mean that Congress cannot give the executive branch a blank check to write a code of conduct governing private conduct for a half-million people.") (quoting The Federalist No. 78, at 465 (Hamilton)).

3. Whether EPA Has Authority to Designate PFOA and PFOS as "Hazardous Substances" Under CERCLA Section 102(a) is a "Major Question"

As discussed above, EPA's proposed designation has a broad and substantial impact economically, legally, and socially. When the "sheer scope of the [EPA's] claimed authority, [and] its 'unprecedented nature'" is raised, the Supreme Court has indicated that it constitutes a major question that puts the burden on the agency to show a clear statement in the statute authorizing the proposed course of action.[242]

In arguing that CERCLA Section 102(a) "empowers it to" encumber many, many sites across America with retroactive effect, EPA once again seeks to apply a statutory authority it has never seen fit to use until now in a manner that "represent[s] a 'transformative expansion in [its] regulatory authority.'"[243] The Supreme Court struck down the Occupational Safety and Health Administration's COVID-19 vaccine mandate because the Court "found it 'telling that OSHA, in its half century of existence,' had never relied on its authority to regulate occupational hazards" to impact "84 million Americans."[244] The fact that EPA waited over four decades to propose an expansion of CERCLA liability to practically all Americans makes the previous "major question" cases seem minor in comparison. EPA cannot rewrite statutes to avoid broad negative consequences that follow from an implausible or otherwise unreasonable reading of a statutory provision.[245]

EPA's proposal to designate PFOA and PFOS as "hazardous substances" under CERCLA Section 102(a) with retroactive effect has the potential to subject every person and property in this country to vast and potentially unbounded liability. That prospect is not only implausible, it also strongly suggests that the proposal is based on an untenable view of the agency's statutory authority.

V. The Totality of the Scientific Evidence Does Not Support Listing PFOA and PFOS as Hazardous Substances

A. PFOA and PFOS Chemical and Physical Characteristics

In describing the chemical and physical characteristics of PFOA and PFOS, EPA states that these compounds are "persistent," which EPA defines as being "extremely resistant to degradation in the environment."[246] EPA also notes that they are "extremely resistant to degradation in the environment."[247] However, EPA provides no discussion whatsoever to describe why these characteristics constitute a "substantial danger" and warrant a hazardous substance listing under CERCLA Section 102(a). Many substances in our environment are persistent and extremely resistant to degradation, including rocks and sand or even inert

[242] *West Virginia v. EPA*, 142 S. Ct. 2587, 2608 (2022) (quoting *Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 141 S. Ct. 2485, 2489 (2021)).
[243] *Id.* (quoting *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014)).
[244] *Id.* (quoting *Nat'l Fed. of Ind't Bus. v. OSHA*, 142 S. Ct. 661, 665-66 (2022)).
[245] *See Util. Air Regulatory Group v. EPA*, 573 U.S. 302, 319-20 (2014).
[246] 87 Fed. Reg. at 54,424.
[247] *Id*.

substances like nitrogen or argon gases, yet EPA has not labeled them as constituting a "substantial danger" in the environment. As discussed below, the toxicity of these compounds is not well understood, and there is seemingly no agreement among authoritative bodies when it comes to defining a safe level. Additionally, EPA contends that the prevalence of PFOA and PFOS is widespread. If we consider the chemical and physical characteristics, in concert with the toxicity and prevalence, as EPA suggests, there still is no explanation for why these compounds constitute a "substantial danger." Rocks, sand, and inert gases are prevalent in the environment, as are other persistent compounds, yet none of these are labelled as a "substantial danger."

We recommend that EPA provide a supplemental scientific support document that provides a clear explanation for the determination that the chemical and physical characteristics for PFOA and PFOS support a "substantial danger" label. It cannot be that the mere presence of a substance in the environment for an extended period constitutes "substantial danger." Persistence does not equate to risk. If EPA were allowed to set such a precedent here, what would keep it from listing hundreds of other substances as a "substantial danger"? The answer to this question must be understood before EPA moves forward with listing these compounds as hazardous substances.

B. Toxicity and Toxicokinetics

EPA states, in Section V of the proposed rule preamble, that PFOA and PFOS are associated with a variety of health effects. When describing health effects, EPA refers to the draft updated health effects documents that it released in 2021 to inform a National Primary Drinking Water Regulation, the EPA 2016 Health Effects Support Documents for PFOA and PFOS, and numerous peer-reviewed publications. In Section VII of the proposed rule preamble, EPA discusses the health-based toxicity values and cleanup values that are in place throughout other federal agencies, states, and international organizations.

What is striking about these discussions is that there is clearly no agreement on the toxicity of PFOA and PFOS. For example, the World Health Organization (WHO 2022) recently reviewed the PFOA and PFOS hazard information to inform their health-based values and not only found significant uncertainties in the data (discussed below) but also came to the same conclusion regarding the lack of scientific agreement.[248] WHO 2022 found that the values derived by different organizations varied significantly.[249]

In 2014, when evaluating PFOA, EPA proposed to rely on liver weight changes as the adverse effect. After peer reviewers questioned whether this effect was adverse, EPA pivoted to a different endpoint.[250] Peer reviewers also questioned whether the persistence of PFOA might

[248] World Health Organization (WHO), PFOS and PFOA in Drinking-water Background document for development of WHO Guidelines for Drinking-water Quality (29 Sep. 2022) version for public review, available at https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water/per-and-polyfluoroalkyl-substances.
[249] *Id*. at 80.
[250] *See* EPA, 2016 Response to External Peer Review Comments on Comments on EPA Draft Documents: Health Effects Support Document for Perfluorooctanoic Acid (PFOA) and Health Effects Support Document for Perfluorooctane Sulfonate (PFOS), available at https://www.epa.gov/sites/default/files/2016-05/documents/response_to_pfoa_pfos_peer_review_comments_508.pdf.

lead to the induction of enzymes that could be beneficial to removing toxins from the body.[251] In fact, in response to peer reviewers and public comment, EPA ended up rewriting major sections of the health effects documents for both PFOA and PFOS. This process took EPA two full years to complete.

Now, in 2022, we are dealing with a similar situation all over again. In November 2021, EPA released proposed approaches for deriving draft Maximum Contaminant Level Goals for PFOA and PFOS.[252] These documents were then reviewed by EPA's Science Advisory Board (SAB). While the SAB has released their final peer review report to EPA (in August 2022), the agency has not yet responded to the SAB and public comments, nor has it finalized the scientific support documents. The 2021 documents were intended to present the state of the science; however, the SAB expressed significant concerns with the scientific evaluation reflected in those documents. For instance, the SAB, in their final report, stated that the supporting documents have "a number of methodological flaws," including but not limited to concerns about the consistent application of inclusion and exclusion criteria for epidemiology data and animal studies and "concerns about the study evaluation and evidence synthesis process used by EPA."[253] The SAB urged EPA to address these problems, essentially telling EPA that it was necessary to go back to the drawing board to objectively, consistently, and transparently address the fundamental concerns with EPA's health assessments for PFOA and PFOS.

In addition to the methodological concerns, the SAB also questioned some of the agency's important scientific choices, including but not limited to: the endpoints EPA chose for the non-cancer value, suggesting that an appropriate endpoint was not considered; the toxicokinetic model used; and the choice of benchmark responses chosen.[254] Each of these decision points can have substantial impact on the final health values for PFOA and PFOS. Public commenters also questioned the endpoints EPA chose as well as how those data were interpreted by EPA.[255]

EPA has not yet provided any response to public comment on these documents, nor has it finalized the health effects documents. Considering the significance of the proposed action, which is directly tied to understanding the toxicity of PFOA and PFOS, EPA must first address the significant concerns from the peer reviewers and public commenters before finalizing the health assessments. The appropriate time for considering whether or not PFOA and PFOS constitute a "substantial danger" is when health assessments, which represent the best available science, are finalized by EPA. As was noted by WHO 2022, there are significant uncertainties in the science.[256]

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[251] *Id.* at 7.
[252] See release information at https://www.epa.gov/newsreleases/epa-advances-science-protect-public-pfoa-and-pfos-drinking-water.
[253] *See* SAB 2022 report to EPA, at 2, available at https://sab.epa.gov/ords/sab/f?p=100:18:17420269388783:::RP,18:P18_ID:2601#report.
[254] *Id.* at 2-3.
[255] *See* public comments presented to the Chartered SAB available at https://sab.epa.gov/ords/sab/f?p=100:19:17420269388783:::RP,19:P19_ID:975.
[256] World Health Organization (WHO), PFOS and PFOA in Drinking-water Background document for development of WHO Guidelines for Drinking-water Quality (29 Sep. 2022), version for public review, at 20, available at

It is also worth noting that EPA's evaluation of health effects includes significant reliance on human epidemiology studies.[257] Human epidemiology studies have significant limitations, including an ability to establish causation. This is particularly problematic for cross-sectional studies; positive associations are scientifically simply not the same as proving a causal relationship. Whether an association is causal must be evaluated in light of possible alternative explanations, including bias, confounding, and chance.[258] While many EPA assessments of other chemicals have conducted this type of evaluation, it is notable that, in the proposed rule, EPA is only able to discuss health effects that are associated with PFOA and PFOS, as causal relationships have not been established.

WHO 2022 provides the most recent draft assessment of PFOA and PFOS human health toxicity. Noting significant uncertainties in the science describing these two chemicals, and the significant differences in the evaluations that have been conducted to date by other scientific bodies, including EPA and many U.S. states, WHO took a "pragmatic approach" to reducing risk by taking into consideration analytical methods and treatment achievability.[259] WHO 2022 also noted that "monitoring and removing PFAS in drinking-water can be costly and complex as described in section 8 and may be unfeasible to implement in many low- and middle-income settings."[260] In light of the questions and challenges noted herein, the proposed rule does not persuasively explain why a substantial danger is present as to PFOA and PFOS that would warrant designation.

C. Environmental Prevalence

It is well accepted that PFOA and PFOS are common substances in the environment.[261] It is also well accepted that presence of a substance in the body, or in the environment, does not in

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https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water/per-and-polyfluoroalkyl-substances;.

[257] Human studies were also used in EPA's 2021 proposed approaches for deriving draft Maximum Contaminant Level Goals for PFOA and PFOS for consideration of immunological effects. The non-cancer values for PFOA and PFOS were based on evaluating serum PFOA and PFOS levels in children at age 5 and then evaluating tetanus or diphtheria vaccine antibody concentrations at age 7. While some SAB members questioned whether or not these responses constituted an adverse effect, the SAB panel endorsed this endpoint while also asking EPA to provide a stronger justification for the choice of response levels. *See* SAB 2022 report to EPA at 3, available at https://sab.epa.gov/ords/sab/f?p=100:18:17420269388783:::RP,18:P18_ID:2601#report. However, there is still not consensus around using these studies at all. For instance, after the final SAB report was released, WHO 2022 stated "Although the reduced antibody response following vaccination has been considered by some agencies as the most robust end point based on epidemiological data, it is unclear whether this correlation results in increased rates of infection and hence the clinical implications are uncertain." *See* World Health Organization (WHO), PFOS and PFOA in Drinking-water Background document for development of WHO Guidelines for Drinking-water Quality (29 Sep. 2022), version for public review, at 79, available at https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water/per-and-polyfluoroalkyl-substances.

[258] The Bradford Hill Criteria (1965) provide well-accepted guidelines for evaluating strength of association, consistency, specificity, temporality, biological gradient, biological plausibility, coherence, experiment, and analogy. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1898525/.

[259] *Id.* at 80.

[260] *Id.* at 81.

[261] Ian T. Cousins, Jana H. Johansson, Matthew E. Salter, Bo Sha, and Martin Scheringer, *Environmental Science & Technology* 2022 56 (16), 11172-11179, https://doi.org/10.1021/acs.est.2c02765.

itself imply danger. Courts have held that the mere presence of contaminants alone cannot support claims of endangerment.[262] The standard must consider the level of exposure and the hazard of the contaminant. As such, EPA must consider exposure levels and whether there is exposure that causes danger. While EPA correctly notes that the mean concentrations of PFOA and PFOS in the serum have been steadily decreasing since 1999-2000,[263] it does not provide discussion of what these levels are today. Nor does it provide any discussion that would link current exposure levels and the existing science regarding the hazard of PFOA and PFOS to inform a finding of "substantial danger."

Because they are no longer actively in commerce, PFOA and PFOS levels are already declining in human serum and the environment, and the potential for future releases is even less. From 1999-2000 to 2017-2018, blood PFOS levels declined by more than 85 percent, and over a similar timeframe blood PFOA levels declined by more than 70 percent.[264]

EPA has not explained why this hazardous substance listing is appropriate and has not analyzed and presented the full impacts of the proposed listing. EPA must conduct the analyses necessary to justify a hazardous substance listing. Once these analyses are complete, an opportunity for notice and comment must be provided to the public.

D. Inclusion of Unidentified Salts and Isomers Is Not Justified

EPA's scope of this action is not just PFOA and PFOS, but all the salts and structural isomers of PFOA and PFOS. In clarifying what this means, EPA simply states that "[l]inear and branched structural isomers of PFOA and PFOS maintain the carboxylic acid and sulfonic acid functional groups, respectively, but have different arrangements of the carbon atoms in the fluorinated carbon chain."[265] Yet, in this proposal, EPA makes no attempt at all to clarify the meaning of the broad category.

The NDAA added only five PFOS salts and three salts of PFOA to the Toxic Release Inventory,[266] yet we know that many more isomers and salts exist. For instance, while common salts of PFOS include the ammonium, diethanolamine, potassium, and lithium forms, the universe is larger. Additionally, PFOS is routinely present in environmental samples as a mixture of the linear isomer and 10 branched isomers, and independent research has shown that 89

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[262] See *Maine People's Alliance and Natural Resources Defense Council v. Mallinckrodt, Inc*., 471 F. 3d 277, 282 (1st Cir. 2006) (holding that the mere presence of mercury contaminated sediments alone was not enough to constitute an imminent and substantial endangerment for purposes of RCRA).
[263] 87 Fed. Reg. at 54,429.
[264] See ATSDR, "PFAS in the U.S. Population," available at https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html.
[265] 87 Fed. Reg. at 54,417.
[266] See NDAA 2020, available at https://www.govinfo.gov/content/pkg/BILLS-116s1790enr/pdf/BILLS-116s1790enr.pdf. This listing includes: PFOA (CAS #335-67-1) and its salts (CAS #s: 3825-26-1, 335-95-5, 68141-02-6) and PFOS (CAS # 1763-23-1) and its salts (CAS #s: 2795-39-3, 29457-72-5, 56773-42-3, 29081-56-9, 70225-14-8).

isomers are theoretically possible.[267] PFOS has not been produced in the U.S. since 2000.[268] Without identifying the specific salts and isomers, EPA has not met its burden to clarify what exactly will be listed.

In discussing PFOA production, EPA acknowledges that that there are different linear and branched isomers that may exist, and that their presence depends on the manufacturing process.[269] EPA also acknowledges that there are different ways to measure these isomers.[270] If they can be measured, EPA must identify each of the salts and isomers it intends to include in the listing.

Finally, as discussed in the EPA PFAS Strategic Roadmap,[271] EPA reportedly is working to take the diverse class of PFAS and break them into smaller categories based on defined parameters, including structure, to help understand their toxicity. These groupings, if done properly, can help to inform hazard characterization and risk. As described by EPA, 75 PFAS were chosen for this project based on structural diversity, available toxicity data, and other factors.[272] The list of 75 includes not just PFOA and PFOS but also ammonium perfluorooctanoate (APFO), a salt of PFOA, and potassium perfluorooctanesulfonate, a salt of PFOS. The fact that EPA included not just PFOA and PFOS but also a salt of each in this limited set is an important acknowledgement that the hazards of PFOA and PFOS and their salts are not equal. EPA should not be treating all the salts and isomers the same, just as it should not treat all PFAS the same. EPA must justify the need to list each compound that will be designated a hazardous substance.

VI. Conclusion

In light of the likely highly problematic consequences of the proposed listing of PFOA and PFOS as hazardous substances under CERCLA, EPA must withdraw the proposed rule and instead must utilize its other existing authorities and tools to target specific sites for PFOA and PFOS remediation as appropriate. These authorities would allow EPA to accomplish the goal of addressing PFOA and PFOS exposures in a far more effective and less harmful manner. As drafted, the proposed rule far from justifies the troubling precedent that it would set with this rulemaking in utilizing CERCLA in a way that Congress never intended to extend liability to many, many new sites across the country and to entangle unknown numbers of businesses, landowners, and other parties in costly, burdensome cost recovery settlements and litigation for decades to come. Additionally, EPA has not demonstrated that this approach to addressing

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[267] Buck RC, Franklin J, Berger U, Conder JM, Cousins IT, de Voogt P, Jensen AA, Kannan K, Mabury SA, van Leeuwen SP. *Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins*. Integr. Environ Assess Manag. 2011 Oct;7(4):513-41. doi: 10.1002/ieam.258.
[268] California Office of Environmental Health Hazard Assessment, 2010 available at https://oehha.ca.gov/media/downloads/crnr/070910pfoscic.pdf.
[269] 87 Fed. Reg. at 54,424.
[270] 87 Fed. Reg. at 54,424 (EPA states: "Analytical chemistry methods used to detect and measure PFOA may measure the different isomers separately.").
[271] *See* https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.
[272] *See* EPA project description, available at https://www.epa.gov/sciencematters/epa-and-partners-describe-chemical-category-prioritization-approach-select-75-pfas.

PFOA and PFOS will result in any measurable protections to the public health and welfare or the environment.

EPA must reevaluate how it interprets Section 102(a) under CERCLA so that its exercise of authority in the future for other substances does not become unwieldy, creating more uncertainties for the regulated community. EPA must also provide data and sufficient support for this rulemaking by performing a full RIA and consultation with small businesses as well as state, local, and tribal governments, which includes a complete evaluation of the scope of the proposed rule and estimated costs of site cleanup and related settlement and litigation activities.

The business community supports accelerating cleanups of PFOA and PFOS contamination, consistent with the best science and appropriate consideration of risk, to protect human health and the environment in communities across our nation. The Coalition welcomes any questions and further discussion from EPA on this important, precedent-setting rulemaking. Please contact Chuck Chaitovitz, Vice President of Environmental Affairs and Sustainability at the U.S. Chamber of Commerce (cchaitovitz@uschamber.com), with any questions regarding these comments.

Aerospace Industries Association
American Chemistry Council
American Forest and Paper Association
American Fuel and Petrochemical Manufacturers
American Petroleum Institute
Associated Builders and Contractors
Council of Industrial Boiler Owners
Flexible Packaging Association
Fluid Sealing Association National
National Association of Chemical Distributors
National Association of Printing Ink Manufacturers
National Association for Surface Finishing
National Council of Textile Organizations
National Oilseed Processors Association
National Mining Association
Plastics Industry Association
PRINTING United Alliance
Superfund Settlements Project
TRSA - The Linen, Uniform and Facility Services Association
U.S. Chamber of Commerce