November 7, 2022

The Honorable Michael S. Regan
Administrator
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Designation of perfluorooctanoic acid (PFOA)and perfluorooctanesulfonic acid (PFOS) as CERCLA hazardous substances, Proposed Rule, 87 *Federal Register* 54415 (September 6, 2022), EPA-HQ-OLEM-2019-0341

Dear Administrator Regan:

The American Chemistry Council (ACC) submits the enclosed comments on the proposal to designate perfluorooctanoic acid (PFOA)and perfluorooctanesulfonic acid (PFOS) as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). ACC supports efforts to accelerate remediation of PFOA and PFOS contamination to protect public health and the environment that are supported by the best available science. The proposal to designate these substances under CERCLA will not result in a faster pace of cleanups. Instead, designation will slow remediation efforts as responsible parties struggle with CERCLA's strict liability system. As discussed in the enclosed comments, EPA already has sufficient enforcement tools at its disposal to address PFOA and PFOS without the designation them as hazardous substances.

Given the potential for significant impacts across both the public and private sectors, the Agency should withdraw the current proposal and explore greater use of its existing tools.

Sincerely,

Steve Risotto

Stephen P. Risotto
Senior Director

Enclosure

Comments of the American Chemistry Council
Proposal to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances
87 *Federal Register* 54415 (September 6, 2022)
EPA-HQ-OLEM-2019-0341

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Executive Summary

The proposal to designate perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) and their salts and isomers as hazardous substances under Section 102(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) would result in potentially significant economic impacts but will not provide additional information on releases or facilitate timely cleanup of sites contaminated with the two substances. The magnitude of these impacts will be determined by the outcome of the Agency's ongoing efforts to develop drinking and ground water standards for the substances and to provide clear guidance on appropriate disposal and destruction methods. EPA should not move forward with the proposal until it has established an appropriate cleanup level based on the best available science and determined that sufficient capacity exists for the remediation and disposal of PFOA and PFOS wastes. Only then can it conduct a comprehensive regulatory impact analysis for the proposal. As part of that analysis, the Agency should consider its existing enforcement tools to determine whether they offer a more effective approach to addressing PFOA and PFOS contamination than designation under CERCLA.

Introduction

EPA has proposed to use its authority under Section 102(a) of CERCLA for the first time to designate PFOA and PFOS as hazardous substances. The designation requires a finding of "substantial danger" which neither the Agency nor the courts have defined for the purposes of CERCLA designation. The proposal contends that CERCLA designation will provide EPA with a better understanding of the location and magnitude of releases of these two substances. The Agency further argues that designation will result in a faster pace of cleanups and allow EPA, delegated agencies, and private parties to recover cost. EPA interprets Section 102(a) as excluding consideration of cost in a designation decision, but has requested comment on whether, and how, costs should be considered. Despite deciding that it is not possible at this time to fully evaluate costs, the Agency is aware that the designation will be a significant burden to many stakeholders and has announced its intention to use enforcement discretion to minimize impacts to some parties (*e.g.*, municipalities, small businesses). EPA has not provided information, however, on how such discretion would be applied.

EPA has not conducted a robust regulatory impact analysis of the impacts required for an economically significant rule

In its proposal EPA explains that CERCLA was enacted to promote the timely cleanup of contaminated sites and to 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.[1] However, the Agency attempts to decouple the decision to designate

[1] 87 *Fed. Reg.* 54,420.

PFOA and PFOS as "hazardous" under CERCLA from the enforcement process that it notes was the intent of the legislation. Rather than avoid the direct connection, EPA must recognize that the hazardous substance designation process and the Agency's implementation of cleanup activities are inherently linked.

In light of the significant impacts and numerous uncertainties associated with the designation of the two substances under CERCLA, it is critically important that EPA fully consider the costs associated with the proposal. EPA's current economic analysis for the proposal fails to meet long-established federal criteria for analysis of economically significant rules[2] in the following considerations:

- the Agency has not identified a compelling public need for the proposed action;
- the Agency fails to establish a clear baseline;
- the Agency does not describe certain expected impacts in qualitative or quantitative (and monetized) terms;
- the Agency does not consider a reasonable number of regulatory alternatives; and
- the Agency has not characterized uncertainty.

These deficiencies are described in more detail below.

EPA has not identified a compelling public need for the proposed action

According to the Office of Management and Budget's (OMB) Circular A-4,[3] an agency "should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy." For interventions apart from market failure, an agency "should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values."

In its economic assessment, EPA supports its proposal with four arguments: that the proposal would (1) "further CERCLA's primary goal of protecting public health and welfare and the environment" by informing EPA of the "number and location of releases that exceed the reportable quantity" and (2) signal to markets that "there is value in preventing such releases."

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[2] These criteria are embodied in Executive Order 12866 on regulatory review, Executive Order 13563 on improving regulation and regulatory review, and Office of Management and Budget (OMB) Circular A-4 on regulatory analysis. Each is applicable to EPA's proposed rule, which have been deemed an "economically significant" regulation by OMB.

[3] https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf

The Agency also lists (3) the potential to transfer costs from the public to polluters. Finally, the Agency says the proposed rule is (4) consistent with many actions by federal, state, and local and tribal authorities to address PFOA and PFOS contamination. Each argument is unconvincing.

As described elsewhere in the comment, the proposed rule is not likely to be particularly informative. Use of PFOA and PFOS in commerce is extremely limited, if at all. As a result, the proposal is unlikely to prevent releases. The signal to markets that "there is value in preventing releases" ignores the *signal distortion* that CERCLA's liability provisions provide. Due to concerns over CERCLA's unique (strict, joint, and several) liability provisions, markets will not just adjust, but over-adjust—creating a net social cost. The transfer of costs "from the public to polluters" could occur in the absence of the proposed rule, suggesting that the rulemaking is unnecessary. The "consistency" between the proposed rule and ongoing actions to address PFOA and PFOS contamination is irrelevant to a determination that the proposal meets a compelling public need.

EPA fails to establish a clear baseline for its analysis

To conduct a benefit-cost analysis, the Agency must first construct a baseline. According to Circular A-4, this baseline should be "the best assessment of the way the world would look absent the proposed action" and "may require consideration of a wide range of potential factors," including other federal and state regulations. The Circular notes that "[I]t may be reasonable to forecast that the world absent the regulation will resemble the present."

The Agency's economic assessment briefly discusses the baseline by acknowledging some other regulations to address PFOA/PFOS. This brief discussion, however, is insufficient. What is necessary is a quantitative and monetized estimate of costs associated with a baseline that reflects ongoing "upstream" waste management behavior to address PFOA and PFOS and ongoing "downstream" costs associated with the cleanup of PFOA- and PFOS-contaminated sites on the NPL. Such a baseline could be then used to identify the incremental costs associated with the proposed rule and its alternatives.

EPA does not describe certain expected impacts of the proposal in qualitative or quantitative terms

With respect to an economically significant regulation, Executive Order (EO) 12866[4] calls for an assessment of costs anticipated by the regulatory action ("such as, but not limited to,

[4] https://www.epa.gov/laws-regulations/summary-executive-order-12866-regulatory-planning-and-review

direct cost") together with, to the extent feasible, a quantification of those costs. Circular A-4 recommends monetizing quantitative estimates whenever possible.

The Agency's economic analysis identifies and quantifies, in cursory fashion, the direct impact of the proposed rule:

- reporting of releases equal to or greater than the reportable quantity to the National Response Center;
- disclosure of the storage or release of a hazardous substance during the sale or transfer of federal property; and
- listing by the Department of Transportation of the hazardous substance in the Hazardous Materials Regulations under the Hazardous Materials Transportation Act.

However, this description fails to capture all of the expected additional costs of the proposed rule. Table 1 below illustrates three categories of social costs. The first of these—costs associated with reporting of future releases—are acknowledged in the Agency's economic assessment. To the extent the proposal yields little to no new information on releases (given that these chemicals have been phased out of production and use in the US), it lacks practical utility — raising a significant question about the merit of the information collection request accompanying the proposal.[5]

The second category of cost relates to waste management practices. The Agency devotes scant attention to this behavioral response, simply suggesting that waste management activities will adjust to encourage prevention of potential releases. Although some adjustment can be beneficial, too much can be detrimental—an issue left unaddressed in the economic assessment. An *over-adjustment problem* occurs when social costs exceed social benefits. For example, a slower pace for cleanup under the Brownfields Program[6] will reduce the number of brownfields transactions, which have a very favorable benefit-cost ratio.[7] More municipalities will be required to treat landfill leachate before sending it to a publicly owned treatment work (POTW), raising costs.[8] POTWs will reduce the amount of biosolids sold for agricultural

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[5] The Paperwork Reduction Act (PRA) requires that agency information collections must "maximize practical utility and public benefit" and "minimize burden." The proposed rule represents an information collection and therefore is subject to the standards of the PRA.

[6] 42 U.S.C. Section 9601(39).

[7] Haninger K *et al*. The value of brownfield remediation. *J Assoc Environ Resource Economists*, *4*(1):197-241 (2017). https://www.journals.uchicago.edu/doi/full/10.1086/689743

[8] Letter to Ariana Sutton-Grier, Office of Management and Budget from Darrell K. Smith, National Waste and Recycling Association. PFAS Management Costs for Municipal Solid Waste Landfills (February 8, 2022).

application and will be forced to find other options for handling this material, reducing revenues and increasing costs. Industrial waste managers will divert higher-PFAS-concentrated waste from Class D municipal landfills to more expensive Class C landfills. The expected costs are likely to increase significantly as responsible parties scramble to identify the limited options available to meet CERCLA requirements. Competition and price increases due to a dwindling capacity available in the Class C landfills will drive out low bids, putting PFAS disposal at a premium, which will result in passing cost down to consumers and the US economy as a whole. And, as waste management practices change, so might the availability of products made from perfluorinated substances as some manufacturers seek to limit potential liability, which will reduce consumer demand and producer supply. We believe over-adjustment can be expected due to CERCLA's unique liability provisions.

Table 1. Social Costs of the Proposed CERCLA Rule.

Impact	*Concern/Problem*	*Applicability*	
		PFOA/PFOS	*Other PFAS*
reporting of releases	releases above RQ unlikely	✓	NA
changes in waste management	over-adjustment due to CERCLA liability concerns	✓	✓
additions to the NPL	CERCLA utilized over other, more cost-effective authorities	✓	✓

The third category of cost relates to CERCLA's remediation program. The proposed designations would allow EPA and other agencies to require cleanups and recover response costs and allow private parties to file claims for cost recovery and contribution. The designations could result in some sites being added to the NPL,[9] significant increases in sampling, analysis, and delineation at existing sites, amendments to sites implementing EPA

https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=2050-AH09&meetingId=114123&acronym=2050-EPA/OLEM

[9] In the past, EPA has adopted Safe Drinking Water Act Lifetime Health Advisories (LHAs) as interim cleanup levels via guidance. States have adopted LHAs as groundwater cleanup levels for state superfund program sites. With the new interim LHAs for PFOA/PFOS (where the cleanup level is now close to zero), sites with trace levels of PFOA or PFOS could be eligible for NPL listing. This could greatly expand the number of potentially responsible parties, citizen suits, and private party actions.

selected remedies, triggering the reopening of previously closed CERCLA sites, and the initiation of costly private party litigation unbounded by any Agency discretion or any reasonable evaluation of risk. PFOA and PFOS could be included in the scope of all Phase I Environmental Site Assessments in order to satisfy numerous "hazardous substance" aspects of the "all appropriate inquiries" rule. EPA has completely failed to identify and evaluate these potential costs – which are expected to be substantial. Although some additional use of CERCLA can be beneficial, too much can be detrimental. An *over-use problem* arises when sites are addressed by mandating a remedy for PFOA and PFOS under CERCLA versus other, more cost-effective remediation programs (see discussion below).[10] We believe overuse can be expected because the size of the CERCLA Superfund budget (which is expected to increase significantly due to recent legislation) will provide funds for regulators tasked with overseeing remediation of hazardous waste sites.

Importantly, two of these categories of indirect costs are not limited to PFOA and PFOS. EPA's actions could be seen as a precedent for future designations of additional PFAS – a group of thousands of chemicals with vastly different properties and risk profiles.

We recommend that the Agency revise its economic assessment to not just identify issues, but to quantify all of the impacts of the proposed rule, both direct and indirect. Quantification and monetization are needed to meet the standards set by EO 12866 and Circular A-4. The Agency cannot dismiss such an exercise simply because precise information is unavailable. Rather, the Agency' failure to capture the uncertainties and to appropriately weigh them as a reason to withdraw the proposed CERCLA listing. In fact, the lack of available information strongly suggests that the Agency should not move forward with this action until more data are gathered.

EPA does not consider a reasonable number of regulatory alternatives

Circular A-4 recommends that agencies consider a manageable number of alternatives including those that differ in terms of stringency. For each, benefits and costs should be assessed. EO 12866 is based on the principle that regulation should maximize net benefits within the statutory discretion of the agency. As discussed below, EPA has several enforcement tools available to it. The Agency has not identified these tools or any other approaches as regulatory alternatives in its economic assessment.

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[10] For more information on the costs of federal Superfund sites, see Congressional Budget Office. *The Total Costs of Cleaning Up Nonfederal Superfund Sites*, Congress of the United States (1994). https://www.cbo.gov/sites/default/files/103rd-congress-1993-1994/reports/entirereport_11.pdf#:~:text=According%20to%20a%20new%20Congressional%20Budget%20Office%20%28CBO%29,more%20and%20could%20continue%20through%20the%20year%202075.

EPA has failed to characterize uncertainty

Although EPA's economic assessment points to various uncertainties in support of its decision to exclude consideration of cost in its proposal to designate PFOA and PFOS as hazardous substances, several groups have developed estimates of the likely impacts. Among those estimates is a report by the US Chamber of Commerce which suggests that the annualized cleanup costs at National Priorities List (NPL) sites over the next 30 years would total as much as $1.1 billion[11] based on the Department of Defense's (DOD) experience in remediation at military sites to the existing criteria established by EPA. The expected costs will increase substantially once EPA establishes drinking water standards for PFOA and PFOS in 2023 as the number of affected sites, and the cost per site, increase.

In considering uncertainties, OMB's Circular A-4 recommends that –

> Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. . . When uncertainty has significant effects on the final conclusion about net benefits, your agency should consider additional research prior to rulemaking. The costs of being wrong may outweigh the benefits of a faster decision. This is true especially for cases with irreversible or large upfront investments. If your agency decides to proceed with rulemaking, you should explain why the costs of developing additional information—including any harm from delay in public protection—exceed the value of that information. . . .For major rules involving annual economic effects of $1 billion or more, you should try to provide some estimate of the probability distribution of regulatory benefits and costs.

In its economic assessment, the Agency acknowledges significant uncertainties in the estimated impact of the proposed rule, including -

- the number of sites with PFOA or PFOS contamination that would require cleanup,
- the extent and type of PFOA and PFOS contamination at these sites;
- the extent and type of other contamination at the sites;

[11] US Chamber of Commerce. PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites (June 2022). Submitted to the Office of Management and Budget. https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule-false&rin2050-AH09&meetingId=113973&acronym-2050-EPA/OLEM

- the incremental cost of addressing the PFOA and/or PFOS contamination; and
- the cleanup level required for these substances.[12]

Rather than throw up its hands, EPA should follow OMB guidance and conduct a formal quantitative analysis of relevant uncertainties (*e.g.*, the number of sites to be remediated, the cost of available cleanup technologies, the cleanup level goals for each possible media). Consistent with recommendations in Circular A-4, the Agency should delay any decision to finalize this rulemaking until it obtains sufficient data.

The uncertainties that EPA has identified are sufficient to justify a formal, probabilistic analysis of uncertainty. Regardless of whether this proposal exceeds the billion-dollar threshold for formal uncertainty analysis, Circular A-4 does not prevent an agency from conducting such an analysis if it would inform agency decision making. Indeed, such an analysis would help identify major sources of variability and prioritize information-gathering that could improve the Biden Administration's PFAS Strategic Roadmap.[13] Software for Monte Carlo analysis is available and inexpensive; it could be used to conduct an uncertainty analysis.

EPA has not properly assessed the impacts on small business and public entities

Because of the narrow focus of the Agency's impact analysis, the EPA proposal indicates that the action will not have a significant regulatory burden for all "directly regulated small entities." This conclusion conflicts with subsequent statements by the Agency that it would use enforcement discretion to ensure fairness for various sectors and parties.[14] Moreover, data developed by the National Waste & Recycling Association (NWRA) indicate the increased costs associated with PFAS management[15] could total approximately $966 million to $6.3 billion per year for the nation's 1,200 municipal solid waste landfills, many of which are operated by small businesses or municipalities.[16] The proposal also will significantly increase costs for the

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[12] 87 *Fed. Reg.* at 54,423.

[13] Uncertainty analysis should also be used to characterize the cost to cleanup community water systems, an effort with direct relevance to the Strategic Roadmap. Recent published research indicates that groundwater across the eastern USA has been shown to contain more than trace amounts of PFAS. McMahon PB *et al.* Perfluoroalkyl and Polyfluoroalkyl Substances in Groundwater Used as a Source of Drinking Water in the Eastern United States. *Environ Sci & Tech 56*(4):2279-2288 (2022) https://doi.org/10.1021/acs.est.1c04795

[14] EPA. EPA Proposes Designating Certain PFAS Chemicals as Hazardous Substances Under Superfund to Protect People's Health (August 26,2022 News Release). https://www.epa.gov/newsreleases/epa-proposes-designating-certain-pfas-chemicals-hazardous-substances-under-superfund

[15] The bulk of these costs are attributable to PFOA and PFOS contamination.

[16] Letter to OMB from Darrell K. Smith, NWRA, February 8, 2022.

disposal of biosolids from the nation's more than 15,000 publicly owned treatment works (POTWs), many of which are operated by small entities.

EPA's ability to implement an enforcement discretion policy is limited

Based on the concerns expressed by multiple sectors, both public and private, EPA has indicated that it will use its enforcement discretion to minimize the unintended consequences of the proposal. Yet, it appears that the Agency is limited in its ability to provide assurances of no action outside the context of a particular enforcement action. EPA policy prevents such "no action" promises except when specified by statute or regulation or in "extremely unusual" cases to serve the public interest that "no other mechanism can address adequately."[17] The policy explains that assurances of no action "may erode the credibility of EPA's enforcement program by creating real or perceived inequities in the Agency's treatment of the regulated community." EPA has explicitly affirmed that its general policy concerning "no action assurances" applies to sites subject to CERCLA.[18]

In cases where EPA has established no-action policies, moreover, the Agency generally does not provide a blanket waiver. In its recent policy regarding enforcement of environmental obligations during the COVID-19 pandemic,[19] for example, the Agency's determination not to seek penalties for noncompliance was based on a case-by-case determination that the noncompliance was caused by the pandemic.[20]

Even when EPA implements a policy providing enforcement discretion, such discretion only applies for actions administered by the Agency. For example, despite implementing a policy to exclude municipalities responsible for municipal solid waste (MSW) or sewage sludge derived from households from the Superfund settlement process in 1989,[21] the Agency revised the policy in 1998 in response to contribution claims by private parties against MSW and sludge

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17 EPA. Memo from Courtney Price, Policy Against "No Action Assurance" (November 16, 1984). https://www.epa.gov/enforcement/guidance-no-action-assurances-policy

18 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.

19 https://www.epa.gov/enforcement/covid-19-enforcement-and-compliance-resources#naa

20 EPA. EPA Corrects the Record after Reckless Reporting on Temporary Compliance Guidance (March 20, 2020 Press Release). https://www.epa.gov/newsreleases/epa-corrects-record-after-reckless-reporting-temporary-compliance-guidance

21 EPA. Transmittal of "Interim Policy on CERCLA Settlements Involving Municipalities and Municipal Wastes. Office of Solid Waste and Emergency Response (December 1989). The policy does not apply if the waste contains a hazardous substance from a commercial, institutional, or industrial process or activity. https://www.epa.gov/enforcement/guidance-interim-municipal-settlement-policy

generators.[22] The revised policy offers settlements to municipal owners/operators of MSW facilities who wish to settle their Superfund liability.[23] Moreover, the MSW exemption does not apply at sites that are not on the NPL.[24]

It is possible that EPA could craft an enforcement policy that exempts certain parties from liability for cleanup of PFOA and PFOS (once deemed hazardous) that is in the national interest. The policy would need to be based, however, on traditional considerations of *de minimis* (or *de micromis*) contribution to the contamination or of the parties' ability to pay.[25] It is difficult to imagine how the Agency could make such determinations for an entire sector, since such decisions are generally site specific. Moreover, no amount of enforcement discretion will be sufficient to overcome CERCLA's expansive definitions and unforgiving liability scheme. Whatever policy EPA were to develop would not be applicable at non-NPL sites or to private party actions at NPL sites.

Since enforcement is generally left to the EPA Regional offices, a discretionary policy could result in a patchwork of unequal enforcement across the country, lead to significant uncertainty for the regulated community, and expose both the Agency and regulated entities to third-party suits and liability. Without understanding how (and for whom) EPA might apply enforcement discretion to PFOA and PFOS cleanups, it is not possible for stakeholders to fully assess the impacts of the listing proposal on their organization or sector. The Agency should not move forward with the proposal until it has provided interested parties with detailed plans on its enforcement scheme that will ensure fairness to all affected stakeholders.

The proposal will not result in additional information on releases of PFOA/PFOS

Manufacture of PFOS in the United States ended in the early 2000s; subsequent phaseout of PFOA manufacture followed as a result of the PFOA Stewardship Program. Under the program, eight major companies committed to eliminate PFOA, precursor chemicals, and

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[22] EPA. Transmittal of Policy for Municipality and Municipal Solid Waste CERCLA Settlements at NPL Co-Disposal Sites. Office of Enforcement and Compliance Assurance (Feb 5, 1998). https://www.epa.gov/enforcement/guidance-policy-municipality-and-msw-cercla-settlements-npl-co-disposal-sites

[23] The policy established 20 percent of total estimated response costs for the site as a presumptive baseline settlement amount for an individual municipality to resolve its owner/operator liability at the site.

[24] The MSW policy was further revised in 2002 by the Small Business Liability Relief and Brownfields Revitalization Act (Pub. L. No. 107-118) to exempt certain residential, small business and no-profit generators of MSW at NPL sites. Eligibility is generally determined on a case-by-case basis by the EPA Regional office.

[25] EPA. General Policy on Superfund Ability to Pay Determinations. Memo from Barry Breen, Office of Site Remediation Enforcement (September 30, 1997). EPA-HQ-OLEM-2019-0341-0198.

related homologues from emissions and products globally by 2015. According to the Final Progress Report, all of the companies met the goal.[26] As a result of these voluntary efforts, PFOS has not been reported as manufactured (including imported) in the US since the 2002 Chemical Data Reporting (CDR) effort. Similarly, reporting of PFOA manufacture or import was not reported in the 2020 CDR. The already phased-out nature of PFOA and PFOS in the US puts into question the value of such aggressive ruling now.

2020 SNURs prohibit use of PFOA and PFOS except for a limited number of uses in semiconductor manufacture

EPA has issued several significant new use rules (SNURs) over the last 20 years to ensure that PFOA and PFOS will not be reintroduced into the US market, including final rules in March 2002, December 2002, October 2007, October 2013, and July 2020. The latest SNUR, which became effective in September 2020, prohibited manufacture and import of PFOA, PFOS, and related substances for any significant new uses of the chemicals.[27] The rule identified the existing use of the substances for antireflective coating, photoresists, or as a surfactant in photomicrolithography and other process to produce semiconductors or similar components of electronic or other miniaturized devices as ongoing and not subject to the restriction.

US semiconductor manufacturers no longer use PFOA and PFOS

In 2020, EPA identified three applications for PFOA and PFOS in semiconductor manufacture. This was largely based on supply chain concerns from companies unable to determine whether the substances were used in the manufacture of imported components.[28] Existing international and national treaties, regulations, and purchasing requirements create a strong disincentive for US manufacturers of electronics to use either substance. These include the Stockholm Convention on Persistent Organic Pollutants (POPs) under which both PFOA and PFOS are listed as POPs and the European Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) which lists PFOA as a substance of very high concern (SVHC) requiring use authorization. In the US, the Electronic Product Environmental Assessment Tool (EPEAT) establishes environmental performance criteria for material selection, design, end-of-life management, and corporate performance.[29] EPEAT was developed using a grant from EPA as a tool to assist in meeting federal requirements for procuring environmentally sustainable

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[26] https://www.epa.gov/sites/default/files/2017-02/documents/2016_pfoa_stewardship_summary_table_0.pdf

[27] 85 *Fed. Reg.* 45,109 (July 27, 2020).

[28] Id, at 45,114.

[29] https://www.epa.gov/greenerproducts/electronic-product-environmental-assessment-tool-epeat

electronic products, [30] and has become a globally recognized standard for the information technology sector.

EPA's economic assessment for this proposal includes two scenarios to estimate the number of annual notifications that will result from the listing of PFOA and PFOS.[31] The first assumes that the number of notifications will equal those for ammonia, which accounted for the largest number of releases in 2020. Based on the information outlined above, that assumption is clearly inappropriate. The other scenario is that there will be zero notifications of either substance, consistent with the Agency's previous conclusion that PFOA and PFOS are unlikely to be manufactured, imported, or processed after 2015.[32] An analysis of recent reporting data suggests that this scenario seems far more likely, as detailed below.

A total of fourteen companies reported manufacturing, processing, or otherwise using 100 pounds or more of either PFOA and PFOS to the 2020 Toxic Release Inventory (TRI) under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA).[33] Of these, ten companies were engaged in waste treatment and disposal (NAICS Code 562), and the remaining four were chemical/petroleum manufacturers (NAICS Codes 324,325). No companies engaged in computer and electronics manufacturing (NAICS Code 334) reported processing either chemical.

Releases of Aqueous Film Forming Foam will not result in reportable quantities of PFOA or PFOS

As a result of the voluntary phaseout of PFOS in the early 2000s, the substance has not been intentionally added to formulations of aqueous film forming foam (AFFF) manufactured in the United States for over two decades. The SNUR issued in late 2002 subsequently prohibited the import of AFFF manufactured with PFOS. PFOA was used for many years as a processing aid in the production of various fluoropolymers. It was not used in the manufacture of AFFF, although it may occur in trace quantities in the fluorotelomers that are included in the foam. Neither PFOA nor PFOS are intentionally added ingredients in modern foams.

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30 Federal Acquisition Regulations (FAR) subpart 23.704. https://www.acquisition.gov/far/part-23#FAR_Subpart_23_7

31 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. Office of Land and Emergency Management (August 2022). EPA-HQ-OLEM-2019-0341-0035. (EPA Economic Assessment 2022)

32 EPA. 2014 economic analysis of the significant new use rule for long-chain perfluoroalkyl carboxylate chemical substance and perfluoroalkyl sulfonate chemical substances. Cited in EPA Economic Assessment (2022), at 41.

33 2020 was the first reporting year for PFOA and PFOS under TRI. TRI data for 2021 is expected to be available soon.

The absence of AFFF made with PFOS from the market for such an extended period of time makes it extremely unlikely that significant quantities of this material are still in circulation. Heightened awareness about PFOS, combined with legislation passed in 16 states regarding the use of AFFF containing PFAS and efforts by several states to collect this material, have further reduced the likelihood of ongoing storage (and potential use) of PFOS-containing foam.

Although the fluorotelomers used in current AFFF formulations may contain trace quantities of PFOA , the allowable levels are not sufficient to trigger a release of a pound of either substance. As noted by the Agency in its proposal, the military specification for AFFF allows no more than 800 parts per billion (ppb) of either PFOA and PFOS in the liquid concentrate.[34] Because of the rigorous performance criteria established by the military, this specification has been adopted as a de facto industry standard. Assuming the presence of a maximum allowable concentration of PFOA in MILSPEC-compliant foam one would need to release more than 140,000 gallons of fluorotelomer-based AFFF concentrate (more than 2.8 million gallons of water/ concentrate)[35] in a 24-hour period to total one pound of PFOA.

Given the Agency's previous conclusion about ongoing use of PFOA and PFOS, and the information available from the 2020 TRI, it is unclear how EPA could conclude that listing PFOA and PFOS "would give the Agency, state, Tribal, and local governments, and the public a better understanding of where releases occur and the quantities involved."[36]

EPA already has considerable authority to address existing contamination of PFOA/PFOS

The proposal notes that EPA currently has a variety of enforcement tools to address PFAS under CERCLA, the Safe Drinking Water Act (SDWA), and the Resource Conservation and Recovery Act (RCRA).[37] In addition DOD has made considerable progress addressing PFOA- and PFOS-impacted sites through its Environmental Restoration Program. [38]

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[34] U.S. Navy. Performance specification fire extinguishing agent, aqueous film-forming foam (AFFF) liquid concentrate, for fresh and sea water. MIL-PRF-24385F(SH) with Amendment 2. U.S. Navy. Naval Sea Systems Command (Ship Systems).

[35] Assuming a 20:1 mixture.

[36] 87 *Fed. Reg*. 54,418

[37] 87 *Fed. Reg.* 54,436.

[38] https://exwc.navfac.navy.mil/Products-and-Services/Environmental-Security/NAVFAC-Environmental-Restoration-and-BRAC/

Listing under Section 102(a) is the least effective approach to achieving timely cleanup of contamination. Other more effective approaches are available to the Agency

In addition to requiring reporting of releases, designation as a "hazardous substance" under CERCLA can trigger investigation and cleanup liability for potentially responsible parties (PRPs). In an effort to identify as many parties as possible to help pay for cleanup, the definition of PRP under CERCLA broadly covers the current owners and operators of the site, owners or operators of the site at the time the hazardous substances were disposed there, arrangers for disposal including waste generators and brokers, and transporters. Under the strict joint and several liability scheme established under the law, a PRP could be liable for the entire site remediation regardless of its contribution - unless there is a basis to allocate the harm.

Unlike regulation under RCRA, CERCLA does not require EPA to establish a threshold for what concentration of a substance at a site triggers the hazardous designation. Although it is unclear what level of PFOA and PFOS would trigger Agency action (see discussion below), the potential establishment of standards at low- (or sub-) part per trillion (ppt) levels would mean that trace amounts could trigger action under CERCLA. The lack of a concentration threshold, combined with the extremely low concentration levels used for PFOA and PFOS, and the broad definition of PRP make CERCLA a particularly bad fit for addressing these substances. Specifically, promulgation of the listing proposal could lead to contentious, time-consuming, and costly clean-ups and litigation as courts and litigants struggle with applying Superfund's broad enforcement scheme to chemicals measured in the low-ppt range. This litigation will divert resources to transactional costs rather than remediation.

CERCLA's draconian liability and cost recovery scheme could apply to potentially responsible businesses and landowners, including public entities, for any site in the country containing any level of PFOA and PFOS. The proposed designation will facilitate litigation not only between site owners and EPA but among public and private PRPs attempting to shift contribution costs for cleanup

CERCLA Section 104(a)

EPA notes in its proposal that "CERCLA already provides significant authority to federal agencies to address PFOA and PFOS releases because these two chemicals are pollutants and contaminants."[39] CERCLA authorizes EPA cleanup of CERCLA "pollutants or contaminants," and the Agency has used the prospect of treating PFOA and PFOS as such to require their cleanup.

[39] 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

When the Administrator determines that a release of a hazardous substance or any pollutant or contaminant[40] may present an "imminent and substantial danger" to the public health or welfare, Section 104(a) authorizes EPA to remove or provide for remedial action, or take any other response measure consistent with the national contingency plan (NCP), to protect the public health or welfare or the environment.

Safe Drinking Water Act

Section 1431 of the SDWA[41] grants EPA authority to take appropriate enforcement action if it receives information that a contaminant is present in; or likely to enter, drinking water that may present an "imminent and substantial endangerment" to human health. Although the proposal notes that the Agency has used this enforcement tool already to address PFAS contamination, it reasons that it can conduct cleanups at a faster pace if it does not have to make the "imminent and substantial danger finding that is required for responses now."[42]

The SDWA defines contaminant to include "any physical, chemical, biological, or radiological substance or matter in water" and EPA's Section 1431 authority extends to underground sources of drinking water which the Agency has defined as including "both aquifers that currently supply a [public water system (PWS)] and those that simply have the potential to supply a PWS."[43] Courts have found that an endangerment is substantial if there is a reasonable cause for concern that someone may be exposed to a risk of harm.[44] Moreover, the courts have determined that an endangerment can be considered imminent if "conditions which give rise to it are present, even though harm may not be realized for years."[45] Courts

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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.").

[40] The term "pollutant or contaminant" is defined as any element, substance, compound, or mixture that will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions or physical deformations upon release to the environment and subsequent exposure.

[41] 42 U.S.C. Section 300(i)

[42] 87 *Fed. Reg.* 54,418.

[43] USEPA. Updated guidance on emergency authority under Section 1431 of the Safe Drinking Water Act. Memo from Office of Enforcement and Compliance Assurance to EPA Regional Counsel and Enforcement Directors (May 30, 2018). https://www.epa.gov/enforcement/updated-guidance-emergency-authory-under-sdwa-section-1431 (Section 1431 Memo)

[44] U.S. v. Conservation Chemical Co., 619 F. Supp. 194 (W.D. Mo. 1985) (interpreting the term "endangerment" in CERCLA).

[45] USEPA. Section 1431 Memo, at 8.

also have concluded that an imminent hazard may be declared at any point in a chain of events that may ultimately result in harm to the public.[46]

Section 1431 also requires that EPA confirm that state and local authorities have not acted to address the issue, but confirmation may consist of no more than an email or telephone log. EPA may act under Section 1431 regardless of whether a state, territory, or tribe has primary enforcement authority. Such actions can include –

- Provision of alternative water supplies,
- Investigation of the nature and extent of the environmental contamination,
- Monitoring of potential or identified contaminants
- Development of feasibility and engineering studies, and
- Control of the source of contaminants, including cleanup of contaminant soils

EPA can issue administrative orders and/or file a civil action to compel responsible parties to conduct remedial actions. In cases where the responsible party is not clearly known, EPA may issue the order to persons who caused or contributed to the endangerment and require a study to assist in the identification of responsible parties.[47]

Resource Conservation and Recovery Act

EPA's authority under RCRA includes its ability to compel cleanup actions under the corrective action program and its emergency authority under Section 7003. These potential mechanisms are described below and could be used to address releases at active facilities.

Section 3004(u) - Corrective Action Program[48]

In October 2021, EPA announced its intent to add PFOA and PFOS to the list of hazardous constituents in Appendix VIII of RCRA which would trigger a range of requirements under the RCRA corrective action program. Under the program, facilities required to hold a permit for the treatment, storage, or disposal (TSD) of hazardous waste must institute corrective action to protect human health and the environment from all releases of hazardous waste or constituents regardless of the time that the waste was placed in a storage unit. While the statute indicates that the

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[46] Trinity Am. Corp. v. EPA, 150 F.3d 389, 399 (4th Cir 1998) ("EPA need not demonstrate that individuals are drinking contaminated water to justify issuing an emergency order."); Dague v. City of Burlington, 935 F.2d 1343, 1356 (2nd Cir. 1991); U.S. v. Ottati & Goss, Inc., 630 F.Supp 1361, 1395 (D.N.H. 1985).

[47] USEPA Section 1431 Memo, at 17.

[48] 40 CFR Section 264.1019(a)

releases must be from a solid waste management unit (SWMU), EPA takes the position that the term extends to management units that are not subject to permitting and to units where waste have been routinely and systematically released (*e.g.*, a loading dock).[49] In addition, the Agency has indicated that even areas that do not qualify as SWMUs can be addressed through EPA's omnibus permitting authority under RCRA.[50]

Section 7003[51]

RCRA Section 7003 provides EPA with broad and effective enforcement tools that can be used to abate conditions that may present an imminent and substantial endangerment to health or the environment. It allows EPA to address situations where the handling, storage, treatment, transportation, or disposal of any solid waste[52] may present such an endangerment. In these situations, EPA can initiate judicial action or issue an administrative order to any person who has contributed or is contributing to such handling, storage, treatment, transportation, or disposal to require the person to refrain from those activities or to take any necessary action. Importantly, this authority can be used at sites and facilities that are not subject to RCRA permitting requirements or other environmental regulation. As with SDWA Section 1431, the endangerment standard of Section 7003 has been interpreted quite broadly.[53]

U.S. Department of Defense Responsibilities

Under its Installation Restoration Program (IRP) policy DOD has taken steps to address PFOA and PFOS-impacted drinking water sources. According to the latest report DOD obligated $1 billion through FY 2020 for investigating and cleaning up releases of PFAS at military facilities.[54] Based on current information, the Department estimates that budget requirements for PFAS remediation for beyond FY 2021 will exceed $2 billion annually. DoD expects this estimate to increase as it completes initial assessments and gathers more information about the required extent of the cleanup.

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[49] 61 *Fed. Reg.* 19,432, 19, 442 (May 1, 1996).

[50] Id, at 19,443.

[51] 42 U.S.C Section 6973

[52] Solid waste is defined as any solid, semi-solid, liquid, or contained gaseous materials discarded from industrial, commercial, mining, or agricultural operations, and from community activities.

[53] EPA. Guidance on the use of Section 7003 of RCRA. Office of Enforcement and Compliance Assurance. (October 1997). https://www.epa.gov/sites/default/files/2013-10/documents/use-sec7003-mem.pdf

[54] Defense Environmental Programs Annual Report to Congress for FY 2020. https://denix.osd.mil/arc/dep-arc-fy-2020/report/dep-arc-fy-2020/

As part of the National Defense Authorization Act (NDAA) for Fiscal Year 2021, Congress imposed several requirements and obligations on the DoD with regard to 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 who conducted the testing. In addition, Section 332 required the DoD, when conducting removal or remedial actions pursuant to PFOA and/or PFOS contamination found in drinking or ground water to ensure that they achieve the most stringent of any enforceable state and federal drinking, surface, or groundwater standards or health advisories issued pursuant to the SDWA.

EPA has not established that sufficient capacity exists for the disposal and destruction of waste containing PFOA and PFOS

As a result of designating PFOA and PFOS as hazardous substances, generators of wastes containing these substances will need to find appropriate methods for their disposal. Among the concerns identified with CERCLA response actions is the availability of sufficient capacity for the disposal of the material that is generated.[55] In the case of the PFOA and PFOS, this material may include contaminated soil, spent granular activated carbon generated from treating contaminated water sources, and biosolids from wastewater treatment works. One estimate suggests that the number of sites potentially requiring remediation may total in the tens of thousands.[56]

EPA's 2020 disposal/destruction guidance does not provide sufficient clarity on practices that are acceptable to EPA

Despite the likely need for increased capacity for the disposal of wastes containing PFOA and PFOS if those substances are considered "hazardous substances" under CERCLA, EPA has not attempted to evaluate whether sufficient disposal capacity exists. In fact, EPA has not provided clear guidance on what disposal options it considers to be appropriate for PFOA and PFOS. Draft interim guidance released by Office of Land and Emergency Management (OLEM) in 2020 discusses three possible disposal/destruction approaches that may be effective and are commercially available – landfilling, thermal treatment, and underground injection. However, the EPA report notes -

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[55] An assurance of the availability of hazardous waste disposal capacity is a requirement of remedial response action for hazardous substances under CERCLA Section 104(c)(3).

[56] Salvatore D *et al.* Presumptive contamination: a new approach to PFAS contamination based on likely sources. *Environ Sci Technol Lett* 100(37): 2c00502 (2022). https://doi.org/10.1021/acs.estlett.2c00502

> . . . significant uncertainties remain with respect to the potential for migration to the environment associated with the destruction and disposal of PFAS and PFAS-containing materials using the technologies identified . . . EPA recognizes that the relative uncertainty associated with technologies' capabilities to control migration of PFAS to the environment is one of several factors that the public considers in determining how to destroy or dispose of PFAS-containing materials. Other factors would include whether it is imperative to destroy or dispose of the waste immediately versus storing it and waiting for those uncertainties to be reduced, the cost and availability of destruction and disposal options, the type of waste materials, and the concentrations of PFAS in the waste.[57]

In order to reduce the uncertainties,[58] the draft guidance indicates that "interim storage [from 2 to 5 years] may be considered for PFAS or PFAS-containing material."[59]

OLEM's 2020 interim guidance has not yet been finalized, but creates considerable confusion about what disposal methods the Agency will find to be acceptable for waste materials containing PFOA or PFOS.[60] Recent comments from EPA[61] and DOD[62] indicate the problems associated with this uncertainty, yet OLEM has indicated that it does not plan to update the draft interim guidance until late 2023 – about the same time that EPA has indicated it will finalize the CERCLA designation for the two substances, PFOA and PFOS. This leaves a substantial gap in the ability to properly dispose of waste that may be identified as part of the proposed designation.

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[57] EPA. Interim guidance on the destruction and disposal of perfluoroalkyl and polyfluoroalkyl substances and materials containing perfluoroalkyl and polyfluoroalkyl substances. Interim Guidance for Public Comment. OLEM. (December 18, 2020). (Draft Interim Guidance) https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf

[58] Although the draft guidance lists underground injection wells as the having relatively less uncertainty, it notes that well capacity is limited. Consequently, injection is likely not a viable disposal options for most facilities.

[59] EPA Draft Interim Guidance, at 5.

[60] In addition, the suggestion to consider interim storage would trigger requirements for a large number of facilities to obtain TSD permits under RCRA Section 3004(u). Although OLEM administers the RCRA permitting program, the draft Interim Guidance does not discuss the impacts of such a permitting requirement.

[61] Inside EPA. *EPA Pledges to Preserve Biosolids Disposal Options in Face of PFAS Fears*. October 11, 2022. "EPA water chief Radhika Fox says EPA is facing a 'frontier issue' as it grapples with addressing per- and polyfluoroalkyl substances (PFAS) in biosolids but is pledging to work with key groups to preserve the three management methods – land application, incineration and landfilling – that wastewater treatment facilities currently use to dispose of biosolids while also protecting public health."

[62] Inside EPA. *DOD Rules Out Storage While Stressing Need for PFAS Disposal Options* (October 24, 2022).

Uncertainty about the capacity for proper disposal of wastes containing PFOA and PFOS is further heightened by the ongoing shortfall in incineration capacity for hazardous waste.[63] Although it was expected that the capacity shortfall to be resolved by now, it appears that it will continue until additional capacity is expected to come online in 2024-2025.[64]

Before moving ahead with this listing proposal, EPA must clarify the following issues –

- what disposal or remediation options it considers appropriate for wastes containing PFOA and PFOS, and
- the existing capacity of the allowable options to handle the influx of this large amount of waste material.

Without this critical information, stakeholders will not be able to fully assess the impacts of the Agency's listing proposal.

Significant uncertainty exists regarding the target clean-up levels for PFOA and PFOS

The proposal to designate PFOA and PFOS as hazardous substances cannot be considered in isolation from the concentration that EPA will consider as the target for cleanup of contaminated sites. Designation of these two substances will require that their presence be considered in identifying sites for addition to the NPL and that PFOA and PFOS contamination be addressed at NPL sites – both new and existing. CERCLA designation can also trigger RCRA corrective action at TSD permitted sites and likely lead to new requirements in state and private cleanup actions. In all cases, the concentration target established by EPA will determine the number of sites that could potentially be subject to cleanup requirements and the amount of cleanup required at each site. Without this information, it is not possible to assess the full impacts of the proposal. Given that considerable confusion exists about what concentration the Agency will determine to be the cleanup targets for various media, it is clearly premature for EPA to be taking this action at this time.

In 2019 OLEM released draft recommendations for preliminary groundwater remediation goals (PRGs) of 70 ppt for PFOA and PFOS in groundwater that is a current or potential drinking water source. The recommendation was based on the 2016 Lifetime Health Advisories (LHAs) developed by the Water Office. OLEM also recommended a screening level of

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[63] EPA. Memo from Carolyn Hoskinson, Office of Resource Conservation and Recovery. Regulatory Options for Addressing the Temporary Backlog of Containerized Hazardous Waste Needing Incineration (August 10, 2021). https://rcrapublic.epa.gov/rcraonline/details.xhtml?rcra=14939

[64] Inside EPA. *State Officials Warn of Ongoing Capacity Shortage for PFAS Disposal* (October 21, 2022).

40 ppt for PFOA or PFOS. Although OLEM indicated at the time that the recommendations were interim and subject to revision, the Agency has not updated these recommendations.

More recently, OLEM revised the regional screening level (RSL) for PFOA and PFOS in tap water to 60 ppt and 40 ppt, respectively, when the substances are present individually and 6 and 4 ppt when they are found together.[65] These values are based on the analysis conducted by the Agency for Toxic Substances and Disease Registry (ATSDR).[66]

In late 2021, however, the Office of Water issued draft assessments of PFOA and PFOS in preparation of issuing National Primary Drinking Water Standards for the two substances. Based on these draft documents, the Water Office issued interim LHAs of 0.004 ppt for PFOA and 0.020 ppt for PFOA in June 2022. At the time of release EPA indicated that the LHAs were interim and subject to revision, pending the outcome of the review of the draft assessments by the Agency's Science Advisory Board (SAB). The SAB raised a number of concerns with the assessments in its August comments on the draft assessments,[67] but the Water Office has provided no indication of plans to revise the interim LHAs.

The Water Office has indicated that it will promulgate drinking water standards for PFOA and PFOS by the end of 2023.[68] These standards will create a national target for cleanups at NPL, state-led, and private sites. Since the interim LHAs are below the reporting limits of EPA validated test methods and the capability of existing treatment technologies, it is not clear what standards the Agency will determine are technically and economically feasible, per SDWA requirements.

Based on recent communications from the Agency, it appears that future cleanup targets for PFOA and PFOS may be set at the minimum detection level for the substances using EPA's validated analytical methods.[69] Assuming these analytical methods continue to improve, the targets for cleanup will likely drop as the detection limit is lowered. As a consequence,

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65 Consistent with standard practice, the values for presence of the individual substance are based on a Hazard Quotient (HQ) of 1.0; the values for the combined presence are based on an HQ of 0.1. The HQ represents the ratio if the potential exposure to the substances and the level at which no adverse effects are expected.

66 ATSDR. Toxicological Profile for Perfluoroalkyls. TP200. US Dept of Health and Human Services (May 2021). https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237

67 SAB. Letter to Michael S. Regan, EPA Administrator. Transmittal of the Science Advisory Board Report titled "Review of EPA's Analysis to Support EPA National Primary Drinking Water Rulemaking for PFAS. EPA-SAB-22-008 (August 22, 2022). https://sab.epa.gov/ords/sab/f?p=114:18:9170848539727:::RP,18:P18_ID:2601#report

68 Proposed standards are currently under review by the Office of Management and Budget.

69 "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.

PRPs would have no way of knowing if existing PFOA and PFOS levels are below those EPA will deem to be sufficiently protective - meaning that their duty for cleanup would conceivably never end.

Without an understanding of the cleanup target that will be applied to cleanups required or triggered by the proposed listing, stakeholders (and EPA) cannot fully assess the potential impacts of the proposal.

EPA has not established that PFOA and PFOS present a "substantial danger"

Listing under Section 102(a) requires that EPA determine that the substance "may present substantial danger to the public health or environment"

Under CERCLA Section 102(a), EPA "shall promulgate … regulations designating as hazardous substances … such elements, compounds, mixtures, solutions, and substances which, when released into the environment *may present substantial danger to the public health or welfare or the environment.*"[70] To date, no substance has been listed under the CERCLA Section 102(a) process, so there is uncertainty around what "substantial danger" means in this context, how EPA would meet that standard, and whether it would involve a review of a specific substance or class of substances. Although the phrase "substantial danger" is used elsewhere in CERCLA, those references provide little insight into what may meet this standard under Section 102(a).

In its proposal, EPA offers the following general description of its approach -

> 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

[70] 42 U.S.C. Section 9602(a) (*emphasis added).*

> information to determine whether the substance, when released, may present a ''substantial danger.''[71]

EPA has not indicated what weight it will apply to the (non-exhaustive) criteria identified in the proposal or what metrics it will use to assess the severity of each of the identified criterion. In its consideration for PFOA and PFOS, EPA outlines three areas – chemical/physical characteristics, toxicity and toxicokinetics, and environmental persistence. The proposal notes that, while the widespread distribution of these substances "significantly contributes" to its proposed finding, the evidence for adverse health effects "plays a major role."

The evidence for potential adverse health effects is drawn from the 2016 LHAs developed by the Office of Water which, although subject to peer review, are non-enforceable and were not subject to regulatory notice and comment.[72] The proposal also references the draft updated health effects analyses developed by the Water Office to support the development of National Primary Drinking Water Regulations that have not yet been proposed. Further, those documents were subject to criticism by the SAB, as discussed above.

Rather than define "substantial danger" for the purposes of implementing Section 102(a), EPA has historically relied on other statutory authorities for designating hazardous substances as outlined in Section 101(14), including the CWA, RCRA, and the Toxic Substances Control Act (TSCA) - but not the SDWA. EPA has not conducted assessments of PFOA or PFOS under these other statutes. In fact, the Agency has indicated that it has yet to evaluate the existing data for either substances or establish a record to support a proposal to identify them as hazardous constituents under RCRA (40 CFR part 261 Appendix VIII).[73]

Rather than depend on the ongoing SDWA evaluation, OLEM should conduct its own evaluation of the available data under the established mechanisms outlined in CERCLA. EPA also should clearly outline how it will apply the criteria it has identified for this and future proposals under Section 102(a) before moving ahead with designation of PFOA and PFOS.

This proposed rulemaking would affect a broad set of stakeholders beyond those simply interested in PFOA and PFOS because of how it will affect EPA decisions on future hazardous substance designation decisions. EPA has already announced plans to release an advanced

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71 87 *Fed. Reg.* 54421.

72 In pending litigation regarding interim Health Advisories issued in June 2022 for PFOA and PFOS, EPA argues that Health Advisories are "merely informational documents imposing no rights, obligations, or legal consequences on any party." ACC v. US EPA Case No. 22-1177 (DC Circuit). Respondent's Motion to Dismiss. September 15, 2022.

73 87 *Fed. Reg.* 54,431.

notice of proposed rulemaking to consider using its 102(a) authority to designate additional PFAS as hazardous substances.

The Water Office's draft assessments of PFOA and PFOS are flawed and should not be used as the basis for a determination of "substantial danger"

The reference doses for both PFOA and PFOS in the draft assessments developed by EPA's Office of Water are based on the finding of reduced vaccine response in a unique population of children. However, the epidemiology data do not provide clear evidence of an association with reduced vaccine response or increased incidence in illness in children. In the Faroe Island study, the researchers observed an association between maternal serum concentrations and antibodies in only one of two cohorts of children investigated - a cohort with lower serum concentrations of the two substances. Moreover, the evidence for an increase in infection rates among children is minimal and conflicting.

In assessing the potential carcinogenicity of PFOA, EPA is based on an epidemiology study with a relatively small number of cancer cases that does not a show clear dose-response. These data also conflict with those available from other epidemiology studies and with the animal evidence.

The vaccine response findings have not been duplicated elsewhere

EPA's analysis of immune effects focuses on the results from Budtz-Jorgensen and Grandjean (2018)[74] suggesting the following findings from the study of diphtheria and tetanus antibody concentrations associations among Faroe Islands children –

- An association between prenatal exposure to PFOA/PFOS and antibody concentrations at 5 years of age, and
- An association between PFOA/PFOS serum concentrations at age 5 and antibody concentrations at age 7.[75]

In an earlier publication by Grandjean et al. (2012),[76] however, this research group did not observe an association between maternal PFOA/PFOS serum concentrations and tetanus

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[74] Budtz-Jorgensen E and Grandjean P. Application of benchmark analysis for mixed contaminant exposures: mutual adjustment of perfluoroalkyl substances associated with immunotoxicity. *PLoS ONE* 13:e0205388 (2018). https://doi.org/10.1371/journal.pone.0205388

[75] The draft approaches select the benchmark dose modeling results for the serum levels at age 5 and antibody levels at age 7 from the cohort of children born between 1997-2000 to calculate the reference doses.

[76] Grandjean P *et al.* Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. *J Amer Med Assn* 307(4):391-397 (2012). https://doi.org/10.1001/jama.2011.2034

vaccine antibody concentrations at age 5, or PFOS serum concentrations at age 5 and tetanus vaccine antibody concentrations at age 7, in a cohort of children born between 1997 and 2000. Although the researchers reported an association in a cohort of Faroe Islands children born from 2007 and 2009, serum concentrations were lower than in the earlier cohort (**see Table 2**).

Table 2. Comparison of Serum Concentrations at Birth and 60 months in the Studies of Faroe Islands Children

	Median Concentration (Interquartile Range)			
	1997-2000 Cohort[a]		2007-2009 Cohort[b]	
	At birth	At 60 months	At birth	At 60 months
PFOS (ng/mL)[1]	27.3 (23.2,33.1)	16.7 (13.5,21.1)	n/a	4.7 (3.5,6.3)
PFOA	3.20 (2.6,4.0)	4.1 (3.3,4.9)	n/a	2.2 (1.8,2.8)
[a] Source: Table 2, Grandjean *et al.* 2012;				
[b] Source: Table 1, Grandjean *et al.* 2017a[77]				
[1] ng/mL – nanograms per milliliter				

Among 7-year olds, the Faroe Islands researchers did not find an association between serum concentrations at 7 and antibody levels after excluding children suspected of receiving additional antibodies (*i.e.*, no booster, ER visit, or unexplained antibody increase).[78] Although the 2012 publication reports an association between serum levels of PFOA at age 5 and tetanus antibody concentrations at age 7,[79] the analysis does not control for children receiving additional antibodies between ages 5 and 7. Given the potential impact on the results, this would appear to be a significant oversight that raises additional questions about the broad conclusion that exposure to PFOA or PFOS reduces vaccine response in children.

The results in Faroe Island children were not associated with an incidence of the disease

In the draft assessments for PFOA and PFOS, EPA suggests that a decrease in antibody concentrations may reduce the prevention of diphtheria and tetanus in children. There is no evidence for an increased incidence of diphtheria and tetanus, however. Further, results of

[77] Grandjean P *et al.* Estimated exposures to perfluorinated compounds in infancy predict antibody concentrations at age 5 years. *J Immunol* 14(1):188-195 (2017). Maternal serum concentrations are not provided. https://doi.org/10.1080/1547691X.2017.1360968

[78] Grandjean P *et al.* Serum vaccine antibody concentrations in adolescents exposed to perfluorinated compounds. *Environ Health Perspect* 125:077018 (2017). https://doi.org/10.1289/EHP275

[79] No association is observed between PFOS serum concentrations at age 5 and diphtheria antibody concentrations at age 7, after adjusting for the antibody concentration at age 5.

associations between PFOA exposure and childhood infection are at best mixed, with studies reporting both increased and decreased associations with reported infections.[80] As a result, the National Toxicology Program (NTP) concluded that there is low confidence that exposure to either substance is associated with an increased incidence of infectious disease or a lower ability to resist or respond to infectious disease.[81]

The epidemiological evidence for an association between PFOA and PFOS exposure and hypersensitivity and autoimmune disease is also mixed. Studies that observed significant associations with "ever" or "current" asthma were seen primarily in sex- or age-specific subgroups but were null or insignificant in whole study analyses. For allergy and eczema outcomes, results were inconsistent across studies. Studies of PFOS exposure and autoimmune condition in humans are limited, and the results from studies of PFOA exposure and human autoimmune disease are mixed. While Steenland *et al.* reported an association with ulcerative colitis,[82] the association was only found in the retrospective analysis, not the prospective one, and the analysis did not adequately control for confounding factors such as gastrointestinal infection and family history.[83]

EPA's determination that PFOA is likely to be carcinogenic to humans is based on limited human evidence of kidney tumors

The Water Office has developed a cancer slope factor for PFOA based on elevated levels of kidney cancer (renal cell carcinoma, or RCC) reported by Shearer *et al. (2021).*[84] The Agency concluded that the available data do not support the development of a cancer estimate for PFOS.

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80 Steenland K *et al.* Review: Evolution of evidence on PFOA and health following the assessments of the C8 Science Panel. *Environ Int* 145: 106125 (2020). https://doi.org/10.1016/j.envint.2020.106125

81 NTP. Immunotoxicity Associated with Exposure to Perfluorooctanoic acid or Perfluorooctane Sulfonate. NTP Monograph. US Department of Health and Human Services. (September 2016) https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf

82 Steenland K *et al.* Ulcerative colitis and perfluorooctanoic acid (PFOA) in a highly exposed population of community residents and workers in the mid-Ohio valley. *Environ Health Perspect* 121: 900-905 (2013). https://doi.org/10.1289/ehp.1206449

83 http://www.c8sciencepanel.org/study.html.

84 Shearer JJ *et al.* Serum concentrations of per-and polyfluoroalkyl substances and risk of renal cell carcinoma. *J Natl Cancer Inst* 113:580-587 (2021). https://doi.org/10.1093/jnci/djaa143

The key study is limited in size and does not show a clear dose response with the exposure quartiles

Shearer *et al.* (2021) identified 324 cases of renal cell carcinoma (RCC) among 75,000 participants of a multi-site study from medical centers in 10 US cities.[85] The subjects had baseline serum collected during 1993-2002, although the samples were not analyzed for PFOA and other PFAS until 2018. The cases were diagnosed with RCC subsequent to serum collection. A control group of 324 individuals who had never had RCC was selected from among the same study participants – matched to the RCC cases by age (>50 years of age), sex, ethnicity, study center, and year of blood draw.

The researchers calculated odds ratios (ORs) for exposure quartiles and for continuous exposure, controlling for multiple potential confounding factors[86] in addition to the case-control matching factors. The quartiles were assigned based on serum concentrations of PFOA among controls, resulting in an uneven distribution in the ranges of the quartiles, which can skew the analyses for exposure-response trends. It is unclear whether the covariates were addressed one at a time (varying each potential confounder, to see how the fit of the model changed) or all at once. No equation was presented to help understand their view of the interactions of all the confounders present when assessing the correlations with RCC.

As shown in **Table 3** and as emphasized with shading, the data do not support a positive dose-response relationship (CI includes 1.0) and would be considered not significantly elevated for the three higher exposure quartiles after adjusting for other PFAS exposure. The results also do not suggest a dose-response pattern, and the p value for a positive trend was not statistically significant (p=0.13) according to the researchers.

Although the OR for the continuous exposure analysis was statistically significant, questions remain about the meaning of this finding. Of primary concern is whether the single serum measurement taken prior to RCC diagnosis (1993-2002) is an appropriate measure of PFOA exposure.

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[85] The total population of 150,00 individuals was divided into two groups – screening and control. RCC cases and controls were identified from the screening group.

[86] These included body mass index, smoking status, hypertension, prior freeze-thaw cycle, year of blood draw, estimated glomerular filtration rate (eGFR), and exposure to other PFAS. Several of these confounders are on their own dose-response continuum, rather than a simple yes/no comparison, which further complicates the ability to pinpoint the effects of PFOA exposure.

Table 3. Odds ratios and 95% confidence intervals (CIs) evaluating PFOA serum concentration and risk of renal cell carcinoma (Shearer *et al.* 2021) [87]

Serum Concentration Quartile (micrograms/Liter)	Controls	Cases	OR	95% CI
<4.0	81	47	1.00	Reference
>4.0-5.5	79	83	1.41	0.69, 2.90
>5.5-7.3	83	69	1.12	0.52, 2.42
>7.3-27.2	81	125	2.19	0.86, 5.61
Continuous[88]			1.68	1.07, 2.63

Conducting an analysis for continuous exposure, in addition to the quartile analysis, helps to address the disparity in the range of the exposures in the quartiles. However, questions remain about the distribution of exposures between the two groups. The supplemental information[89] provided by the authors suggests that the range of serum levels was only slightly higher among the cases compared to the controls, with the exception of a serum level nearly 10 times the high end of the range in the case group. While this value may explain the use of a log base 2 scale for the continuous analysis, Shearer *et al.* do not explain the potential effect of this outlier on their results. However, the broad confidence interval in the highest exposure quartile suggests that such an explanation is necessary to adequately interpret the findings. Typical publications of this type will generally develop an equation that explains the relationship between the continuous variables, as well as provide a robust uncertainty or sensitivity analysis. These elements are missing from the Shearer *et al.* (2021) publication and would be considered "best practice" for epidemiology that is expected to become the basis for a public health regulation.

Although the researchers were able to use several factors to match controls to the RCC cases, the decision to select an equal number of controls may also limit the significance of the continuous exposure finding. While the number of controls selected per case may vary, it is common in the nested case-control literature to find four or five controls per case.[90] The researchers do not provide an explanation for the decision to identify only 324 controls,

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[87] Source: Table 2 of Shearer *et al.* 2021. Shading is applied to demonstrate that the 95%CI range includes the odds of 1.00, meaning the finding is *not statistically significant* and is not found to be a significantly elevated odds ratio.

[88] Continuous OR is in relation to a 1-unit increase in serum PFOA concentration on the log base 2 scale.

[89] https://academic.oup.com/jnci/article/113/5/580/5906528#supplementary-data

[90] Ernster VL. Nest case-control studies. *Prevent Med* 23(5):587-590 (1994). https://doi.org/10.1006/pmed.1994.1093

particularly given the fact that they appear to have had such a large pool of individuals for whom a serum sample had been collected.

Finally, a key topic related to the variety of RCC subtypes that can be diagnosed is the differentiation in tumor type, by genetic basis. An analysis of the subtype of RCC has been a topic of recent interest[91] due to the variable survival rates and seemingly different course of both development and treatment. Not all RCC are the same which raises concern that any study linking PFOA to generic RCC could be conflating correlation with causation artificially, by not evaluating by RCC subtype. Analysis of the raw data by subtype may yield a different conclusion, and also provide clues to where to look in the animal data for subtle mode-of-action data that could clear up the discordance between human and laboratory animal kidney disease attributed to PFOA.

Other epidemiology studies report conflicting findings

Two publications explore the incidence of kidney cancer among residents of the Mid-Ohio Valley exposed to PFOA in drinking water – Vieira *et al.* (2023)[92] and Barry *et al.* (2013).[93] The study by Barry *et al.* was conducted in the same study area as Vieira *et al*. and likely included many of the same participants. However, Barry *et al.* included information from additional years of follow-up and provides a more recent analysis of cancer incidence in the Mid-Ohio River Valley. Also, as indicated above and as described in more detail below, Barry *et al.* includes a more comprehensive assessment of exposure. Moreover, Barry *et al.* included an analysis of cancer incidence among the workers of the manufacturing facility, whereas the previous study of these workers by Steenland and Woskie (2012)[94] was limited to cancer mortality.

The cohort assembled by Barry *et al.* included 28,541 residents and 3,713 workers who participated in at least one of the follow-up surveys conducted between 2008 and 2011 and for whom an exposure estimate was available. A total of 105 cases of kidney cancer were identified with a complete data set within the cohort – 87 among the residents and 18 among the workers. Barry *et al.* developed estimates of the cumulative PFOA serum concentration using the same model as Vieira *et al.*, but accounted for each participant's reported residential

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91 Wang Z *et al.* Cause-specific mortality among survivors from T1N0M0 renal cell carcinoma: a registry-based cohort study. *Frontiers in Oncology* (2021). https://doi.org/10.3389/fonc.2021.604724

92 Vieira VM *et al.* Perfluorooctanoic acid exposure and cancer outcomes in a contaminated community: a geographic analysis. *Environ Health Perspect* 121: 318-323 (2013). https://doi.org/10.1289/ehp.1205829

93 Barry V *et al.* Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. *Environ Health Perspect* 121: 1313-1318 (2013). https://doi.org/10.1289/ehp.1306615

94 Steenland K and Woskie S. Cohort mortality study of workers exposed to perfluorooctanoic acid. *Am J Epidemiol* 176: 909-917 (2012). https://doi.org/10.1093/aje/kws171

history, drinking water source, tap water consumption, and workplace water consumption.[95] The researchers calculated hazard ratios (HRs) for an increase in kidney cancer among residents, workers, and the combined group cohort for both continuous and quartiles of PFOA serum concentration.[96]

Table 4. Exposure quartiles and continuous log estimated cumulative PFOA serum concentration and risk of kidney cancer risk with a 10-year lag (Barry *et al.* 2013)[97]

Serum Concentration Quartile	Residents		Workers		Total	
	HR (95% CI)	p-Value	HR (95% CI)	p-Value	HR (95% CI)	p-Value
Quartile 1	1.0		1.0		1.0	
Quartile 2	0.94 (0.45, 1.99)	0.02	1.22 (0.28, 5.3)	0.42	0.99 (0.53, 1.85)	0.34
Quartile 3	1.08 (0.52, 2.25)		3.27 (0.76, 14.10)		1.69 (0.93, 3.07)	
Quartile 4	1.50 (0.72, 3.13)		0.99 (0.21, 4.68)		1.43 (0.76, 2.69)	
Continuous	1.11 (0.96, 1.29)	0.17	0.99 (0.67, 1.46)	0.97	1.09 (0.97, 1,21)	0.15

As a result of the additional follow up, refined exposure assessment, and larger cohort size in the analysis by Barry *et al.*, the association between PFOA exposure and risk of kidney cancer is substantially reduced. Significantly, the hazard ratio is weakest for workers with a significantly higher median estimated exposure.

A recently published report of cancer incidence in a Swedish cohort with elevated drinking water exposures to PFAS, including PFOS and PFOA, also did not find a statistically significant association between elevated exposure and kidney cancer incidence overall.[98] Although the authors do report a small increase in a subgroup with more recent exposure, they did not observe an association when among individuals exposed for a longer period of time.

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[95] Based on measurements taken in 2005-2006, mean serum concentrations were 0.024 mg/L for community residents and 0.113 mg/L for workers.

[96] The cutoffs for the exposure quartiles are not provided in the publication of supplemental material. The model was adjusted for the same potential confounders as in the analysis by Vieira *et al.*

[97] Source: Barry *et al.* 2013 and supplemental material available at https://ehp.niehs.nih.gov/doi/suppl/10.1289/ehp.1306615.

[98] Li *et al.* Cancer incidence in a Swedish cohort with high exposure to perfluoroalkyl substances in drinking water. *Environ. Res.* 204:112217 (2022). https://doi.org/10.1016/j.envres.2021.112217

Kidney tumors were not observed in animal bioassays

Considering the uncertainty in the epidemiological database, it is important to look at the results of cancer studies in laboratory animals. While several bioassays have been conducted, none have reported an increase in kidney cancer among the exposed animals. Reported cancers have included liver, pancreas, and Leydig cell cancers. The most recent of these studies was conducted by the National Toxicology Program (NTP).[99] In addition, no plausible biological basis for the development of tumors from PFOA exposure has been reported. Without it, there does not appear to be sufficient information to establish causation.

[99] NTP. Technical report on the toxicology and carcinogenesis studies of perfluorooctanoic acid administered in feed to Sprague-Dawley rats. Technical Report 598. Department of Health and Human Services. Research Triangle Park, North Carolina (2019). https://doi.org/10/22427/NTP-TR-598