U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

November 7, 2022

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

Re: **Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, Docket ID: EPA-HQ-OLEM-2019-0341**

Dear Administrator Regan:

On September 6, 2022, the U.S. Environmental Protection Agency (EPA) published a proposed rule titled *Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*.[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule.

Advocacy is concerned that the agency does not provide an adequate factual basis to support its certification under the Regulatory Flexibility Act (RFA)[2] that the rule will not have a significant economic impact on a substantial number of entities. In its analysis, the agency omits some costs associated with direct impacts of the rule. Advocacy believes that those costs will likely pose a significant economic burden on a substantial number of small entities. Therefore, Advocacy recommends that EPA convene a SBREFA panel to assess all direct costs, including those the agency mis-identifies as indirect costs, of the rule on small entities and to consider less burdensome alternatives.

[1] 87 Fed. Reg. 54415, (Sept. 6, 2022).

[2] 5 U.S.C. Sec. 601, et seq.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA). As such the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[4] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, unless the agency certifies that the public interest is not served by doing so.[5]

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[6]

B. The Proposed Rule

On September 6, 2022, EPA proposed designation of PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). According to EPA, adverse human health effects, mobility, persistence, prevalence, and other factors related to PFOA and PFOS support its proposed finding that these substances, when released into the environment, may present substantial danger to the public health or welfare or the environment. The hazardous substance designation triggers a reporting requirement. Entities must immediately report releases of PFOA and PFOS that meet or exceed the reportable quantity of 1 pound or more in a 24-hour period. The entities potentially affected by this proposed action include PFOA and/or PFOS manufacturers (including importers and importers of articles), processors, downstream users of products containing PFOA and/or PFOS, waste management and wastewater treatment facilities, farms, and municipalities.

The agency provides direct costs from the rulemaking to include the reporting obligation noted above. EPA also qualitatively discusses what the agency is describing as indirect costs. These include clean up and recovery costs from contaminated sites. EPA certifies, based only on the

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[3] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

[4] Small Business Jobs Act of 2010 (PL. 111-240) §1601.

[5] *Id*.

[6] *Id.*

costs associated with reporting releases for PFOA and PFOS, that the rule will not have a significant economic impact on small entities.

II. Advocacy's Small Business Concerns

Advocacy is concerned that the agency does not provide an adequate factual basis to support its certification under the RFA. The agency does not include all the costs associated with direct impacts of the rule. Based on feedback from small entities, Advocacy believes that those impacts will likely pose a significant economic burden on a substantial number of small entities.

A. EPA Has Improperly Certified the Rule under the RFA Because the Agency Does not Provide an Adequate Factual Basis for its Certification

If after conducting an analysis on the proposed rule, an agency determines that a rule will not have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify. The certification must include a statement providing the factual basis for this determination. Under the RFA, a certification must include, at a minimum, a description of the affected entities and the impacts that clearly justify the "no impact" certification.[7] The agency's reasoning and assumptions underlying its certification should be explicit in order to obtain meaningful public comment and thus receive information that would be used to evaluate the certification.[8] Agency certifications of final rules are subject to judicial review.[9] Courts evaluate certifications by determining whether the statement of basis and purpose accompanying the rule identifies a "factual basis" to support them.[10]

If an agency covered by Section 609 of the RFA, such as EPA,[11] is unable to certify, the agency must conduct a SBREFA panel to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.[12] In addition, the agency must produce an initial regulatory flexibility analysis (IRFA) in the *Federal Register* at the same time it publishes the proposed rulemaking. The IRFA is required to include discussion of specific elements including a description of any significant alternatives to the proposed rule that minimize significant economic impacts on small entities while accomplishing the agency's objectives.[13]

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[7] U.S. Small Business Administration, Office of Advocacy, A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act, at 11, (Aug. 2017), How to Comply with the Regulatory Flexibility Act, Updated August 2017 (sba.gov).

[8] *Id.*

[9] 5 U.S.C. § 611(a).

[10] *See* Northport Health Servs. of Ark., LLC v. United States HHS, 14 F.4th 856 (8th Cir. 2021), [Certification must be published in the Federal Register "along with a statement providing the factual basis for such certification"].

[11] 5 U.S.C. § 609(d)(2).

[12] *Id.*

[13] *See* § 603(b)-(c).

EPA proposes to certify that this rule will not have a significant economic impact on a substantial number of small entities. EPA supports this assertion by stating that the rule will only impose a reporting requirement for the releases of PFOA and PFOS. EPA estimates that this will cost $561 per reported release. The agency further estimates that there will only be up to 660 reported releases per year. EPA, however, does not provide an estimate of how many small entities will be expected to report and how many reportable releases could be attributed to them. EPA explains that it is an undeterminable number but expects it to be a small percentage of small entities. Based on this information, the agency concludes that the estimated cost of $561 to report a release of PFOA or PFOS is not greater than 1% of the annual revenues per small entity in any impacted industry. EPA relies on this assessment to support its RFA certification for this rule.

1. EPA Must Include All the Direct Impacts on All the Directly Regulated Small Entities.

EPA's impact analysis for the costs associated with the reporting requirement is incomplete. While EPA identifies the type of small business entities that would be subject to the reporting requirement, the agency does not include information on the impacts on small government entities. These impacted entities will include municipalities that include publicly owned treatment works, fire departments, and municipal solid waste, landfills, and disposal sites. EPA must account for the missing impacts on these entities to support its factual basis.

Furthermore, EPA excludes the consideration of certain impacts imposed directly by the agency on small entities associated with this proposed action. EPA characterizes costs associated with cleanups and liability management as indirect costs. For this reason, the agency did not include these costs in its small entity impact analysis.

According to *EPA's Guidelines for Preparing Economic Analyses,* direct costs are "are those costs that fall directly on regulated entities as the result of the imposition of a regulation."[14] Indirect costs, on the other hand, "are the costs incurred in related markets or experienced by consumers or government agencies not under the direct scope of the regulation."[15]

Recovery of cleanup costs associated with any PFOA or PFOS contamination will fall directly on responsible parties. The proposed hazardous substance designations for these chemicals will enable EPA to directly impose liability and recover those costs from these entities. EPA acknowledges that the release or threatened release of hazardous substances is the trigger that allows EPA to address contamination to ensure cleanup and to ensure that responsible parties bear the cost of those cleanups. In fact, the agency specifically recognizes that "designating PFOA and PFOS as hazardous substances…will allow the Federal government to require responsible private parties to address releases of PFOS and PFOA…and allow the government and private parties to seek to recover cleanup costs from potentially responsible parties…"[16] The

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[14] Guidelines for Preparing Economic Analyses, Guidelines for Preparing Economic Analyses: Analyzing Costs (Chapter 8), (last visited Nov. 2, 2022).

[15] *Id.* at 8-7 through 8-8.

[16] 87 Fed. Reg. at 54420.

agency also noted that "private parties responding to a release or threatened release at their facility must act consistent with CERCLA and the NCP [National Contingency Plan] in order to maintain CERCLA claims for recovery of response costs"[17] as a result of its proposed designations.

Furthermore, CERCLA Section 107(a)(4) confirms that liability for cleanup costs is imposed on responsible parties as a direct result of the release of a hazardous substance. The statute provides that:

> [A]ny person…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.[18]

This further supports that these costs are incurred by entities under the direct scope of the regulation and fall on these entities as a direct result of EPA's proposed hazardous substance designations.

EPA also refers to *Whitman* v. *American Trucking* [19] to characterize that the "hazardous substance designations in the overall structure of CERCLA is much closer to the role of a national ambient air quality standard in the overall structure of the national ambient air quality standard (NAAQS) program…" EPA's reliance on this distinction is misplaced and does not apply here. In the preceding case, *American Trucking Associations, Inc., v. EPA,*[20] EPA's certification of rules to establish a primary NAAQS for ozone was challenged. The basis of the EPA's certification was that the NAAQS regulated small entities only indirectly through state implementation plans. While the plans impose requirements on small entities, the states are the ones required to take action to attain compliance with the NAAQS standards. Under these circumstances, the court found that since the states, not EPA, had the direct authority to impose the burden on small entities, EPA's regulation did not have a direct impact on small entities.

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[17] 87 Fed. Reg. at 54420.

[18] 42 U.S.C. § 9604 at 107(a).

[19] *Whitman* v. *American Trucking,* 531 U.S. 457 (2001).

[20] *American Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1044 (D.C. Cir. 1999), aff'd in part and rev'd in part on other grounds, *Whitman v. American Trucking Ass'ns*, 531 I/S/ 457 (2001).

Here, the agency is not delegating its authority to states to implement a standard based on their broad discretion. EPA has the direct authority to impose liability by issuing these hazardous designations and discretion in determining the extent of clean up or response costs. In addition, EPA has the *sole* authority to determine whether a private party can be released from liability based on its determination of the party's compliance with the National Contingency Plan. Therefore, EPA is required to measure all the direct impacts of the rule and to determine whether those impacts are significant for a substantial number of small entities.

Small business representatives have expressed concerns that the cost to purchase property will increase as a direct result of the proposed designations in this rule. Entities will have to ensure that they have performed all appropriate inquiries under CERCLA to ensure their protection against response cost liabilities. Advocacy is also concerned that these costs are also likely to impose a direct cost on regulated entities and have not been included in the small entity impact analysis. Under section 101(35)(B) of CERCLA, prospective landowners are required to conduct all appropriate inquiries prior to or on the date on which the property is acquired.[21] If these entities do not conduct all appropriate inquiries prior to or on the date of obtaining ownership of the property, they may lose their ability to claim protection from CERCLA liability. Advocacy urges the agency to take these costs into consideration as part of its small entity impact analysis.

As discussed above, the agency only provides costs associated with the release reporting requirement. There are additional costs that will be imposed on small entities as a direct result of this rulemaking. Advocacy urges EPA to consider all direct impacts of the rule on small entities to support its factual basis to certify the rule under the RFA.

2. EPA Must Quantify All of the Direct Costs in its Small Entity Impact Analysis

EPA explains that it was not able to quantitatively assess the costs it identifies as "indirect" "because of the uncertainty about such costs at this early stage in the process."[22] Instead, EPA provides a qualitative discussion of these costs in its economic assessment for this proposal. According to EPA, key information that would enable quantification is unavailable. This information includes:

1) The number and types of sites that might need response activities along with information on the magnitude and extent of PFOA and PFOS contamination.
2) The cleanup standards that must be met by remedial activities.
3) The technologies, and their associated costs, for assessing and remediating the various contaminated media at sites.

[21] 42 U.S.C. § 9601(35)(B).

[22] 87 Fed. Reg at 54423.

According to EPA, it is impractical to quantitatively assess the indirect costs (for response actions) associated with a hazardous substance designation because of the uncertainty about such costs at this early stage in the process. EPA's listed reason for not attempting to quantify response costs contrasts with the agency's analyses in other rulemakings. EPA has repeatedly extrapolated data, often using analogs, to provide estimates. EPA has also used best professional judgments to make assumptions that are used as the bases for its impact analyses.

Advocacy believes EPA can quantify the excluded indirect impacts. EPA has access to available federal and state data to assess the number and types of sites that will be subject to response costs because of PFOA and PFOS contamination. For instance, the agency can use its own National Priorities List proposed and final listings[23] and state clean up data from states like New Hampshire.[24] The agency can also use state and federal data based on recent and existing cleanup for PFAS contamination to examine standards being used to accomplish remedial activities. Finally, the agency can likely use the same federal and state data from previous and ongoing PFAS cleanup activities to assess the costs for technologies used to assess and remediate contaminated sites.

In addition, EPA should also use some of the sources it discusses in its economic assessment. For example, the agency acknowledges that its 2019 NPL Market study provides the relevant cost information but dismisses its utilization here because the costs are not specific to PFOA and PFOS contamination.[25] EPA also identified Department of Defense-released cost estimates associated with PFAS response efforts at military sites but declined to deem them useful in determining costs for this rulemaking. EPA explains the estimates are not specific to PFOA and PFOS because it is limited to federal sites.[26] These types of data limitations have not posed a barrier for EPA in the past in providing estimated impacts. They should not preclude the agency from estimating impacts for this rulemaking.

Given that the agency has access to data, and will likely receive additional data as part of the public comment process that can be used to provide estimates for the impacts of this rule, Advocacy strongly recommends that EPA quantify the costs of all the direct impacts, discussed above.

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[23] U.S. Environmental Protection Agency, Superfund Data and Reports, https://www.epa.gov/superfund/superfund-data-and-reports, (last visited Nov. 11, 2022).

[24] Status Report on the Occurrence of Per-and Polyfluoroalkyl Substances (PFAS) Contamination in New Hampshire, New Hampshire Dep't of Environmental Services, Commissioner Robert R. Scott, (June, 2021), 2021 Status Report on the Occurrence of Per- And Polyfluoroalkyl Substances (PFAS) Contamination In New Hampshire (nh.gov).

[25] 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, [Economic Analysis] (August 2022), pg. 50.

[26] *Id.* at 54-55.

B. Advocacy Recommends EPA Convene a SBREFA Panel and Consider Alternatives as Part of its Initial Regulatory Flexibility Analysis.

For the reasons provided above, EPA's stated factual basis for certification under the RFA does not support a conclusion that the rule will not impose significant economic impacts on a substantial number of small entities. Advocacy is concerned that the rule will likely have direct significant economic impacts on a substantial number of entities.

Moreover, at Advocacy's Roundtable discussion on October 7, 2022, EPA explained that it is considering enforcement discretion to address some of the unintended consequences of its proposal. More specifically, the agency recognized that there are several situations that present equity concerns. These situations include significant concerns by some stakeholders, particularly public service entities like water utilities, municipal airports, and entities using biosolids. According to EPA, the agency does not have authority to exempt any particular entities from liability. Therefore, the agency is preparing to address these types of concerns with various enforcement tools.

To address these and all the other impacts, Advocacy urges EPA to convene a SBREFA panel for this proposed rulemaking. The panel will allow the agency to get direct feedback from small entities on the extent of these impacts and to obtain their recommendations on how to address their potential regulatory burden. A SBREFA panel will also allow the agency to get information on the number of small entities that would be impacted, assess the cost of all the direct impacts of the proposed rule on all the relevant small entities, and consider regulatory alternatives.

III. Conclusion

Advocacy is concerned that the agency does not provide an adequate factual basis to support its certification under the RFA that the rule does not have a significant economic impact on a substantial number of entities. Advocacy recommends that EPA convene a SBREFA panel to assess all direct costs, including those the agency mis-identifies as indirect costs, of the rule on small entities and to consider less burdensome alternatives.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 798-7405 or by email at tayyaba.zeb@sba.gov.

Sincerely,

/s/
Major L. Clark, III
Deputy Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/
Tayyaba Zeb
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Copy to: Sabeel A. Rahman, Associate Administrator
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