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

December 29, 2025

VIA ELECTRONIC SUBMISSION

The Honorable Lee Zeldin
Administrator
U.S. Environmental Protection Agency
Washington, DC 20460

Re: Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Data Reporting and Recordkeeping Under the Toxic Substances Control Act (TSCA); Revision to Regulation; EPA-HQ-OPPT-2020-0549.

Dear Administrator Zeldin:

On November 13, 2025, the U.S. Environmental Protection Agency (EPA) published a request for comments on proposed revisions to TSCA regulations on PFAS reporting and recordkeeping.[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the EPA's request.

Advocacy supports the EPA's proposed revisions. They provide flexibility, reduce regulatory burdens on small entities, and will achieve significant cost savings while also continuing to accomplish the EPA's goal of gathering information on PFAS manufacturing.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy in 1976 under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent voice within the executive branch that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the Small Business Administration or the Administration.

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[2] gives small entities a voice in the rulemaking process.

[1] 90 Fed. Reg. 50923 (Nov. 13, 2025).
[2] Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).

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.[3] If a rule is not expected to have a significant economic impact on a substantial number of small entities, agencies may certify it as such and submit a statement of the factual basis for such a determination that adequately supports its certification.[4]

Additionally, Section 609 of the RFA requires the EPA to conduct special outreach efforts through a small business advocacy review (SBAR) panel.[5] The panel must carefully consider the views of the impacted small entities, assess the impact of the proposed rule on small entities, and consider less burdensome alternatives for small entities.[6] The EPA convened a SBAR panel on TSCA's PFAS reporting and recordkeeping requirements in 2022.[7]

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."[8]

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[9] 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.[10]

B. The EPA's Revisions to the TSCA PFAS Reporting and Recordkeeping Rule.

PFAS are widely used, highly persistent chemicals whose components degrade very slowly over time.[11] As part of the National Defense Authorization Act for Fiscal Year 2020 (NDAA), the EPA was directed to promulgate a rule requiring PFAS manufacturers (including importers) to annually report information on their PFAS use to the agency.[12] In 2021, the EPA proposed a PFAS reporting and recordkeeping rule.[13] After a 90-day comment period, the EPA could not certify that the proposed rule would not have a significant impact on a substantial number of small entities and convened a SBAR Panel for the rule.[14]

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[3] 5 U.S.C. § 603.
[4] *Id.* § 605(b).
[5] *Id.* § 609.
[6] *Id.*
[7] U.S. ENV'T PROT. AGENCY, SMALL BUSINESS ADVOCACY REVIEW PANEL: REPORT ON TSCA SECTION 8 (A)(7) RULE: REPORTING AND RECORDKEEPING REQUIREMENTS FOR PERFLUOROALKYL AND POLY FLUOROALKYL SUBSTANCES" (Aug. 2, 2022), https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0123.
[8] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[9] Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).
[10] *Id.*
[11] U.S. Env't Prot. Agency, *PFAS Explained*, https://www.epa.gov/pfas/pfas-explained (last updated Sept. 30, 2025).
[12] Pub. L. No. 116-92, § 7351.
[13] 86 Fed. Reg. 33296 (June 28, 2021).
[14] U.S. ENV'T PROT. AGENCY, *supra* note 7.

Following the SBAR Panel, the EPA published an initial regulatory flexibility analysis (IRFA) on the rule and opened a second public comment period in 2022.[15] The EPA then published a final rule in 2023.[16] The final rule established a 10-month data collection period followed by a six-month data submission period.[17] Small manufacturers were given additional time to comply.[18] However, due to complications in developing the reporting application as well as, "related information technology infrastructure challenges," submission deadlines have been extended multiple times, and no information has been reported under the rule.[19]

Advocacy expressed concerns with both the 2023 rule and the EPA's 2022 IRFA. Specifically, we submitted two comment letters raising concerns over the rule's broad scope, which could hinder the ability of small businesses to comply, and the compliance costs in the IRFA, which were underestimated.[20]

The EPA's current proposal seeks to narrow the scope of PFAS reporting and recordkeeping requirements by creating a series of exemptions for activities which would not yield any useful information. Specifically, the EPA points out that the final regulatory flexibility analysis (FRFA) for the 2023 rule:

> assumed that, of all small article importers conducting due diligence to identify any reportable PFAS, only 10% would ultimately determine that they had known or reasonably ascertainable information to report on PFAS imported in articles. That is, 90% of the small article importers would be burdened by compliance determination activities only to then determine that they do not need to report because the information is not known or reasonably ascertainable.[21]

Under the 2023 rule, nine out of every 10 small businesses that were directed to report under the rule would have no useful information to share with the agency. Despite this fact, the 2023 rule mandated that these small businesses participate in the reporting process.

To remedy this situation, the EPA's current proposal includes the following exemptions from PFAS reporting requirements:

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[15] 87 Fed. Reg. 72439 (Nov. 25, 2022).
[16] 88 Fed. Reg. 70516 (Oct. 11, 2023).
[17] 90 Fed. Reg. 50923, 50926 (Nov. 13, 2025).
[18] *Id*.
[19] *Id*.
[20] See U.S. Small Bus. Admin., Off. of Advoc., Comment Letter on EPA's Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances under the Toxic Substance Control Act (Sept. 27, 2021), https://advocacy.sba.gov/2021/09/28/advocacy-comments-on-epas-reporting-and-recordkeeping-requirements-for-perfluoroalkyland-polyfluoroalkyl-substances-under-the-toxic-substance-control-act/; U.S. Small Bus. Admin., Off. of Advoc., Comment Letter on EPA's Initial Regulatory Flexibility Analysis for its Proposed Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances Under the Toxic Substance Control Act (Dec. 19, 2022), https://advocacy.sba.gov/2022/12/20/advocacy-comments-on-epas-initial-regulatory-flexibility-analysis-for-its-proposed-reporting-and-recordkeeping-requirements-for-perfluoroalkyl-and-polyfluoroalkyl-substances-under-the-toxic-s/.
[21] 90 Fed. Reg. 50923, 50926 (Nov. 13, 2025).

- A de minimis exemption in mixtures or articles[22] with PFAS concentrations below 0.1%.[23]
- PFAS imported as part of an article.[24]
- PFAS manufactured as a byproduct, impurity, and non-isolated intermediary.[25]
- PFAS manufactured in small quantities for research and development (R&D) purposes.[26]

Advocacy held a small entity roundtable to discuss the EPA's proposed rule on December 4, 2025. EPA staff participated in the roundtable and small entities expressed general support for the revisions.

II. The EPA's Proposed Rule Properly Complies with the TSCA's Requirement to Reduce Unnecessary or Duplicative Reporting.

On April 9, 2025, President Trump issued a memorandum[27] to all federal agencies requiring that existing regulations be reviewed in light of 10 specific Supreme Court decisions, including *Loper Bright Enterprises v. Raimondo*.[28] *Loper Bright* requires that agencies align regulations with the best meaning of the statute in question.[29] The EPA's proposed rule accomplishes this goal by reflecting the best possible reading of TSCA.

TSCA directs the EPA to not require unnecessary or duplicative reporting.[30] During the SBAR panel for the 2023 rule, small businesses noted that the information being requested was "unnecessary" and would not be "meaningful for achieving the agency's stated goal" of PFAS data collection.[31] Additionally, as evidenced by the fact that no data has been collected so far, the EPA was also unprepared to receive the information requested under the 2023 rule.

In setting the proposed rule's de minimis exemption, the EPA noted input from the SBAR panel, explaining that small businesses are unlikely to have records for PFAS levels at or below 0.1% because it is below what current U.S. and international standards require.[32] In other words, the EPA is now choosing not to ask small businesses for information that it knows they do not have.

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[22] An "article" is defined as "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design." 40 C.F.R. § 704.3.
[23] 90 Fed. Reg. 50923, 50926 (Nov. 13, 2025).
[24] *Id*. at 50,928.
[25] *Id*.
[26] *Id*. at 50,930.
[27] The White House, *Memorandum for the Heads of Executive Departments and Agencies, Directing the Repeal of Unlawful Regulations*, (April 9, 2025), https://www.whitehouse.gov/presidential-actions/2025/04/directing-the-repeal-of-unlawful-regulations/.
[28] 603 U.S. 369 (2024).
[29] *Id*.
[30] 15 U.S.C. § 2607(a)(5)(A).
[31] U.S. ENV'T PROT. AGENCY, *supra* note 7, at 37.
[32] 90 Fed. Reg. 50923, 50927 (Nov. 13, 2025).

Additionally, PFAS levels below 0.1% do not meaningfully contribute to the EPA's PFAS reporting goals.[33]

The EPA has also proposed exempting PFAS imported as part of an article. Exempting PFAS imports was specifically recommended by the SBAR panel[34] in part because:

> [M]any small entities may not know or be able to reasonably ascertain whether they have imported PFAS in their articles or products, especially if the PFAS is present as a confidential chemical whose generic name does not include "fluor" or as an impurity or in de minimis amounts. Such entities would have to rely on the cooperation of their suppliers, which may include suppliers with which the PFAS manufacturer no longer has a business relationship.[35]

The EPA acknowledges that importers are unlikely to have relevant information, making the requirement unnecessary.[36] Following *Loper Bright*, the EPA also notes that the NDAA, which required promulgation of the PFAS reporting and recordkeeping requirements, refers specifically to "each person who has manufactured" PFAS[37] and not to "importers" of PFAS.[38]

Other exemptions include PFAS manufactured as a byproduct, impurity, and/or non-isolated intermediary.[39] The EPA is exempting these items because it has deemed the information "unnecessary."[40] The EPA is also exempting PFAS manufactured in small quantities for R&D purposes.[41] This exemption is based in part from SBAR panel input from a small business who manufactures PFAS for laboratory and analytical purposes.[42]

Advocacy supports the EPA's proposed exemptions from the PFAS reporting and recordkeeping rule because they will reduce unnecessary regulatory burdens on small entities while still adhering to the best possible reading of TSCA. Advocacy also recommends the EPA prepare compliance materials to help small entities understand the scope of the proposed exemptions.

III. The EPA's Proposed Rule Complies with TSCA's Requirement to Minimize Impacts on Small Businesses.

Under TSCA, the EPA is required to minimize compliance costs on small manufacturers.[43] A "small manufacturer" is defined as a manufacturer that either has annual revenues less than $120 million and manufactures less than 100,000 pounds of a chemical substance or has annual revenues of less than $12 million regardless of production volume.[44] Additionally, President Trump's Executive Order (EO) 14219, *Ensuring Lawful Governance and Implementing the*

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[33] *Id*.
[34] U.S. ENV'T PROT. AGENCY, *supra* note 7, at 47.
[35] *Id*. at 36.
[36] 90 Fed. Reg. 50923, 50928 (Nov. 13, 2025).
[37] Pub. L. No. 116-92, § 7351.
[38] 90 Fed. Reg. 50923, 50925 (Nov. 13, 2025).
[39] *Id.* at 50,928.
[40] *Id*.
[41] *Id.* at 50,930.
[42] *Id*.
[43] 15 U.S.C. § 2607(a)(5)(B).
[44] 40 C.F.R. § 704.3.

President's "Department of Governmental Efficiency" Initiative,[45] instructs agencies to specifically identify "regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship."[46]

During the SBAR process, small businesses expressed multiple concerns about the 2023 PFAS reporting and recordkeeping requirements. The EPA estimated the total reporting cost to small businesses to be $791 million.[47] While this figure is significant, members of the SBAR panel were concerned that it "still did not fully capture the burden of entities conducting their due diligence to determine whether they need to report."[48]

Specifically, small entity representatives (SERs) highlighted the following costs associated with the 2023 rule:

- A business may carry up to 10,000 units requiring inspection. At a labor rate of $50 per hour, the SER estimated that the total cost of testing in this case would be $2.5 million.
- A SER shared that "information gathering activities should cost in the hundreds of thousands of dollars and the costs of collecting the information would exceed $1 million."
- Based on testing and obtaining quotes, a SER stated that it could cost between $5,000 and $10,000 to test for each chemical covered under the rule, resulting in a potential price of $6-7 million per article.
- A SER estimated that they would need between 400 and 544 hours to comply with the rule at a cost of $43,704. This would put them out of business.[49]

The EPA estimates that the proposed revisions to the PFAS reporting and recordkeeping requirements would exempt 127,469 small businesses from the 2023 rule's scope.[50] Additionally, 241 of the small businesses still impacted by the revised requirements would see lower reporting costs.[51] This would result, according to the EPA's estimate, in a savings of between $703-$761 million for small businesses.[52]

Advocacy supports the EPA's changes to the PFAS reporting and recordkeeping requirements because they strike a proper balance between accomplishing the EPA's goal of gathering necessary information on PFAS while minimizing impacts to small entities.

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[45] 90 Fed. Reg. 10583 (Feb. 25, 2025).
[46] *Id*.
[47] U.S. ENV'T PROT. AGENCY, ECONOMIC ANALYSIS FOR THE FINAL RULE ENTITLED: "TSCA SECTION 8(A)(7) REPORTING AND RECORDKEEPING REQUIREMENTS FOR PERFLUOROALKYL AND POLYFLUOROALKYL SUBSTANCES," (Sept. 2023), sec. 7.5, https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0271.
[48] U.S. ENV'T PROT. AGENCY, *supra* note 7, at 38.
[49] *Id*. at 39.
[50] 90 Fed. Reg. 50923, 50934 (Nov. 13, 2025).
[51] *Id*.
[52] *Id*.

IV. EPA Should Publish Compliance Materials to Help Small Entities Understand Their Obligations Under the Proposed Rule.

EO 12866 directs agencies to draft "regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty."[53] This helps small entities with limited staff and resources who often do not have dedicated regulatory professionals on staff better understand their compliance obligations.

One method of helping small entities with their compliance obligations is publication of a small entity compliance guide pursuant to Section 212 of SBREFA.[54] Small entity compliance guides (SECGs) "explain the actions a small entity is required to take to comply with a rule."[55] EPA published a small entity compliance guide for the 2023 rule.[56]

During Advocacy's December 4, 2025, small entity roundtable, a small business was uncertain whether exemptions for imports also extend to associated packaging (arguably it does). The EPA does not directly address this issue in the proposed rule.

Although this question concerns import packaging, it illustrates a broader compliance challenge for small entities: recurring, fact-specific interpretive questions that are not addressed directly in the proposed rule text. Advocacy recommends EPA (1) clarify key interpretive points in the final rule and (2) publish comprehensive compliance materials—either by updating its existing SECG or issuing a supplemental guide—that walk small entities through common compliance scenarios, definitions, and edge cases and provide clear, step-by-step instructions for meeting the reporting and recordkeeping requirements.

V. Conclusion

Advocacy supports the EPA's revisions to the TSCA PFAS reporting and recordkeeping rule. The exemptions proposed by the EPA will reduce unnecessary regulatory costs for small entities while also allowing the EPA to meet its statutory obligations under TSCA. Advocacy also recommends the EPA publish or update compliance materials to help small businesses understand the scope of the proposed exemptions.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Nick Goldstein at (202) 772-6948 or nick.goldstein@sba.gov.

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[53] 58 Fed. Reg. 51735, 51736 (Oct. 4, 1993).
[54] Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996).
[55] *Id*.
[56] U.S. ENV'T PROT. AGENCY, "SMALL ENTITY COMPLIANCE GUIDANCE FOR THE TSCA PFAS DATA CALL, TSCA SECTION 8(A)(7) REPORTING AND RECORDKEEPING REQUIREMENTS FOR PERFLUOROALKYL AND POLYFLUOROALKYL SUBSTANCES," (Oct. 2023), https://www.epa.gov/system/files/documents/2023-11/tsca-8a7-small-entity-compliance-guidance-10-11-23.pdf.

Sincerely,

/s/

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/s/

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Copy to: Mr. Jeffrey B. Clark, Sr. Associate Administrator
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