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

December 19, 2022

VIA ELECTRONIC SUBMISSION

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

Re: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment (Docket ID No. EPA-HQ-OPPT-2020-0549)

Dear Administrator Regan:

On November 25, 2022, the Environmental Protection Agency (EPA) announced[1] the availability of an Initial Regulatory Flexibility Analysis (IRFA) and updated economic analysis,[2] after completing a Small Business Advocacy Review (SBREFA) panel[3] for its previously

[1] TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment, 87 Fed. Reg. 72439, (Nov. 25, 2022).

[2] Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, U.S. EPA, Office of Pollution Prevention and Toxics, https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0125, (Nov. 2022). [hereinafter IRFA]

[3] Final Report of the Small Business Advocacy Review Panel on EPA's Proposed Rule Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, U.S. Small Business Administration, Office of Advocacy, https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0123, (Aug. 2, 2022).

proposed rule on reporting and recordkeeping requirements for per- and polyfluoroalkyl substances (PFAS)[4] under the Toxic Substance Control Act (TSCA).[5]

Advocacy is concerned that EPA's compliance costs provided in the IRFA are underestimated, and that the agency does not identify whether it will consider any of the regulatory flexibility alternatives discussed in the IRFA as viable policy options to address small business compliance concerns. Advocacy recommends that EPA provide one or more alternatives to address the disproportionate impact on small businesses in the final rule.

I. Background

A. The Office of Advocacy

Congress established 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),[6] 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.[7] The agency must include, in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[8]

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."[9]

B. The Proposed Rule and the Published IRFA

On June 28, 2021, EPA proposed reporting and recordkeeping requirements under TSCA Section 8(a)(7) to require any person who manufactures or has manufactured PFAS to electronically

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[4] 86 Fed. Reg. 33926 (June 28, 2021).

[5] 15 U.S.C. § 2601 et. seq.

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

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

[8] *Id*.

[9] 5 U.S.C. § 601 note.

report information regarding its chemical identity, uses, production volumes, disposal, exposures, disposal, and hazards, retrospectively dating back to January 1, 2011.[10] This section was recently added to TSCA by the National Defense Authorization Act for Fiscal Year 2020.[11] The statutory requirement is limited to the collection of detailed information on PFAS. EPA anticipates that this information collection could satisfy EPA's research need to better understand potential routes of exposure and potential human health and environmental impacts of certain PFAS.

EPA's interpretation of the statute includes 1,346 listed PFAS and an unknown number of unlisted chemicals that meet a structural definition provided by the agency. In addition, the agency proposed to require all manufacturers and importers of PFAS, including importers of articles and other commonly excluded entities such as manufacturers of impurities and byproducts, to report on PFAS.

EPA proposed to require the reporting of information "known to or reasonably ascertainable by" manufacturers of PFAS. The agency explained that "known to or reasonably ascertainable by" is defined to include "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."[12] The agency interprets this standard to require affected entities to evaluate their current knowledge level of their manufactured products and imports, as well as to evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. The agency provided a six-month submission period, which would begin six months following the effective date of the final rule, essentially allowing one year to collect and submit all required information to EPA.

Initially, EPA certified that the proposed rule would not have a significant impact on a substantial number of small entities under the RFA. Advocacy provided public comments on the proposal to raise concerns about EPA's RFA certification related to the agency's incomplete impact estimates, express concerns about small businesses' ability to comply, and to recommend the agency convene a SBREFA panel to solicit small business feedback and consider regulatory alternatives. Based on public comments and additional data sources on PFAS-containing article importers, EPA convened the SBREFA panel for the proposed rule and evaluated the economic impact of the proposed rule on small entities.

On November 25, 2022, EPA published an IRFA and updated economic analysis, after completing a SBREFA panel for the above-mentioned proposed rule for reporting and

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[10] *See* 86 Fed. Reg. at 33926.

[11] Pub. L. 116-92, Section 7351. "Not later than January 1, 2023, the Administrator shall promulgate a rule in accordance with this subsection requiring each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011, to submit to the Administrator a report that includes, for each year since January 1, 2011, the information described in subparagraphs (A) through (G) of paragraph (2)."

[12] 86 Fed. Reg. at 33928.

recordkeeping requirements for PFAS. The agency is seeking public comment on underlying data and assumptions in developing its impact estimates and alternatives to minimize the economic impact on small businesses, among other related issues. EPA also updated its estimate of costs for the proposed rule from approximately $10.8 million to $875 million.

II. EPA Should Have Reproposed the Rule Based on the IRFA and the Updated Economic Analysis

Advocacy thanks EPA for convening a SBREFA panel to seek small business feedback on its proposal and for publishing an IRFA with updated economic impact information for public comment. Advocacy, however, would have preferred that EPA re-propose the rule when issuing the IRFA because that is the process contemplated under the RFA.[13] This would have allowed the public to benefit from the notice and opportunity to comment on the agency's decisions regarding the alternatives EPA discusses in the IRFA. It is not clear from the IRFA which regulatory flexibilities the agency considers to be viable options for the final rule to reduce the compliance burden on small entities.

III. Advocacy Recommends that EPA Provide Regulatory Flexibility Alternatives to Address the Disproportionate Impact on Small Businesses.

As part of the panel, EPA recommended regulatory flexibility alternatives which included:

- An exemption for all small entities including small chemical manufacturers and small importers of articles as a significant alternative to the proposed rule.
- Only reporting for a finite list of chemicals; reporting exemptions for imported articles, R&D substances, byproducts, impurities, recyclers, and intermediates.
- Implementing a reporting threshold.
- Reconsidering the proposed timeframe and/or consider providing additional compliance time to small entities.
- A tiered approach with different deadlines for article importers than for domestic producers and bulk importers, including first requiring reporting from chemical manufacturers, then extending the requirement to importers of articles.[14]

In the IRFA, EPA only considered small business exemptions, reporting for a finite list of PFAS, reporting threshold exemptions, a limited extension of the reporting timeline and simplified reporting forms for certain entities. However, the agency did not consider a tiered approach with different timelines for reporting. Moreover, EPA did not clearly state why it is not adopting the flexibilities it did consider. Instead, the agency concluded that due to the decreased number of reports, the agency would not be able to meet its stated statutory objective "to collect all known or reasonably ascertainable historical PFAS data manufacturers and importers."[15] In essence, EPA is concluding that the alternatives it agreed to as a panel member no longer qualify as true

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[13] 5 U.S.C. § 603(a).

[14] *See* IRFA at 56-58.

[15] IRFA at 59, 60, 62, 63, 65, and 71.

alternatives because the agency now considers them to be contrary to its unchanged interpretation of the statutory objective.

A. EPA Should Limit the Scope of the Rule to Address its Underestimated Compliance Costs.

Although the agency has updated and provided cost impact information for importers of articles affected by the agency's action, Advocacy remains concerned that EPA's impacts are underestimated because the agency continues to rely on information from its Chemical Data Reporting (CDR) database, which does not represent all the impacted entities and/or potentially reportable PFAS.[16] It is likely that the burden on small businesses is going to be more than the estimated amount especially since the agency does not account for the burden imposed on CDR-exempt entities. EPA must provide an exemption or consider a longer timeframe for compliance for these entities. In addition, to address the underrepresented number of PFAS chemicals, the agency should limit the scope of reporting to listed or known PFAS, especially for importers of articles.

B. EPA Should Include Significant Regulatory Alternatives Contemplated by the RFA in the Final Rule.

EPA should finalize regulatory flexibilities contemplated by the RFA that include exemptions and compliance delay for small manufacturers.[17] These regulatory flexibilities will reduce the burden on small businesses. This will also enable the agency to meet its statutory objective in collecting PFAS information from chemical manufacturers dating back to 2011 while avoiding unnecessary and duplicative reporting, minimizing the cost of compliance on small manufacturers and processors, and applying any reporting obligations to those persons likely to have responsive information.[18] This is supported by the agency's analysis for the various exemptions considered in the IRFA.

For instance, in the IRFA, EPA identifies that under exemptions evaluated for small manufacturers under varying thresholds, the compliance cost will be significantly reduced by 92%, 86% , 85%, and 69% with the agency potentially only losing 25%, 22%, 22%, and 16% of PFAS reports, respectively.[19] The agency also acknowledges that most of the PFAS information (up to 84%) would be received from the highest earners (i.e. large businesses).[20] The updated small business entity impact analysis, on the other hand, demonstrates that most of the compliance burden, approximately 98% of $875 million, would be borne by 127,794 small

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[16] The CDR rule provides exemptions for articles, byproducts, impurities, non-isolated intermediates, research and development, and small manufacturers and importers and certain polymers. 40 C.F.R. §§ 704.5 and 711.6. The CDR rule also exempts materials manufactured in quantities of less than 2,500 pounds. *Id.* at § 711.15.

[17] 5 U.S.C. § 603.

[18] *See* IRFA at 29, *See also* 15 U.S.C. § 2607(a)(7) and (a)(5).

[19] *Id*. at 58-72.

[20] *Id*. at 50.

businesses, who will likely only provide up to 25% amount of information under the exemptions considered by EPA.

In addition to the small manufacturer exemptions discussed in the IRFA, the agency must also provide extended reporting timelines (beyond 6 months) or implement a phased-in (or tiered) reporting approach for different substances or entities. If the agency provides extended time for reporting for small entities, the reporting period should be the same for all entities (i.e., from 2011 to the effective date of the final rule).

C. EPA Should Provide an Alternative Due Diligence Standard for Reporting.

Since most of the compliance burden is associated with compliance determination,[21] EPA should provide a modified due diligence standard for reporting, particularly for importers of articles, who incur almost $4,000 in compliance determination costs per PFAS. Based on the argument the agency presents to justify not incorporating the small manufacturer exemption included in TSCA 8(a)(1)[22] for this rulemaking, the agency is also not constrained by the requirements and provisions in 8(a)(2) ,[23] which refer specifically to the reporting requirements under 8(a)(1), to impose the "known or reasonably ascertainable" standard for the implementation of 8(a)(7).[24] Moreover, Advocacy included this alternative as an independent recommendation in the panel report and the agency did not dispute it there or in the IRFA. The agency has the authority to require only known information for the reporting requirements, especially when it comes to importers of articles, and should do so here.

IV. Conclusion

Advocacy is concerned that the agency's compliance costs provided in the IRFA are underestimated and that the agency does not identify whether it will consider any of the regulatory flexibility alternatives discussed in the IRFA as viable policy options to address small business compliance concerns. Advocacy recommends that EPA provide less burdensome alternatives to address the disproportionate impact on small businesses in the final rule.

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[21] IRFA at 9 and at 66.

[22] "Unlike TSCA section 8(a)(1), which provides an express exemption for small manufacturers and processors, TSCA section 8(a)(7) specifically states that 'each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance' shall be subject to the rule. Rather than amend TSCA section 8(a)(1), Congress chose to add an entirely new, standalone subsection to TSCA section 8(a). This indicates an intent for TSCA section 8(a)(7) to constitute separate, freestanding rulemaking authority; therefore, it is not constrained by requirements and provisions in TSCA section 8(a)(1)." 86 Fed. Reg. at 33929, *See also* 15 U.S.C. § 2607(a)(1) and (a)(7).

[23] "The Administrator may require under paragraph (1) [8(a)(1)] maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable…"15 U.S.C. § 2607(a)(2).

[24] *Id.* at 2607(a)(7).

Advocacy looks forward to working with you to reduce the regulatory burden on small businesses. If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 205-6790 or by email at tayyaba.zeb@sba.gov.

Sincerely,

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

/s/
Tayyaba Zeb
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: Sabeel A. Rahman, Associate Administrator
Office of Information and Regulatory Affairs
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