

December 27, 2022

Dr. Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Proposed Rule, Environmental Protection Agency; TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (87 Fed. Reg. 72,439-72,441, November 25, 2022)

Dear Dr. Freedhoff:

The undersigned organizations are pleased to provide comments regarding the Initial Regulatory Flexibility Analysis and Updated Economic Analysis for the proposed Toxic Substances Control Act (TSCA) section 8 (a)(7) reporting and recordkeeping rule.

In our [extension request](#), we underscored our appreciation for EPA's work with regard to assessing the costs of the proposal for small businesses across the U.S.¹ Convening the Small Business Regulatory Enforcement Fairness Act panel rightly identified these and other challenges and also recognized significant additional impacts of the proposed rule. The revised analysis, however, still does not comply with EPA's obligations under the Executive Orders for regulatory review, the Regulatory Flexibility Act, and the Paperwork Reduction Act (PRA). In addition, with the new cost estimate, EPA's proposal is an economically significant regulatory action under the Executive Orders for regulatory review and is a major rule under the Congressional Review Act. Due to its costs, EPA must comply with the regulatory analysis requirements in Circular A-4 and estimate the incremental social benefits and costs of different regulatory options.

Under the Regulatory Flexibility Act, the agency is obligated to consider lower cost options that will yield similar results. EPA must also show the corresponding analysis under the PRA and that the proposed option has practical utility and is the least burdensome option to collect the information, the benefit of its regulatory option and consideration of possible alternatives. The revised economic analysis shows several options that would reduce or eliminate the severe economic impacts. To inform public comments, EPA must estimate the value of the additional information to compare against the costs of substantial business failures that may result due to the tremendous costs of the proposed rule.

Because the revised economic analysis lacks sufficient information to comply with EPA's legal requirements and to offer the public adequate information to comment, EPA must revise the economic analysis to include the incremental social benefits and costs of its proposed option and less burdensome options. EPA should then solicit public comment on these options

¹ See: regulations.gov comment ID number EPA-HQ-OPPT-2020-0549-0131 available at <https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0549-0131>.

once the analysis is complete. In addition, we have the following recommendations on specific issues to help ensure that EPA issues a reasoned final decision that fulfills its statutory obligations:

- 1) **Provide flexibility for a five-year lookback period for small businesses and other businesses that would be particularly burdened by a longer period.** A lookback period of ten years will be infeasible and extremely burdensome, especially (but not only) for small businesses and article manufacturers and importers. A five-year period would be more reasonable.
- 2) **Establish a phased approach.** We made this suggestion in our previous coalition comments.² Implementing a phased approach would be consistent with the recommendations of the Small Business Advocacy Review Panel (SBAR Panel) which recommended that EPA first consider requiring reporting from manufacturers only.³ During phase 1, the agency should focus on the largest manufacturers and importers, likely collecting more than 90% of the data. Based on this data collection, EPA can then evaluate the practical utility of the data collection and then evaluate the potential practical utility, if any, of additional data gathering from other businesses. The SBAR panel also recommended that different reporting deadlines be considered for each group, considering domestic manufacturers, bulk importers, and article importers separately. This would be consistent with a phased approach.
- 3) **Implement traditional exemptions allowed under previous TSCA reporting regimes.** The agency could articulate phase 1 exemptions, including for small businesses, de minimis amounts, articles, byproducts, impurities, recyclers, and non-isolated intermediaries.⁴ These exemptions could be limited as an initial matter to three to five years to ensure proper evaluation and provide further information on the practical utility of the initial data to inform a subsequent decision whether to extend the exemptions, whether fully or in part. Phase 1 would offer a way to build awareness of and prepare for the requirements, should a second phase be deemed necessary. EPA's analysis indicates that a significant number of small businesses could fail due to this rule. We, therefore, suggest that EPA also implement additional exemptions based on the revenue of businesses, as noted in the EPA analysis of alternatives considered.⁵ Exempting small businesses that have less than \$6 million or \$12 million in sales would help to minimize costs on small manufacturers. While EPA recognizes that a single small entity representative (SER) would have reportable PFAS information that may potentially not be collected with this approach, EPA needs to balance the overall impact on SERs with the desire to collect information

² See: regulations.gov comment ID number EPA-HQ-OPPT-2020-0549-0066 available at <https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0549-0066>.

³ See: TSCA 8(a)7 Panel Report Executive Summary, recommendation 9, available at: <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0123>.

⁴ The SBAR panel recommended flexibilities including: "only reporting for a finite list of chemicals; reporting exemptions for imported articles, R&D substances, byproducts, impurities, recyclers, and intermediates; and implementing a reporting threshold". See TSCA 8(a)7 Panel Report Executive Summary, recommendation 5, available at: <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0123>.

⁵ See: Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)7 Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances available at: <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0125>.

from 100% of all manufacturers and importers. EPA has focused its economic analysis on the number of manufacturers and importers that will report; however, EPA has not taken into account the reality that not all firms are the same size and that in many instances, smaller revenue manufacturers and importers will likely not use PFAS to the same extent, nor have as much information regarding those PFAS, as comparable higher revenue manufacturers and importers. EPA thus should not assume that the value of the information collected from a small manufacturer or importer will be equivalent to the value of information collected from an otherwise comparable larger manufacturer or importer. A robust evaluation of the incremental benefits and costs of alternatives is necessary to inform EPA's decision making. This is consistent with the SBAR Panel recommendation for an examination of potential trade-offs associated with the alternatives in the Initial Regulatory Flexibility Analysis.⁶

- 4) **Develop a limited test with regard to the consequences of lifting some of the exemptions, including for articles and small businesses.** During phase 1, EPA could determine the feasibility of collecting additional information and the associated practical utility of data collected from a small sample of the exempted groups. It is likely that EPA would find that there is not a robust understanding of the implications and presence of PFAS in supply chains.
- 5) **Provide a specific list of PFAS as known to be in commerce.** As you state in your analysis, EPA should follow through to cite a finite list of PFAS subject to the final rule identified by their CASRNs or, when necessary, by an EPA Accession Number, or unique identifier number. This approach would focus more properly on substances known to be active in U.S. commerce for purposes of understanding information that has a more direct relationship to assessing potential exposures and releases of substances that might be of greater concern and would supply information which is more directly related to potential risk. EPA could model Maine's suggestion to use a dropdown menu of CAS numbers for reporting. The elimination of the structural definition should be accompanied by a clarification that fluoropolymers and many gases should not be subject to reporting pursuant to the proposed TSCA 8(a)(7) rule.
- 6) **Deploy phase 2, but only if needed.** TSCA does allow the agency to issue exemptions, and there is nothing in the National Defense Authorization Act for Fiscal Year 2020 that prevents EPA from fulfilling the statutory obligation consistent with the manner in which EPA has implemented TSCA in the past. This includes consideration of exemptions and burden reduction approaches that are frequently used to ensure that the benefits of rules outweigh the costs and that the information collected has practical utility. EPA must explore and consider all potential regulatory options for which outcomes are similar for less cost to the taxpayers and the regulated community. By EPA's own analysis, the adverse impact on small businesses demands commonsense alternatives, such as a phased approach and the consideration of exemptions.

⁶ See: TSCA 8(a)(7) Panel Report Executive Summary, recommendation 10, available at: <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0123>.

Also, we raise a seventh recommendation here that warrants more explanation. EPA's Initial Regulatory Flexibility Analysis and Updated Economic Analysis provide examples of different reporting scenarios under the proposed rule and the due diligence that EPA expects companies would perform to determine whether their imports contain PFAS if the proposed rule is made final. Unfortunately, as with the proposed rule,⁷ EPA's analysis fails to provide certainty to importers regarding how to satisfy the "known to or reasonably ascertainable by" standard, in general, and confirm, in particular, that queries of upstream suppliers is unnecessary. For example, in some sections of the Initial Regulatory Flexibility Analysis and Updated Economic Analysis, EPA states that importers "may choose" to contact upstream suppliers,⁸ whereas in other sections, EPA states that importers "should contact" such suppliers.⁹ However, no meaningful distinctions may be drawn between the "may choose" and "should contact" scenarios. Further, even assuming some importer level of engagement with a supplier, EPA concludes that "only 5% of importers will submit production volume information."¹⁰

There is simply no rational basis to require importers to perform any level of inquiry of upstream suppliers, when such efforts will likely only result in 5% of such importers providing information to EPA. As noted in our comments on the proposal, a member of one of the Coalition's members identified nearly 3,200 unique Harmonized Tariff Schedule codes in over 2,300 shipments over a two-year period.¹¹ Extrapolating to ten years to correspond to the proposed lookback period, this company could have over 11,500 imports from potentially thousands of distinct suppliers (and the burden would be serious even if a shorter lookback period were adopted, as we recommend above). Performing any outreach to even a subset of these suppliers would be a costly and time-consuming exercise involving telephone conversations and emails exchanges, all of which would need to occur during the six-month phase-in period for the rule. This company would need to hire additional personnel to develop questionnaires, identify appropriate contacts (some of which may be based on 10-year-old

⁷ 86 Fed. Reg. 33926, 33928 (June 28, 2021) ("This standard may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. Such activities may, though not necessarily, include phone calls or email inquiries to upstream suppliers . . .").

⁸ EPA, "Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances," at 4 (Nov. 2022) ("Importers may choose to obtain verification from identified suppliers that PFAS is or is not found in the article."), 7 ("The submitter may need to contact the resulting company about the combination of the supplying conducted by the original companies during the calendar years of the reporting period."), 9 (The reporting standard would require reporting entities to evaluate their current level of knowledge of their imported articles, as well as conduct a reasonable inquiry within the full scope of their organization and may also entail inquiries outside the organization to fill gaps in the submitter's knowledge.") (emphasis added).

⁹ See, e.g., *id.* at 6 ("If Company Y is the continuation of the part of Company X that supplied the pertinent article(s), then submitters should contact Company Y for information on all the supplying that Company X did during the calendar years of the reporting period, including the supplying that it did while it was a unit of Company X.") (emphasis added).

¹⁰ *Id.* at 13.

¹¹ Coalition Comments, at 2, n. 1.

information), perform the outreach (which may involve multiple attempts to locate the appropriate person), and document the results. The level of effort in this one example goes far beyond the anticipated burdens identified in the Initial Regulatory Flexibility Analysis and Updated Economic Analysis for importers and would likely provide little or no reportable information based on EPA's own estimates. Failure to fully consider the real economic impact of the relevant requirements would be arbitrary and capricious.

Accordingly, we request that EPA make clear in the final rule that there is no obligation on importers to perform any level of outreach to upstream suppliers to satisfy the "known to or reasonably ascertainable by" reporting standard for PFAS reporting.

Consistent with our comments and recommendations above, we urge EPA to include our recommended steps, and the topics discussed herein, in a supplemental proposal to ensure that the agency meets its full administrative and legal obligations. The evidence of burden of compliance with the proposed rule requires a thoughtful exploration and analysis of the practical utility of collecting this information and engagement with the business community.

Thank you for your consideration.

Sincerely,

Alliance for Automotive Innovation
American Apparel & Footwear Association
American Chemistry Council
American Coatings Association
American Forest & Paper Association
American Fuel and Petrochemical Manufacturers
American Petroleum Institute
Flexible Packaging Association
Fluid Sealing Association
National Association of Chemical Distributors
National Association of Printing Ink Manufacturers
National Council of Textile Organizations
National Mining Association
National Oilseed Processors Association
Plastics Industry Association
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TRSA – The Linen, Uniform and Facility Services Association
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