September 27, 2021

Dr. Michal Freedhoff
Assistant Administrator
Office of Pollution Prevention and Toxics
Environmental Protection Agency
Washington, DC 20460-0001

RE: EPA-HQ-OPPT-2020-0549

Dear Assistant Administrator Freedhoff:

The undersigned organizations appreciate the opportunity to provide input on EPA's proposed rulemaking regarding Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS). EPA's proposal does not comply with the Paperwork Reduction Act (PRA), the Regulatory Flexibility Act (RFA), the Unfunded Mandates Reform Act (UMRA), and several executive orders. We urge EPA to revise and repropose this action not only to bring EPA's proposal into compliance with these requirements, but also to give EPA actionable, high-quality, information to support EPA near-term PFAS policies and possible regulatory actions.

EPA must demonstrate that its collection has practical utility to comply with the PRA. For decades, EPA has recognized that practical utility means that the data must be valid and be able to be used by the Agency in a timely manner. EPA, therefore, should implement a phased and tiered reporting system to collect the most useful and the most likely to be accurate PFAS data first. Examples of this category of information are specific PFAS for which EPA has independently peer-reviewed toxicity data and for which EPA and respondents can use EPA-approved test methods, based on sound science and risk, to validate the reported data.

If EPA collects data of specific PFAS for which human health effect data may not be known for several years, manufacturing data collected today will be out of date by then, and thus lack practical utility. Similarly, if EPA requires companies to estimate their use of a specific PFAS that currently lacks a valid quantification method, EPA's collected data will have varying quality, accuracy, precision, and cannot be independently verified—in other words, not scientific and devoid of practical utility.

We recommend that EPA further tailor the initial data collection to comply with the PRA's requirement to collect data with practical utility in the least burdensome manner. In this first phase, EPA should offer exemptions established in other TSCA reporting requirements to reduce this data collection's potential cost and administrative burdens, especially for small businesses. The initial phase should include EPA's typical TSCA exemptions, including for articles, both domestic and imported, impurities, byproducts, research and development, de minimis quantities, polymers, and small businesses. We submitted an extension request and

comments dated July 28, 2021 that summarized many of the relevant issues, which are underscored below:

- **Eliminate possible duplication to report on substances currently on the TSCA Inventory (all PFAS in scope).** To the extent that any data required to be provided to EPA under the PFAS reporting rule has already been provided, especially under TSCA, compliance with this data collection should be notification that EPA already has the data.
- **Provide exemptions consistent with other TSCA reporting**:
    - Develop a de minimis threshold for reporting based on sound science and risk.
    - Exclude small businesses based on revenue and in a manner consistent with other TSCA reporting requirements.
    - Include basic exemptions that are already part of the TSCA, such as non-isolated intermediates, domestically produced or imported as part of an article, impurities, byproducts destined for certain commercial uses are exempt from reporting, and research and development on specific chemistries.
- **Remove articles from current scope.** It is high unlikely that cost and time burden for gathering information for articles would have practical utility. [1] As demonstrated in the footnoted example, the proposal will impose substantial resources and due diligence burdens on companies to identify whether or not the components of those articles include PFAS. This burden is not commensurate with the practical utility of the information.

  An importer of an article will also unlikely possess any information regarding the inclusion of PFAS in an imported article. An articles "standard may also entail inquiries outside the organization to fill gaps in the submitter's knowledge."[2] These efforts present an

---

[1] A real-world example from a large multinational company that does not manufacture PFAS illustrates this point. This company indicated that over the last two years, it imported items covered by nearly 3,200 unique Harmonized Tariff Schedule (HTS) codes in over 2,300 shipments. Extrapolating to 10 years, this could result in more than 11,500 shipments. Import records (currently maintained on the Customs and Border Protection ACE system) contain generic material and equipment descriptions associated with the HTS codes and are of limited use in identifying the presence of PFAS and requiring importers to assess the associated shipping paperwork (if the records are still available). Typical paperwork accompanying an import include the Entry Summary, Commercial Invoice, Packing List and the relevant Trade Agreement Certificate(s), if applicable. Likely, none would conclusively indicate the presence of PFAS. In this example, 30,000 plus records would need to be reviewed and little or no information regarding the presence of PFAS in articles would be discovered.

[2] *Id.* EPA does acknowledge "that it is possible that an importer, particularly an importer of articles containing PFAS, may not have knowledge that they have imported PFAS and thus not report under the rule, even after they have conducted their due diligence under this reporting standard …." 86 Fed. Reg. at 33,929. However, elsewhere, EPA states that if information is not known to or reasonably ascertainable by a manufacturer (or importer), "reasonable estimate[s] should be used when actual data are not available." 86 Fed. Reg. at 33,931. This suggests that if actual data are not known to or reasonably ascertainable by a manufacturer (or importer), the manufacturer (or importer) should still file a report with "reasonable" estimates. Yet, no guidance is provided on how to generate such "reasonable" estimates, or what is "reasonable." In the proposed regulations (at proposed § 705.15), EPA appears to temper the obligation to provide "reasonable" estimates by stating: "In the event that actual data is not known to or reasonably ascertainable by the submitter, then reasonable estimates *may* be submitted." (emphasis added). If importers of articles are required to report in the final rule, EPA's regulations must be modified to explicitly state that if the data are not known to or reasonably available to the manufacturer (or importer), then the manufacturer (or importer) is *not required to report*. Otherwise, as currently drafted, there is no discernable standard for determining "reasonable" estimates.

unreasonable expectation that the information is known or reasonably ascertainable[3], given the tens of thousands of articles that can be imported by one company in just one year as well as the efforts needed to meet the ten-year lookback requirement of the proposal.

EPA must provide justification of reasonable exposure of the chemistry in an article, for much of which the data does not exist. This is the standard that Congress recently adopted in the Lautenberg Act for EPA to act regarding articles. [4] Instead of focusing on articles, the best opportunity is to identify whether there is PFAS present is in the "roots" of the supply chain.

In subsequent phases of this reporting rule, EPA can decide whether the exempted information has practical utility based on a specific, identified agency use and can be collected accurately and with acceptable burden. Since the PRA requires EPA to seek renewal of its information collection request (ICR) every three years, EPA can update its reporting requirements to support future agency priorities and to build from scientific advances.

Conducting a phased-in sequence to gather the most useful information first also assists EPA's compliance with the PRA and the RFA. As proposed, EPA fails to estimate the burden of the collection, and provides insufficient information and economic analysis to justify its certification under the RFA that the regulatory action will not have a significant impact on a substantial number of small entities. As EPA notes in the supporting statement for the ICR economic analysis, none of the burden estimates provided in the proposed rule include the burden for any article importers, producers of PFAS as byproducts, and small businesses. Thus, the number of respondents impacted by this rule and the total associated burden hours and cost estimates are likely to be tremendously underestimated. By streamlining the reporting to the most useful and scientifically valid information first, EPA can better fulfill the mandate to estimate the rulemaking's economic impacts and burden.

For example, EPA's estimate in the proposed rule—zero burden hours and zero associated costs—are clearly incorrect for article importers. This is particularly the case in light of EPA's expansive reporting standard and application of the proposed rule to stakeholders historically exempt from TSCA reporting. Based on information available to EPA in a single

---

[3] Under other Section 8(a) regulations EPA has expressly stated that the "reasonably ascertainable" standard does ***not*** require that the respondent conduct any new testing. *See, e.g., Working Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce (August 2017)* at 8. EPA should clarify that new testing also is not required under the Section 8(a)(7) rule to satisfy the "reasonably ascertainable" standard. Indeed, such a requirement would be impossible to comply with. In this regard, we note that the White House has concluded that it is "not feasible" to test a list of fewer than two dozen categories of articles procured by the Department of Defense to ascertain whether PFAS compounds are present in those articles. *See* Executive Office of the President, Office of Management and Budget, *Statement of Administration Policy: H.R. 4350 – National Defense Authorization Act for Fiscal Year 2022* (September 21, 2021) at 4. It is certainly not feasible for companies that import thousands of articles and components to conduct such testing.

[4] See TSCA Section No

rulemaking, the promulgation of the long chain SNUR rule in July 2020, the Agency has already listed more than a dozen current uses of PFAS chemicals and PFAS surface coatings in articles, which likely alone represents thousands of reporters. EPA listed the following "non-exhaustive list" of potential articles that my use long chain PFAS chemical as part of surface coatings on articles: apparel, outdoor equipment, automotive parts, carpets, furniture, electronic components, light bulbs, solar panels, paper goods, luggage and construction material.[5] Despite the detailed knowledge obtained in this rulemaking, the ICR identifies only 234 respondents, all within the chemical industry.

Accordingly, and with more than one-year remaining until EPA's implementation deadline, we request that EPA convene a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel to provide advice and recommendations on regulatory alternatives to minimize the burden on small companies. The Agency has considerable time in early 2022, well in advance of January 2023, to complete the required analysis of regulatory alternatives and have the opportunity to gain experience from the small business' public comments.

The business community understands and appreciates the value of collecting more data to enhance the identification of potential PFAS-related risks and accelerate cleanup in impacted communities. However, EPA must have capacity to use the data collected in a timely manner and to focus on the data that will optimize the human health benefits of policies and will limit the burdens on impacted sectors. We therefore urge EPA to implement a phased approach that appropriately accounts for exemptions and burdens on regulated entities for reasonably reporting the required information.

Sincerely,

Alliance for Automotive Innovations
American Apparel & Footwear Association
American Chemistry Council
American Coatings Association
American Forest & Paper Association
Flexible Packaging Association
National Association of Chemical Distributors
National Association of Printing Ink Manufacturers
National Association for Surface Finishing
National Council of Textile Organizations
National Mining Association
National Oilseed Processors Association
Plastics Industry Association
PRINTING United Alliance
The Aluminum Association
U.S. Chamber of Commerce

[5] Long Chain PFAS SNUR Guidance, Page 7 (January 19, 2021) EPA Guidance, RIN 2070-ZA23.