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July 28, 2021

Dr. Michal Freedhoff
Assistant Administrator
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

RE: EPA-HQ-OPPT-2020-0549

Dear Assistant Administrator Freedhoff:

We appreciate the opportunity to provide input on EPA's proposed information collection request (ICR) under the Paperwork Reduction Act (PRA) rulemaking regarding Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS).

We urge EPA to extend its information collection request (ICR) and comment period by 60 days to appropriately allow impacted industries to explore the potential costs and recommend less burdensome approaches, and comment on the practical utility of the draft ICR. As EPA notes in the supporting statement for the ICR, none of the burden estimates provided in the proposed rule include the burden for any article importers. Thus, the number of respondents impacted by this rule, and the total associated burden hours and costs estimates, are likely to be tremendously underestimated. Additional time is needed for our members, including many small businesses, to determine the potential impact this rule may have on them. We know that zero burden hours and zero associated costs is incorrect for article importers, particularly in light of EPA's expansive reporting standard and application of the proposed rule to stakeholders historically exempt from TSCA reporting. Sufficient time is necessary to provide realistic burden information so that the Office of Management and Budget (OMB) can appropriately consider the practical utility of this proposed reporting rule.

Second, our initial review of EPA's supporting statement for the ICR finds that EPA should revise it to comply with the PRA. For example, EPA acknowledges that many other parties will have reporting and recordkeeping, burden but fails to estimate this burden. This approach is not allowed under the PRA.

Third, in addition revising the ICR to improve the burden estimate, EPA must also comply with other provisions of the PRA in the supporting statement, specifically demonstrating that the collection has practical utility and is the least burdensome approach. Our initial review finds that EPA could improve the practical utility of the collection in the following ways:

- **Eliminate the articles requirement:** Costs for firms to track PFAS in parts and articles are greater than EPA's de minimis cost estimate. EPA should first demonstrate that there is significant value to federal decision making for the additional information challenge for inventorying articles and be able to outline specific costs. This effort should include impacts up and down complex supply chains. Gluge et. al., in 20201 identified more than 200 use categories and subcategories for more than 1,400 PFAS. Without any effort from EPA to prioritize these uses, EPA will be imposing an extraordinary burden. The 2016 CDR identified 19 sectors for PFAS use; however, more than 80% of the PFAS reported in the U.S. are in only two categories.[2]

  EPA fails to appreciate the complexity of supply chains and the burdens the rule would place on article manufacturers and importers. Imposing these burdens would have comparably little benefit for EPA, because chemicals incorporated into articles are less likely to result in human or environmental exposure. Information already reported through TSCA would be more value versus industry doing due diligence within their supply chain trying to identify whether specific data that are not readily available. There is no clear explanation for the practical utility of including articles in the data collection. We note that EPA recently excluded articles from the TSCA fees rule due to the excessive burden. The draft ICR provides no explanation as to why the difficulties with identifying chemical identity would be any different in that rule from this data collection.
- **Exclude small businesses:** EPA should allow exclusions for small businesses for which reporting does not meet the "known and reasonably ascertainable" standard and is a significant cost, practical, and logistics burden. The Small Business Administration Office of Advocacy is slated to hold a roundtable on the impacts on small business for Friday, August 13, 2021. Suggestions on the ICR requirements from this discussion should be considered. The proposal preamble specifically suggested that it would not require information that was duplicative or unnecessary. EPA failed to examine whether the coverage of small businesses (which covers very few businesses under TSCA section 8(a), would yield new information with practical utility relative to the burden of collection. For example, it is highly unlikely that small businesses would have developed any scientific studies regarding human health and environmental effects.
- **Develop exemptions:** Besides exempting articles (as detailed above), appropriate exemptions should be adopted for issues around impurities and disposal especially for importers. The TSCA fees rule addresses very similar issues to this proposal. EPA adopted a series of exemptions after issuing a rule without exemptions, just like the EPA proposal at issue here. Those exemptions included: (1) small business, (2) impurities (3)

[5]See Gluge et. al. Environ. Sci.: Processes Impacts, 2020, 22, 2345; available at: https://pubs.rsc.org/en/content/articlelanding/2020/em/d0em00291g#!divAbstract.

[2] ibid., see Table 3 in the article.

byproducts (4) quantities of less than 2,500 pounds, and (5) research and development. As a result, EPA should issue a No Action Assurance for three categories of exemption. Substances that fall under these common TSCA exemptions would be among the most challenging for companies to report. Yet, because these substances are least likely to result in exposure to humans or the environment, reports on these substances would provide the least benefit to EPA. In addition, EPA should apply TSCA's *de minimis* exemption to any finalized reporting rule. Given the wealth of information developed about exemptions in the TSCA fees rule, EPA should use that information to supplement the record with new analyses for public comment.

- **Incorporate appropriate exclusions for certain PFAS**. The proposed rule mandates reporting for all PFAS. However, including all PFAS in scope of the PFAS reporting rule would unduly burden industry. Any rulemaking should focus solely on substances for which EPA already has a documented basis for concern based on available toxicity and exposure data. This data simply does not exist for all PFAS. Additionally, including all PFAS in the proposed rule would also hamper the response by the regulated community, which would hinder EPA's efforts to gather meaningful data that would inform EPA's policies. Finally, EPA should exclude PFAS substances for which EPA already has obtained data or for which substantial data is already publicly available, such as PFOA and PFOS.
- **Avoid requiring the regulated community to report duplicative information.** The information required to be reported under the Proposed Rule would be very similar to that already required to be provided to EPA under the CDR rule (e.g., chemical identity and manufacturing information). 40 C.F.R. Part 711. To the extent any data required to be provided to EPA under the PFAS reporting rule has already been provided to EPA, manufacturers should be permitted to merely point this out to EPA, rather than providing the same information again. Further, to the extent certain information has already been provided to EPA under the CDR rule for a principal CDR reporting year, but not for other reporting years, companies should not be required to needlessly gather and repeat the same data elements for past non-principal reporting years.
- **Provide more time for reporting.** Although EPA notes in the preamble to the proposed rule that the CDR submission period is typically four months, this is merely the time allowed for data entry into EPA's CDX portal. The time investment by many manufacturers is much longer than four months. CDR reporting is also aided by the fact that companies in nearly all cases know years in advance what data elements they are required to collect and report. In the present case, EPA is announcing now what companies must report for manufacturing or importing activities that may be more than a decade old. EPA also fails to recognize in the Proposed Rule that for many companies, CDR data gathering is a continuous four-year data gathering exercise. The work is not limited to the length of the submission period. Finally, the scope of information that would be required under the Proposed Rule is broader than required under the CDR.
- **Protect confidential business information.** The proposed rule does not discuss or anticipate how to deal with supplier trade secret information, other than a request for comments on adding joint submission functionality similar to CDR. TSCA Section 14 requires EPA to take appropriate measures to protect CBI. This is critical for fostering

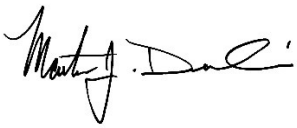
domestic innovation and must remain secret. If foreign and domestic competitors learn, for free, what chemistries other companies have researched but not pursued commercially, it would give competitors undue but valuable insight into proprietary structure-function knowledge.

- **Substantially increase projected industry compliance costs.** When it published the proposed rule, EPA requested comment on its estimated costs for industry compliance. EPA's estimate is that 234 companies would be subject to the PFAS reporting rule, as proposed, at a cost of approximately $42,000 per company. EPA's per-company cost figure is a drastic underestimate. For example, EPA has estimated that each company will spend less than one person-hour familiarizing itself with the proposed rule, six person-hours on CBI substantiation, and six person-hours on recordkeeping. Any company taking its regulatory responsibilities seriously will need to spend more than one person-hour familiarizing itself with the proposed rule and EPA's associated guidance (e.g., website, Federal Register preamble, supporting materials, etc.). EPA expects regulated entities to read and understand these documents and should recognize it takes substantially more than one person-hour to do so. Similarly, carefully evaluating and substantiating CBI claims and ensuring that records are stored properly for five years will take significantly more than six person-hours each.

The business community supports the value of collecting more data to enhance identification of potential PFAS-related risks and accelerate cleanup in impacted communities. However, any approach to do so must advance smart public policy and focus on the areas of data that will optimize the benefits and limit burdens to impacted sectors. EPA's approach must also meet its requirements under the Paperwork Reduction Act.

We again request a 60-day extension so that the business community can offer appropriate contributions and increase transparency to improve the agency's work on this important issue. As the statutory deadline for this final rulemaking is not until January 1, 2023, it is sensible and reasonable for EPA to provide potentially impacted stakeholders with additional time to inform the potential scope of this rulemaking. We stand ready to assist you as this proposal moves forward.

Sincerely,



Martin J. Durbin