September 27, 2021

Via Regulations. gov

Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Avenue NW
Washington, DC 20004

Re: Docket No. EPA–HQ–OPPT–2020–0549
TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Proposed Rule, 86 Fed. Reg. 33,926 (Jun. 28, 2021)

Dear Dr. Freedhoff:

The Ad Hoc Downstream Users Coalition on PFAS (Coalition) is comprised of trade associations representing a broad cross-section of U.S. industry -- the Alliance for Automotive Innovation (Auto Innovators), the American Forest & Paper Association (AF&PA), the Association of Equipment Manufacturers (AEM), the Motor & Equipment Manufacturers Association (MEMA), the Outdoor Power Equipment Institute (OPEI), the Plastics Industry Association (PLASTICS), and the Toy Association. These associations together speak for thousands of their respective individual member companies that are product and product component manufacturers and companies involved in downstream portions of the consumer and commercial product supply chain.[1] A detailed description of the Coalition members for this rulemaking is enclosed.

We appreciate the opportunity to comment on the Environmental Protection Agency's (EPA) proposed reporting rule for perfluoroalkyl and polyfluoroalkyl substances, proposed under the authority of Toxic Substance Control Act (TSCA) section 8(a)(7), and on the associated Information Collection Request (ICR). We also appreciate the Agency's decision to extend the public comment period on this significant regulatory action until September 27, 2021.[2]

A. SUMMARY OF COMMENTS

We generally support collecting existing PFAS health, exposure and use information from industry to support good public policy and meet well defined information needs. However, in this case, the information collection program outlined in EPA's proposed rule was not designed to meet particular unmet information needs and, in our view, is needlessly burdensome. As discussed herein, this flaw arises from a mistaken view of the extent of EPA's discretion under the statute to tailor the rule to its actual information needs. EPA has viewed its discretion too narrowly. In fact, EPA has both the discretion and the time to design a practicable information collection rule that will generate useful information for policy making, without undue burden on the entire regulated community.

---

[1] Each association is a not-for-profit organization serving as a collective voice for their respective members.

[2] 86 Fed. Reg. 41,802 (Aug. 3, 2021).

As discussed more fully below:

1. EPA is required to issue a PFAS reporting rule in accordance with the information collection planning and burden limiting provisions of the Paperwork Reduction Act (PRA) and TSCA section 8(a). EPA is mistaken to the extent it concludes that it has no discretion to create exemptions and tailor the reporting rule to its current information needs. The reporting rule must be tailored to:

    - avoid duplication to the extent feasible;
    - avoid unnecessary reporting to the extent feasible;
    - limit reporting to information that will be of practical utility to EPA (in substance and in a format) to address particular needs;
    - use the least burdensome approach necessary for the proper performance of the Agency's function;
    - exempt qualifying small businesses; and
    - to distinguish to the extent feasible among classes of persons and direct reporting obligations to those likely to have useful, responsive information.

    Congress directed EPA to promulgate a reporting rule in accordance with these guidelines. Failure to do so would be a violation of TSCA and the Administrative Procedures Act.

2. Given its past interpretation of section 8(a)(7), EPA has never assessed its particular PFAS information objectives that might be addressed by TSCA section 8(a)(7) reporting. At this stage, EPA should redraft the rule based on a principled assessment of its unmet information needs, and a clear plan that will allow it to make practical use of the collected information. The rule then can be tailored to generate the required information while also avoiding unnecessary, duplicative, or needlessly burdensome requests.

3. EPA has grossly underestimated the practical scope and burden associated with the proposed reporting and EPA's PRA ICR should be rejected in its current form.

4. There are techniques available to EPA to tailor the reporting rule that balance EPA's reasonable information needs, differences in the kind and extent of information available to companies in the value chain and burden on the regulated community. These include establishing different response obligations corresponding to a respondent's expected level of knowledge and using tiered and phased approaches to focus reporting on the most relevant and reliable information and to defer or make conditional reporting on information that is less useful, less reliable or significantly more difficult to obtain.

5. We respectfully request that EPA narrow the scope of required reporting with additional proper exclusions for:
    - Imported articles
    - Materials manufactured without a separate commercial purpose as described in 40 CFR §720.30 (incidental manufacture, R&D materials, wastes, impurities, byproducts, non-isolated intermediates)
    - Small businesses
    - Materials manufactured in quantities of less than 2,500 lbs.
    - Materials for which EPA has not listed a specific chemical identity
    - Most fluoropolymers, consistent with EPA's approach in its TSCA Chemical Data Reporting rule
6. We respectfully request that EPA modify or narrow individual reporting elements to avoid unnecessary, duplicative, or unduly burdensome reporting:
    - Clarify the scope of the "reasonably ascertainable" standard to reasonably limit the extent of required investigation, particularly outside the reporting organization
    - Define data quality standards for reporting quantitative estimates
    - Avoid unnecessary and duplicative reporting respecting health and safety information in the public domain or known to the Administrator
    - Extend the reporting period to at least one year

B. THE PROPOSED RULE

The 2020 National Defense Authorization Act[3] added a new section 8(a)(7) to TSCA, directing EPA to promulgate an information collection rule applicable to manufacturers of "PFAS":

> (7) PFAS DATA.—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).[4]

[3] The National Defense Authorization Act for Fiscal Year 2020 (Pub. L. No. 116-92, section 7351) (added new section 8(a)(7) to TSCA) (NDAA).

[4] 15 U.S.C. § 2607(a)(7) (emphasis added).

TSCA section 8(a)(2) subparagraphs (A) through (G), referred to by the amendment, describe the full range of information for which EPA can require reporting under section 8(a). These include:

- Chemical identity and trade name;
- Categories of use;
- Amounts manufactured or processed, by use and by year;
- All existing environmental and health effects information;
- Description of byproducts from manufacture, processing, use, or disposal;
- The number of workers exposed and the duration of exposure; and
- The manner or method of disposal.

The amendment does not expand EPA's reporting authorities, it merely directs EPA to use them. The statute requires EPA to promulgate the final reporting rule by January 2023 but does not specify a deadline for the reporting itself. Nor does the amendment identify any intended purpose or object for the reporting. The details of the reporting are left to EPA's discretion, but EPA's discretion to set reporting obligations under section 8(a)(7) is not unlimited.

1. PFAS Reporting is Subject to TSCA section 8(a) Prudential Limits.

The statutory text carefully included words to assure that all existing burden mitigation provisions of TSCA section 8(a) were made applicable to this new information collection, just as they are for all other TSCA section 8(a) rules. Congress specifically directed that the new section 8(a)(7) PFAS rule should be promulgated in accordance with the other provisions of subsection 8(a):

> Not later than January 1, 2023, the Administrator shall promulgate a rule *in accordance with this subsection* ….

TSCA § 8(a)(7) (emphasis added). As used in TSCA, "subsection" refers to the first rank subdivision below the numbered section level.[5] Accordingly, this cross reference in TSCA section 8(a)(7) refers to TSCA subsection 8(a) and requires that EPA promulgate this PFAS rule "in accordance with" that subsection.

Subsection 8(a) has several limits that require EPA to use skill and good judgment in the exercise of its broad information collection authorities to require others to expend resources. These prudential limits closely parallel but are more restrictive than the 5 CFR § 1320.5(d) standards for ICR approval under the PRA:

- EPA may only require reporting that is "reasonable" [§8(a)(1)(A)];
- "Small manufacturers and processors" are exempt from section 8(a) reporting in most circumstances [§ 8(a)(1)];

[5] See, e.g., references to "subsection" (b) in TSCA section 8(a)(1) and (3); references to "subsection" (a) in TSCA section 8(b)(1).

- Reporting can be required for mixtures (e.g., articles) and R&D material only if EPA determines that such reporting is necessary for effective enforcement of TSCA [§ 8(a)(1)(B)];
- Reporting is required only to the extent that the information sought is "known or reasonably ascertainable" [§ 8(a)(2)];
- Only existing health and safety information must be reported, new data development cannot be required [§ 8(a)(2)(E)];
- Reporting rules must specify the level of detail to be reported, including the manner by which exposure and use information may be reported [§ 8(a)(4)(B)];
- To the extent feasible, EPA must not require reporting that is unnecessary [§ 8(a)(5)(A)];
- To the extent feasible, EPA must not require reporting that is duplicative [§ 8(a)(5)(A)];
- To the extent feasible, EPA must minimize the cost of compliance with section 8(a) reporting rules to small manufacturers and processors [§ 8(a)(5)(B)]; and
- To the extent feasible, EPA must direct any reporting obligations to those likely to have the information relevant to the effective implementation of TSCA (and avoid burdening those that do not) [§ 8(a)(5)(C)].

2. PFAS Reporting Is Subject to Paperwork Reduction Act Prudential Limits.

EPA's discretion to promulgate a TSCA reporting rule also is limited by the PRA. Before submitting an ICR for approval, EPA is required first to have a plan for the efficient and effective management and use of the information to be collected, including planning to identify and obtain the necessary resources for that use.[6] The plan must include identifying the steps and allocating the necessary resources for processing the information in a manner that will enhance the utility of the information to the Agency.[7] Indeed, if OCSPP will disseminate the collected information to other parts of the Agency or other agencies, the ICR should outline the specific plans for tabulation and publication, and the time schedule for the entire project.[8]

Based on this planning, the justification in the ICR itself should indicate how, by whom, and for what purpose the information is to be used. Importantly, it is not sufficient to just make general statements about the overall use of the information. The ICR should address each specific item of information being collected and demonstrate that the Agency will be using all information collected for a practical and necessary program purpose.[9] The Office of Management and Budget

---

[6] See 44 U.S.C. § 3506(c)(1)(A)(vi).

[7] See 44 U.S.C § 3506(c)(3)(H).

[8] See, e.g., OPM, Paperwork Reduction Act Guide, Version 2.0 (Apr. 2011) at 45 ("OPM Manual").

[9] See, e.g., OPM Manual at 35-36.

cannot approve the ICR unless EPA demonstrates that it has taken every reasonable step to ensure that the proposed collection:

- Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives [5 CFR § 1320.5(d)(1)(i)];
- Is not duplicative of information otherwise accessible to the agency [5 CFR §1320.5(d)(1)(ii)]; and
- Has practical utility [5 CFR § 1320.5(d)(1)(iii)].

3. The Proposed Rule Violates Prudential Limits on Information Collection Under TSCA Section 8(a) and the PRA.

Regrettably, the rule as proposed does not comply with TSCA limits or the PRA approval standards. Indeed, examination of the ICR indicates that EPA's only articulated purpose in promulgating a rule is to satisfy the new statutory requirements to publish a reporting rule. The content of the proposed rule suggests that no additional effort was made either to identify any PFAS information EPA needs to implement its responsibilities under TSCA, or to tailor the rule to those needs.[10]

Instead of a principled information collection plan, EPA offers only generalized, non-specific information about how the collected information will be used – explaining that the information collection generally "supports the Agency's mission in the PFAS Action Plan to identify and better understand these chemicals and to increase scientific research on them," that EPA generally intends to use information to support assessments of new and existing chemicals under TSCA, and may (or may not) be used in general ways under other environmental statutes.[11] But this is not convincing. No connection is made between the specific information to be reported and how it will be used. EPA does not identify how the collected information will be organized and analyzed to make it practically useful to support assessments of other chemicals, and EPA has not allocated any resources for such work. Indeed, in describing in the ICR the estimated costs to the government of the PFAS reporting, EPA anticipates costs only for collecting the information and then storing it and none for analyzing it to make it useful for assessments.[12] In short, there is little indication from the record that EPA has identified any actual use planned for this information.

This is insufficient under the PRA and TSCA section 8(a). Without identifying a specific need for the information or a plan for its use, it is impossible for EPA to show that the required reporting is a reasonable means to meet legitimate Agency policy aims, that it has limited required reporting to information that is necessary, that it has selected the least burdensome means to

---

[10] See, EPA, Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA), EPA ICR No.: 2682.01 at ¶A.1., A.6 ; 86 Fed. Reg. at 33,927, col. 3.

[11] 86 Fed Reg. at 33,929.

[12] EPA ICR No.: 2682.01 at ¶A.14.

comply with legal requirements and achieve program objectives, that it has minimized costs to small enterprises, and that the collected information will in fact have practical utility.

The proposed rule also would violate TSCA section 8(a)(1), because it does not exempt small businesses, as required.

4. EPA Has Underestimated the Extent of Its Discretion Under Section 8(a)(7).

The root of the problems with the proposed rule is EPA's narrow and incorrect reading of the extent of its discretion under the section 8(a)(7). As EPA reads the statute, section 8(a)(7) is a "standalone section"[13] and reporting rules issued under that section are not subject to the prudential provisions of section 8(a) that would otherwise allow (require) EPA to tailor the rule to EPA's actual information needs and avoid unnecessary or unduly burdensome reporting. Similarly, EPA asserts that language in section 8(a)(7) stating that reports must be obtained from "*each person*" that manufactured a PFAS substance during the look back period effectively prohibits EPA from allowing any exemptions (e.g., for small businesses, or importers of articles, or impurities).

We submit that EPA's view is mistaken. As noted above, the language of section 8(a)(7) expressly provides that rules under 8(a)(7) must be promulgated "*in accordance with*" subsection 8(a), which includes all 8(a) prudential limits. That is, the statute requires EPA to promulgate a reporting rule, but, like all other 8(a) rules, it also must limit the broad statutory scope and applicability consistent with the limitations in section 8(a). In contrast, EPA's view would improperly read the "in accordance with" language wholly out of the statute. EPA also is inconsistent on whether section 8(a)(7) in fact "stands alone." For example, EPA states that both the section 8(a)(2) "known or reasonably ascertainable" due diligence standard and the section 8(a)(5) bar against duplicative or unnecessary reporting are applicable to limit the scope of section 8(a)(7) PFAS reporting, but the section 8(a)(1) exemption for small manufacturers is not.

We also believe EPA's concern with the section 8(a)(7) language requiring a report from "*each person*" is unsupported. TSCA sections 8(a)(1)(A) and (B) use the exact same language to describe reporting obligations[14], and yet there is no disagreement that rules promulgated under those provisions are subject to the all the prudential limits of section 8(a), and that EPA can and does exempt categories of respondents from 8(a) rules other than small manufacturers.

C. EPA SHOULD RESTART THE INFORMATION COLLECTION PROCESS AND REDRAFT THE PROPOSED RULE

By amending TSCA to add the PFAS reporting provision, Congress signaled to EPA that it should move beyond the voluntary efforts it has pursued in the past in various contexts to obtain

---

[13] 86 Fed. Reg. at 33,929 (col. 1).

[14] See, e.g., TSCA section 8(a)(1)(A) (each person … who manufactures or processes or proposes to manufacture or process a chemical substance … shall submit to the Administrator such reports, as the Administrator may reasonably require").

information on PFAS uses and risks. EPA already had the legal authority under TSCA to collect PFAS information by rule. The section 8(a)(7) amendment merely directed EPA to use that authority. Congress gave EPA four years – until January 2023 – to develop and issue a final rule. EPA would not need such a long period if its only responsibility were to prepare a rule that merely parroted the statute. This period is consistent instead with a principled effort to identify TSCA program information needs in light of other information available to EPA and to design a thoughtful information collection program that would (as required by section 8(a) and the PRA), to the extent feasible, direct reporting obligations to those most likely to have useful responsive information, avoid unnecessary or duplicative reporting, minimize the costs to small manufacturers, and assure that the information would have practical utility measured by how well it meets the needs of a cogent plan to distill and use all the information collected.

At this stage, EPA should restart the rulemaking process and ultimately publish a new proposed rule prepared in accordance with the limitations in TSCA section 8(a) and PRA information collection guidelines. The process should begin with a principled assessment of EPA's particular PFAS information needs and an inventory of the relevant information it already has. The rule then can be tailored to generate information of practical utility to fill the identified, unmet needs while also avoiding unnecessary, duplicative, or needlessly burdensome requests. This is necessary not only because, as discussed further below, many terms of the current proposal are unduly burdensome and cannot be justified, but also because important aspects of the proposed rule were premised on the mistaken assumption that EPA had no discretion to choose which information to collect and from whom.

To the extent that EPA believes that importers of articles should be included in future TSCA reporting initiatives, a more significant effort is needed to work with all impacted, regulated sectors to fully understand the practical challenges, relative information benefits to EPA, the quality of the data that should be expected, and the cost implications of such reporting. Therefore, it is appropriate for EPA to develop a broader process, such as one under the Federal Advisory Committee Act (FACA), to fully assess the complexity of gathering data on articles and to obtain the experience and expertise of a diverse group of industries on how best to obtain information on the content of articles. This recommendation is based on EPA's current request for data for this rule, growing requests for data under the TSCA chemical prioritization and risk assessment processes, and the need for an informed approach related to chemical use in articles. Since these information requests go beyond EPA's traditional focus on manufacturers of the bulk chemicals, a FACA process will ensure EPA and the regulated parties are appropriately scoping resource needs, assessing readily available data sources, developing a reporting system specific to articles, and taking into consideration lead time, development time and costs to undertake this effort. A dedicated education program to ensure all regulated parties are informed and engaged will also be necessary.

D. THE PRACTICAL SCOPE AND BURDEN ASSOCIATED WITH THE PROPOSED REPORTING HAS BEEN GROSSLY UNDERESTIMATED

While section 8(a)(7) and the proposed information collection are nominally aimed at chemical "manufacturers," the rule as proposed will have a far broader reach and would include

tens of thousands of companies that import articles each year and may have little or no knowledge of the chemical composition of articles, or the individual components of articles that they import. EPA has grossly underestimated the number of companies that will be required to investigate potentially reportable products, and the time and management burden associated with the necessary investigations and any reporting.

1. EPA's Burden Estimate Excludes Article Importers – a Material Omission.

EPA's ICR for this rule reports that only approximately 234 companies will need to report; however, this figure gives the wrong impression because, as EPA acknowledges elsewhere in the ICR, this figure does not include importers of articles potentially containing "PFAS" as defined by the proposal.[15] Given the broad definition of reportable "PFAS" as defined in the proposed rule, the rule is likely to require reporting by tens of thousands of article importers. Given the relative size of that potential reporting population compared to the number EPA could (apparently) more reliably estimate (234), the Agency was obligated to discuss what it did know about the potential size of that population and the costs involved. The absence of any discussion is a very significant, material omission.

For example, as proposed, the rule requires reporting on a broad range of fluorinated chemical species, including not only the long chain perfluoroalkyl substances regulated by TSCA SNURs, but also short chain perfluoroalkyls and, perhaps most significantly, essentially all fluoropolymers. Defining the reportable substances to include fluoropolymers is significant because, as EPA knows, these materials have extensive applications in the economy, which greatly multiply the number of companies potentially responsible for reporting associated imports. Common fluoropolymers such as polytetrafluoroethylene (PTFE), poly(vinylidene fluoride) (PVDF), fluorinated ethylene propylene copolymer (FEP) and copolymer of ethylene and tetrafluoroethylene (ETFE) are widely used in an extensive range of basic products that are in turn incorporated into an even wider range of more complex but common commercial and consumer products, such as consumer electronics, touchscreens, chemical resistant tubes, hoses and seals used in cars and power equipment, high-performance lubricants, basic wire and cable insulation, some lithium batteries, solar panels, medical devices and equipment, and common oil, water, heat and soil resistant clothing and textiles.[16] Imports of any of these finished consumer and commercial products containing a fluoropolymer would trigger reporting under the rule. And these product

[15] See e.g., EPA (2020). Information Collection Request Supporting Statement. Proposed Rule ICR: Reporting and Recordkeeping Requirements for PFAS. EPA ICR No. 2682.01. November 2020, Dkt. No. EPA-HQ-OPPT-2020-0549-0005, at 7 ("EPA is not able to estimate the number of article importers who may be subject to the proposed rule and thus does not include these firms in the total estimated number of respondents").

[16] See, e.g., Executive Summary: Socio-economic assessment of the US Fluoropolymer Industry, Wood Environment & Infrastructure Solutions UK Limited (February 2020), available at https://fluoropolymerpartnership.com/wp-content/uploads/2020/03/Socio-Economic-Assessment-of-the-US-Fluoropolymer-Industry-Executive-Summary.pdf

types are imported by thousands of companies, including many small and medium sized enterprises.[17]

2. EPA's Burden Estimate Excludes Investigation Costs for Article Importers.

Equally important, imports of any of these finished consumer and commercial articles that are known as classes of products that contain PFAS in some instances will raise the question for individual companies whether their particular imports may contain a reportable PFAS. This may trigger a legal duty to investigate, "to the except known or reasonably ascertainable" – to the full extent of the knowledge of their organizations. EPA's discussion of this standard in the context of this rule has suggested that in some cases companies will need to look outside their organizations, including potentially making inquiries to both customers and suppliers:

> …conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). 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 or downstream users or employees or other agents of the manufacturer, including persons involved in the research and development, import or production, or marketing of the PFAS.[18]

Unless they have special knowledge, this would compel thousands of companies to conduct these investigations. They must conduct the investigations even if, in the end, they do not need to report, either because they establish that their products are "PFAS-free," or after the investigation is complete, it remains unknown whether the article contains a PFAS. EPA's cost estimate does not include any time or cost for this required investigation phase for article importers. See ICR at 3.

An internal company search for information on chemical content or impurities in components made by others and then reaching out and corresponding with one or more suppliers for additional information is time-consuming work, even for one product. And it is not just the inquiring companies that must invest the time – suppliers *receiving* information requests also must spend time doing their own investigations through their own supply chains. The ICR does not include estimates for any of these unavoidable "reciprocal" time investments, which will affect thousands of companies.

---

[17] The proposed rule is applicable to any person that, among other things, imports any finished article or component that may intentionally or inadvertently contain one or more of the thousands of reportable chemicals. The U.S. Census Bureau reports that more than 224,000 individual companies imported goods into the US in 2019. While a portion will be able to avoid the investigations required by the ICR based on their product category, many tens of thousands will remain subject to investigation and reporting obligations. See U.S. Census Bureau, Department of Commerce, "A Profile of U.S. Importing and Exporting Companies, 2018-2019," Release Number: CB21-52 and Table 7c (April 7, 2021) (available at https://www.census.gov/foreign-trade/Press-Release/edb/2019/index.html).

[18] 86 Fed. Reg. at 33,982.

This would be an impracticable burden even for companies working with a small set of simple articles with few components. But particularly given the wide prevalence of some of the PFAS product categories, importing companies may have thousands of different reasonably relevant article SKUs that are imported. Particularly with complex articles, such as any containing electronics or any motor vehicle (air, land, or sea), each individual article may be composed of thousands of individual component parts, manufactured, and assembled from deep, global, integrated supply chains. Particularly for complex goods, such as automobiles and heavy equipment, supply chains are several tiers deep.

Consider a company operating in North America with foam fire retardants that require annual testing, performed in the U.S., to ensure they will work as intended in the event of a fire. This testing would require import of small quantities of products, which the company understands may contain one or more unknown substances, possibly-PFAS, at unknown concentration(s), exclusively for an R&D purpose. These are proprietary mixtures for which the company has no compositional information beyond that there is some sort of fluorine chemistry involved. Their suppliers are formulators, not manufacturers, which means that they are otherwise not involved in this exercise. For the company to comply with the proposed rule, they would have to investigate what fire retardants they may have sent for testing over a ten-year period, identify each supplier, and ask those suppliers if they are willing to disclose the compositions or register in the CDX system to support the company's submissions. This does not even account for whether the company would have a record of the exact volumes sent for testing, particularly going back to 2011. In addition, the compositions have likely changed over that period, which only adds further complexity to the investigation.

The extreme difficulty of article investigations generally would be greatly compounded under this rule due to several factors:

- The number of potentially reportable substances is in the thousands and is not limited to the long list of examples published by EPA.

- Reportable substances are only defined as substances that may correspond to a broad chemical structure. While that structure may be a practicable screen for sophisticated chemical manufacturers with reference to their own products, as a practical matter, how does any article or other importer search for such substances? Substances are not listed in bills of materials in that way. There is no lookup procedure for a listing such as that. Each determination will require specialized chemistry support.

- There is no *de minimis* threshold. In contrast, CDR investigations are generally limited to manufacture in quantities of 25,000 lbs./year or more, which permits companies to summarily screen out a great many products based on volume. This rule would require examining every product.

- The rule does not exclude impurities and byproducts and incidentally produced moieties (e.g., those that are produced due to weathering and UV exposure). No component list or SDS or product component list will identify these "unintentional"

product elements.[19] To identify them, one would have to inquire about their production process, examine the lifecycle of a product, or conduct expensive testing (assuming an appropriate and proven test method exists). EPA may not require testing under TSCA section 8(a) rules.

- The rule does not consider the issue of trade secret information or confidentiality, particularly when collecting data from suppliers throughout an industry's supply chain. It is quite likely that along the supply chain, there will be suppliers who will want to claim proprietary processes as trade secret and decline to share data that they deem to be confidential. This could be further complicated to the extent suppliers are small businesses, lacking the expertise or resources to provide information in a timely manner.

- The failure to exclude incidentally produced PFAS also has the potential to bring in large numbers of users of article containing PFAS, to the extent that the articles undergo any incidental degradation or changes in surface chemistry during storage, use or disposal. EPA's recent experience with fluorinated HDPE containers is a good example. Extensive EPA testing recently demonstrated the presence of eight different PFAS compounds in a collection of used and unused fluorinated HDPE containers, which were produced incidentally as a result of fluorinating the container and/or subsequently with passage of time in storage and exposure to heat and cold. These kinds of changes and resulting PFAS production are known to EPA, potentially affect all producers, distributors, and users of fluorinated articles, but the ICR does not contain any burden estimates for these "manufacturers."[20]

- Likewise, EPA knows from its new chemical program that compounds that will qualify as reportable "PFAS" are used as processing aids in a variety of domestic and overseas manufacturing circumstances. The article or material made with these aids may contain no PFAS as part of its composition, but processing aid PFAS impurities may remain on surfaces and require reporting when imported; or the functioning of the process aid may incidentally produce new PFAS moieties at surfaces and subject even domestic processors to reporting. Neither of these classes of potential reporters is addressed by the ICR burdens assessments.

The ICR does not capture any of these extra difficulties in its estimates. And it is no answer to say that respondents may avoid the cost and time investment by determining that the information is

---

[19] See, e.g., 40 CFR § 720.30 for categories of incidentally manufactured substances recognized by EPA for TSCA purposes.

[20] See generally, Memo from T. Nguyen, Chief, Analytical Chemistry Branch, Biological and Economic Analysis Division, to K. Nesci, Director, EPA's Analytical Chemistry Branch PFAS Testing Rinses from Selected Fluorinated and Non-Fluorinated HDPE Containers (March 4, 2021) (available https://www.epa.gov/sites/default/files/2021-03/documents/results-of-rinsates-samples_03042021.pdf).

not "known to or reasonably ascertainable" because companies must still first conduct the investigations before drawing the conclusion.

3. The Impracticability of Tracing Imported Article Chemical Constituents is well known to EPA.

The practical challenges involved in identifying the individual chemical components of imported articles is not unique to this proposed rule. EPA has long recognized the extreme practical difficulty in identifying the chemical constituents of complex articles. As explained in other Coalition comments, when TSCA was first implemented and EPA was compiling the TSCA Inventory, the agency recognized that "[a]s was discussed in the preamble to these proposed regulations (42 FR 39185) comments from Industry and Trade Associations argued that it would be extremely burdensome for importers to identify the chemical substances contained in the articles they import. According to estimates from the American Importers Association, the total direct cost would range from $187 million to about $437 million [in 1977 dollars;] . . . [a]ccordingly, . . . to require an importer of the article to identify its constituent chemical substances would impose a proportionately greater burden." 42 Fed. Reg. 53804, 53805 (October 3, 1977); 42 Fed. Reg. 39182, 39185 (August 2, 1977). Similarly, when EPA finalized rules for PMN reporting, it stated: "[b]ecause it would be enormously difficult for an importer to determine the identity and Inventory status of each chemical substance in imported articles (e.g., automobiles), the rule does not require persons to submit notices on new substances imported as part of articles." 48 Fed. Reg 21722, 21726 (May 13, 1983).

4. The ICR Does Not Identify How Imported Article Information is of Any Practical Utility to the Agency.

As discussed further below, it is possible that the significant resource investments that would be required to comply with this reporting rule could be justified based on the particular utility of the information likely to be collected and EPA's planned use for that information. But there is none. The ICR and preamble refer only to broad, general uses with conclusory statements that the information will be "useful."[21] The PRA and TSCA section 8(a) require more than that.[22] Indeed, if information on articles was useful, EPA would not arbitrarily confine the information request to imported articles. EPA has the authority under TSCA section 8(a) to collect information from domestic processors of PFAS and in principle could require reporting of this information for most domestically manufactured articles. The fact that EPA has not sought reporting for domestic processing of articles seems to confirm that EPA has not identified any need for article chemical content and exposure information.

---

[21] 86 Fed. Reg. at 33,929.

[22] See 44 U.S.C. § 3506(c)(1)(A)(vi); 15 U.S.C. § 2607(a)(5)(A); 5 CFR § 1320.5(d)(1)(iii).

E. THE RULE SHOULD PROVIDE ADDITIONAL REASONABLE EXCLUSIONS:

1. Exempt Small Manufacturers.

As discussed above, the PFAS reporting rule is subject to the prudential limitations of TSCA section 8(a), including the limitation in section 8(a)(1) excepting small manufacturers from reporting responsibilities under §8(a). The proposed rule should be modified to exempt small manufacturers (including importers) from section 8(a)(7) reporting as required by law.

2. Exempt Reporting for Imported Articles.

As discussed, the burden on article importers to investigate their supply chains to identify products that contain reportable PFAS materials can be extreme. As EPA has acknowledged, in most cases, where articles containing a reportable PFAS are identified, the importer is unlikely to have information of practical utility for EPA's stated TSCA use for the information – assessing new and existing chemicals.[23] Given its typically limited value and high cost, EPA should exempt imported articles from reporting.

EPA has said outside the ICR process that merely knowing that a particular type of article contains a PFAS substance provides some value,[24] but has not explained what that value is, how the information would be used and whether there is a less burdensome way to obtain it. Requiring every company that imports the same type of article to make the same kind of investigation, make the same kind of report and provide EPA with the same information is highly duplicative and very costly. Indeed, for many products, EPA may already know that the type of article often contains a PFAS. EPA is required to avoid wasteful and duplicative reporting to the extent feasible.[25] EPA also is required to focus reporting on persons likely to have responsive information.[26] If EPA truly needs this kind of product use information, it might be much more efficiently obtained from a small number of responses from the top of supply chains rather than through a multitude of responses from article importers. And to avoid other duplicative reporting of information of this type already known to EPA, the Agency should catalog and publish this information and exempt further reporting of such information know to the Administrator.

3. Exempt Reporting for 40 CFR § 720.30 Materials.

The TSCA definition of "manufacturer" is very broad. In addition to conventional understandings of manufacturing, it also includes both import activity and a wide range of other activities that technically result in a chemical reaction but that are only incidental to other activities, de minimis in scope or otherwise occur in circumstances not warranting EPA oversight. Consistent

---

[23] 86 Fed. Reg. 33,930 col. 1-2. EPA acknowledges that article manufacturers, including article importers, may not have such information known to or reasonably ascertainable by them and may not meet the reporting standard as described in Unit II.C. To this end, information that helps EPA better understand data gaps is useful information for EPA to have.

[24] Id.

[25] TSCA § 8(a)(5)(A).

[26] TSCA § 8(a)(5)(C).

with the limitations in section 8 and the prudence required of EPA under TSCA section 2(c), EPA typically exempts these products and activities from TSCA reporting and notice obligations. They are listed together at 40 CFR § 720.30 (exemption from PMN requirements) and include materials manufactured or imported, intentionally or unintentionally, only:

- as an impurity;
- as a byproduct or waste;
- as an R&D material;
- as a non-isolated intermediate;
- by reactions occurring incidental to storage or disposal; or
- by reactions incidental to exposure to another substance, mixture, or article, or to the environment (exposure of a coated article to air, sunlight, etc.);
- by reactions occurring incidental to use (e.g., curing).

Consistent with other TSCA reporting rules (e.g., CDR and PMN programs), EPA should exempt these materials from TSCA section 8(a)(7) reporting. They typically exist in circumstances that do not warrant public health oversight – in small quantities, for short periods of time and/or in circumstances where the technical manufacturer will have little or no information about them, and, indeed, maybe unaware that they are being produced.

The proposed reporting would put EPA and industry in the same unfortunate position recently experienced with the TSCA Fees Rule. There, EPA initially failed to recognize the unintentionally broad reach of its rule and the practical impact of not adopting standard TSCA exemptions (including for articles). It ultimately used enforcement discretion (a "No Action Assurance" letter) as short term, emergency means to limit applicability, which otherwise would have drawn millions of (unintended) individual responses. EPA also recognized the practical inability of downstream users and importers to identify the presence (or not) of particular chemicals in articles they import. EPA concluded that these issues would "adversely impact[ ] the agency's implementation of the TSCA Fees Rule." See EPA "No Action Assurance Regarding Self-Identification Requirement for Certain 'Manufacturers' Subject to the TSCA Fees Rule" Letter, March 24, 2020. The PRA approval criteria – properly applied – should address these concerns and assure that private and government resources to gather more information on PFAS uses and exposure are properly focused to develop useful information for TSCA purposes from those most likely to have it.

4. Exempt Reporting for Materials Produced in Small Volumes.

A low-level reporting threshold would serve as an effective screening tool for companies reviewing operations and investigating for the presence of potentially reportable PFAS materials. For the CDR program, this level is set at 2,500 lbs. (for substances subject to some form of risk management action). Exemption at this level represents a reasonable balance between the limited value of information to be obtained and the costs of obtaining it.

5. Exempt Materials for Which EPA Has Not Listed a Specific Chemical Identity.

The proposed rule defines the materials subject to reporting using a chemical structure definition that is quite broad. It is also difficult to use to search against inventories or as

the basis for inquiries to suppliers or customers. Limiting reporting to the specific PFAS chemical identities EPA has drawn from the TSCA Inventory and LVEs would simplify search procedures while only marginally limiting (if at all) the information to be received by EPA.

6. Exempt Most Fluoropolymers.

As noted, fluoropolymers are widely used in the economy, and most will fall within the scope of the "PFAS" defined for reporting under the proposed rule. Including these in the rule will bring in tens of thousands of additional reporting entities importing articles. EPA could significantly reduce the burden of the rule by exempting these from reporting under section 8(a)(7) as it has from other TSCA rules. For example, the TSCA Chemical Data Reporting rule (CDR), 40 CFR Part 711, exempts all polymers from reporting.[27] Similarly, when EPA initially promulgated and later amended the TSCA SNUR for long chain perfluoroalkyl carboxylates, it excluded from applicability PFAS compounds that are polymers.[28] As EPA has explained, "there is an exceedingly low probability that potential exposure to high molecular weight water-insoluble polymers, as a class, will result in unreasonable risk or injury to human health or the environment." 60 Fed. Reg. 16316, 16322 (Mar 29, 1995). To the extent that EPA has identified one or more sub-groups of polymers that, due to their specific structural features, may be of interest to EPA because they degrade to other PFAS compounds, the Agency could avoid unnecessary reporting by limiting the reportable scope to polymers in those specific sub-groups.

F. MODIFY OR NARROW INDIVIDUAL REPORTING ELEMENTS TO AVOID UNNECESSARY, DUPLICATIVE, OR UNDULY BURDENSOME REPORTING

1. The Rule Should Use Tiering and Phased Reporting Techniques to Mitigate Unnecessary Burden.

It is the Coalition's view that EPA is not precluded by the terms of section 8(a)(7) from using a range of techniques – such as exemptions – to reasonably reduce duplication and unnecessary reporting burden. The Coalition has suggested a number of such exemptions. However, to the extent EPA concludes that the statute does not allow it to grant exemptions of otherwise reportable materials, other techniques exist that nevertheless will provide meaningful relief. Importantly, while the rule must be finalized by January 2023, there is no deadline for completing the reporting itself, which can be deferred or competed in tiers at different times.

Distinguishing among types of respondents and tiered or phased reporting can be used to focus initial reporting on persons likely to have the most useful, responsive information and to defer investigation and responses expected to generate less useful information, information that is

---

[27] 40 CFR 711.6(a)(1).

[28] See 40 CFR § 721.10536(b)(1) (excluding compounds with chain lengths greater than 20 carbons). Fluoropolymers are excluded because they are large, typically insoluble, inert molecules that generally are not expected to be absorbed by biological systems.

difficult to obtain or information the Agency is not ready to use. The following are several potential examples:

- To the extent imported articles are not excluded from reporting, EPA nevertheless could defer section 8(a)(7) investigations and reports for imported articles until it has reviewed and compiled product information it received from other sources and call in the deferred data in the future if it were ever needed.
- In some cases, older exposure and use data may be both harder to reconstruct and of less current value for EPA for review purposes. The rule might defer reporting such older data (e.g., greater than five years old) until such time as it was needed, if ever.
- Given that article importers are unlikely in many cases to have useful health and safety information or useful exposure information, the reporting rule could impose differential reporting obligations for these articles, limited to information article importers are likely to have (e.g., chemical identity and use), and omitting any obligation to investigate or estimate other reporting end points.
- Likewise, PFAS in articles are not used like chemicals being manufactured in bulk. The reporting rule should specify a reduced set of reporting elements consistent with that status and omitting endpoints not relevant to the context.

2. The Rule Should Avoid All Duplicative Reporting of Health and Safety Information.

The rule as proposed requires the submission of all health and safety information for a reported PFAS substance to the extent known or reasonably ascertainable. As defined, this term encompasses published information, including information in public or subscription databases to which the reporter has access. As a result, all manufacturers of the same substance will be searching and submitting duplicative OECD summaries of the same study reports. This information is as available to EPA as it is to reporting entities. Like TSCA 8(e) and 8(d) reporting, all reports available in the literature should be exempt from reporting as well as all other information known to the Administrator by whatever means.

3. Further Guidance on the Scope of Required Diligence and Data Quality.

A significant portion of the burden on article importers and others may be the uncertain obligation to make inquiries of suppliers for chemical content information (identity, concentrations) for products, over years. Current EPA guidance on when such inquiries outside an organization would be required for purposes of this rule are ambiguous:

> 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 or downstream users or employees or

> other agents of the manufacturer, including persons involved in the research and development, import or production, or marketing of the PFAS.[29]

For purposes of this rule, to reduce burden EPA should address the circumstances under which an importer of an article, particularly a complex article, is obligated to make inquiries outside its organization, and the necessary extent of those inquiries (e.g., whether extending beyond first tier supplier). In general, it is the Coalition's view that such inquiries should be rare and, in any event, should not require an importer ever to look beyond the knowledge of a first-tier supplier.

The guidance also should extend to the basis needed to make estimates. The proposed rule would require estimates of various matters, including exposure. The quality of those estimates is likely to vary considerably going back in time and across companies, and it calls into question the utility of that data for comparative analysis or risk assessment by EPA. The rule should establish minimum data quality standards as the basis for such estimates consistent with EPA's intended use. To the extent the reporter does not have a sufficient basis to make a reasonable estimate consistent with the relevant data quality standard, the rule should require the reporter not to estimate and instead to report that the information is not known or reasonably ascertainable.

4. Extend the Reporting Period.

The proposed rule contemplates a reporting period of only six months. Given the potential complexity involved in investigating and assembling the required information going back more than 10 years, a longer reporting period is more appropriate. The Coalition recommends a one-year reporting period beginning six months after publication of the final rule.

CONCLUSION

The proposed rule is premised on the incorrect legal conclusion that the Agency has no authority to tailor the 8(a)(7) rule to meet its own information needs, or to comply with the prudential information collection requirements of TSCA 8(a) or the PRA. As a result, there is little justification for the proposed terms of the proposed rule other than that the information is required by the statute. This is not sufficient.

The reporting contemplated by the rule will require an enormous investment of resources by thousands of companies to generate information covering more than a decade of operations that it appears EPA has no specific plan to use. Since EPA has not articulated a purpose of its own in this rule to guide information collection, it is difficult to craft alternatives that meet EPA's information needs but are also practicable for companies. EPA must not abdicate responsibility for the content of this rule.

We strongly urge the Agency to revisit this proposal and to start with a clear sense of the information that EPA needs and can use at this time, and then to craft a proposal directed toward obtaining that information, in a form and of sufficient quality that it can be used by EPA for its

---

[29] TSCA 8(a)(7) Proposed Rule, 86 Fed. Reg. 33,928.

intended purpose under TSCA, but also consistent with the prudential provisions of TSCA section 8(a) and the PRA.

* * * *

For the Coalition:

Julia Rege
Vice President, Energy & Environment
Alliance for Automotive Innovation
email: jrege@autosinnovate.org
ph: (202) 326-5559

Of counsel:

James G. Votaw
Keller and Heckman LLP
1001 G Street, NW
Suite 500 West
Washington DC 20001
ph: (202) 434-4227

Attachment

About the Ad Hoc Downstream Users Coalition on PFAS

The Ad Hoc Downstream Users Coalition on PFAS (Coalition) is comprised of trade associations representing a broad range of U.S. industry -- the Alliance for Automotive Innovation (Auto Innovators), the American Forest & Paper Association (AF&PA), the Association of Equipment Manufacturers (AEM), the Motor and Equipment Manufacturers Association (MEMA), the Outdoor Power Equipment Institute (OPEI), the Plastics Industry Association (PLASTICS), and the Toy Association. These associations together speak for thousands of their respective individual member companies that are product and product component manufacturers and companies involved in downstream portions of the consumer and commercial product supply chain.

Alliance for Automotive Innovation (Auto Innovators)

Formed in 2020, the Alliance for Automotive Innovation is the singular, authoritative, and respected voice of the automotive industry. Focused on creating a safe and transformative path for sustainable industry growth, the Alliance for Automotive Innovation represents the manufacturers producing nearly 99 percent of cars and light trucks sold in the U.S., original equipment suppliers, as well as technology and other automotive-related companies. The newly established organization, a combination of the Association of Global Automakers and the Alliance of Automobile Manufacturers, is directly involved in regulatory and policy matters impacting the light-duty vehicle market across the country. The auto industry plays an important and critical role to our nation's economy, accounting for 10 million jobs and 5.5% of the annual Gross Domestic Product. The Alliance for Automotive Innovation is headquartered in Washington, DC, with offices in Detroit, MI and Sacramento, CA. For more information, visit our website http://www.autosinnovate.org.

American Forest & Paper Association (AF&PA)

The American Forest & Paper Association (AF&PA) serves to advance a sustainable U.S. pulp, paper, packaging, tissue and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative — Better Practices, Better Planet 2020. The forest products industry accounts for approximately four percent of the total U.S. manufacturing GDP, manufactures nearly $300 billion in products annually and employs approximately 950,000 men and women. The industry meets a payroll of approximately $55 billion annually and is among the top 10 manufacturing sector employers in 45 states.

Association of Equipment Manufacturers (AEM)

AEM is the U.S.-based international trade group representing off-road equipment manufacturers and suppliers, with more than 1,000 companies and more than 200 product lines across the agriculture, construction, forestry, mining, and utility-related industry sectors worldwide. Collectively, the equipment manufacturing industry in the United States supports 2.8 million jobs and contributes roughly $288 billion per year to the U.S. economy.

Motor & Equipment Manufacturers Association (MEMA)

The Motor & Equipment Manufacturers Association (MEMA) represents more than 1,000 members that manufacture motor vehicle systems and component parts for the original equipment and aftermarket segments of the light vehicle and heavy- duty industries. Motor vehicle suppliers provide over 77 percent of the value of a new vehicle and more than 900,000 jobs are directly supported by the motor vehicle supplier industry in all 50 states. MEMA represents its members through four divisions: Automotive Aftermarket Suppliers Association (AASA); Heavy Duty Manufacturers Association (HDMA); MERA – The Association for Sustainable Manufacturing; and the Original Equipment Suppliers Association (OESA).

Outdoor Power Equipment Institute (OPEI)

OPEI is an international trade association representing the manufacturers and their suppliers of non-road gasoline powered engines, utility terrain vehicles / all-terrain vehicles / side by sides, golf cars, and consumer and commercial lawn & garden equipment and outdoor power equipment ("OPE") (e.g., lawnmowers, garden tractors, trimmers, edgers, chain saws, snow throwers, tillers, leaf blowers, pressure washers, multi-purpose engines). The OPE industry currently contributes approximately $16 billion to U.S. GDP, domestically ships nearly 40 million products each year, and directly or indirectly employs 150,000 Americans.

Plastics Industry Association (PLASTICS)

The Plastics Industry Association (PLASTICS) is the only organization that supports the entire plastics supply chain, representing over one million workers in the $432 billion U.S. industry. Since 1937, PLASTICS has been working to make its members and the industry more globally competitive while advancing recycling and sustainability.

The Toy Association

The Toy Association is the North America-based trade association for the toy sector; our membership includes more than 950 businesses – from inventors and designers of toys to toy manufacturers and importers, retailers, and safety testing labs – all involved in bringing safe, fun toys and games to children. The toy sector is a global industry of more than US$90 billion annually, and our members account for more than half this amount, and approximately 90% of North American toy sales by dollar volume. Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard, and it serves as a model for other countries looking to safeguard the health and safety of their citizens with protective standards for children. The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.

****