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September 27, 2021

SUBMITTED VIA REGULATIONS.GOV

U.S. Environmental Protection Agency
EPA Docket Center, Mail Code 28221T
Office of Pollution Prevention and Toxics (OPPT) Docket
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Docket No. EPA-HQ-OPPT-2020-0549; TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Proposed Rule.

As the nation's largest manufacturing association, the NAM represents nearly 14,000 small, medium and large manufacturers in every industrial sector and in all 50 states. Manufacturers in the US are committed to the communities in which they live and serve, and dedicated to protecting the health, safety and vibrancy of those communities. Through constant innovation, investment and dedication, manufacturers in the US have become leaders in environmental stewardship and sustainability, while continuing to be the engine that drives our economic growth and prosperity. The manufacturing sector in the US today is a clean and efficient operation that is technology driven and dedicated to the planet and its people.

The NAM supports human health and environmental protection and is committed to ensuring that products are developed, manufactured, distributed and used safely. No goal is more important than safety to manufacturers. Every member of the value chain has an important part to play in ensuring the products consumers use are safe for their intended use, that the end customer knows how to use them safely and that their products have a sustainable end of life. Manufacturers welcome the opportunity to engage with EPA and others who share our commitment to product safety and environmental stewardship.

Overview

Modern PFAS chemistries are used by a broad range of industries worldwide to make innovative products possible, including personal protective equipment, life-saving medical devices, fuel cells, solar panels, and low-emission vehicles. The NAM recognizes both the importance and the complexity of the task facing EPA in identifying, assessing and appropriately managing any potential risks that may be associated with specific chemistries within the broad universe of thousands of different PFAS chemistries, and manufacturers strongly support those efforts rooted in the best available science. To this end, TSCA Section 8(a)(7) provides EPA with an important tool for gathering information on the manufacture, processing and use of the

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broad array of PFAS compounds in the US, and the data obtained under the Section 8(a)(7) rule can provide valuable insights into patterns of PFAS use and exposure that will allow EPA to more effectively focus and prioritize its regulatory efforts. However, if not thoughtfully tailored, the Section 8(a)(7) rule, requiring reporting on more than a thousand different substances over a period of more than ten years, could create the potential for EPA to be overwhelmed by a large volume of information that is of questionable reliability and limited utility. Such a result could stall critical efforts to better understand these chemistries and be a roadblock to science-based regulatory approaches.

Moreover, as EPA explains in the preamble to the Proposed Rule, TSCA Section 8(a)(5) requires the Agency to ensure that the Section 8(a)(7) rule, to the extent feasible, (i) does not require “unnecessary or duplicative” reporting, (ii) focuses on “those persons likely to have information relevant to effective implementation” of the statute, and (iii) minimizes the cost of compliance for small manufacturers and processors.¹ For these reasons, it is essential that EPA carefully tailor the Section 8(a)(7) rule to ensure that the information it collects will be reliable and actionable, and will further the Agency’s efforts to assess and mitigate the potential risks that may be associated with some PFAS chemicals in the US.

Manufacturers take seriously these important chemical reporting measures and are committed to devoting the significant investments of time and resources to fully and accurately share this information with the EPA. To ensure the success of these efforts, the NAM believes it is critically important for EPA to distinguish between reporting for *chemical substances* and reporting for *articles* that may contain a specific compound. EPA’s decades of experience with the Inventory Update Rule (IUR) and Chemical Data Reporting (CDR) rule demonstrate that the Agency can use Section 8(a) of TSCA to gather highly probative information from chemical manufacturers and importers not only on the manufacture and import of chemical substance, but also on the downstream processing and use of those chemical substances, including as part of articles. Indeed, although the CDR regulations do **not** apply to articles, they have allowed EPA to collect a trove of information on the types of articles and industries in which chemical substances are used in the US.² EPA’s proposal to deviate from its past practice and require reporting on *articles* under the Section 8(a)(7) rule would add an extremely burdensome requirement that is unlikely to enhance the utility of the information EPA receives under the rule.

Manufacturers of articles rely on complex and ever-changing, multi-tiered global supply chains to assemble products and bring them to market. Interrogating such a supply chain to ascertain whether an article or any of its component parts may have been manufactured at some previous step with a specific chemical substance can be extraordinarily difficult and time consuming or often impossible. The task becomes exponentially more complicated when a substance that is the subject of such a query is not identified by CAS number or another unique chemical identifier, but is instead defined by a structural definition (*i.e.*, R-(CF₂)-C(F)(R')R”) that is not easily understood by non-chemists and that encompasses thousands of discrete chemical substances. Further, because product designs and supply chains frequently change over time, the absence or presence of a specific compound in a given article may vary from one month to the next – which means that it can be exceptionally challenging to investigate whether, over a

¹ 86 Fed. Reg. 33,939 (June 28, 2021).

² See 40 C.F.R. Part 711. See *also*, <https://www.epa.gov/chemical-data-reporting/basic-information-about-chemical-data-reporting#how> (CDR reporting provides EPA with information on “manufacture (including import), industrial processing and use, and consumer use” to allow EPA to “develop an understanding of the types, amount, end uses, and possible exposure to chemicals in commerce.”)

period of ten-plus years, a chemical (or a structurally-defined group of thousands of chemicals) has potentially been present in an article. This difficulty is compounded by the fact that suppliers of component parts would not ordinarily be required, or expected, to maintain records documenting the chemical composition(s) of all of the materials used in manufacturing those complex component parts. Thus, by adding reporting requirements for *articles*, not just chemical substances, the Proposed Rule would create an extraordinarily burdensome and in many instances impossible obligation that likely would yield a body of data that is of uneven or dubious quality and little if any utility. This is an outcome that all serious stakeholders wish to avoid.

To ensure the success of this important effort and to address the requirements of TSCA Section 8(a)(5) and the concerns outlined above, EPA should modify the Proposed Rule to focus on gathering information on the manufacture and import of PFAS *chemical substances*, and exclude *articles* from the scope of the rule. However, to the extent EPA desires to include some articles for which data are available, the reporting requirements for articles should be adjusted by:

- Phasing in the requirements, to allow importers and manufacturers of component parts or articles sufficient direction and time to obtain reliable and responsive information from their supply chains;
- Limiting the ten-year “look back” period to manufactures and importers of *chemical substances*, and not requiring manufacturers and importers of articles to report on their activities since 2011;
- Establishing exemptions for PFAS compounds potentially present in articles only as an unintentional impurity or only at *de minimis* levels;
- Clarifying what types of adverse effects information should be submitted for articles and clarifying that only *unpublished* health and safety studies should be provided under the data-in call; and
- Providing guidance on specific steps that importers and manufacturers of articles can take to demonstrate what information is not “known to or reasonably ascertainable” by them.

The bulk of our comments elaborate on these suggested modifications to the Proposed Rule. However, our discussion begins by addressing the potential impacts of the rule if EPA were to require expanded reporting beyond manufacturers and importers of *chemical substances* to add manufacturers and importers of articles and components of articles.

IMPACTS OF THE RULE IF EXPANDED BEYOND CHEMICAL SUBSTANCES TO INCLUDE ARTICLES

In estimating the burden associated with the Proposed Rule, the Agency considered the costs incurred by chemical manufacturers, but EPA did not account for the burdens that would be imposed on manufacturers and importers of articles if the rule required reporting beyond

chemical substances.³ If reporting were to extend beyond chemical substances to include articles, the number of companies required to report for articles and components of articles will almost certainly dwarf the number of chemical manufacturers producing PFAS chemical substances.⁴ To provide EPA with detailed, reliable information regarding the potential impact of a Section 8(a)(7) rule that extends beyond chemical substances and adds manufacturers of articles, the NAM undertook a comprehensive survey of its members examining, among other things, the types of articles in which PFAS chemicals may be used and the steps needed to attempt to obtain the information sought under the Proposed Rule. To protect confidential business information and other competitively sensitive information, the results of this survey were aggregated and anonymized. Key insights are summarized below.

A Wide Range of Articles Could Potentially Contain Some PFAS Compounds

Various PFAS compounds are used in a multitude of applications that span a broad swath of industry. A treatise on just one sub-group of PFAS compounds, fluoropolymers, indicates that these specialty compounds are commonly used in making widely-used articles and components such as gaskets, O-rings, valve stem seals, fuel hoses, coated wire, data cables, printed circuit boards, valve and pump parts, and coatings for pipes, fittings and other types of equipment.⁵

Responses to the NAM survey were consistent with this published information, and confirmed that articles made with components that may contain a PFAS compound include, in no particular order, heavy equipment and machinery used in construction, forestry, mining and agriculture; automotive components; aerospace and defense equipment; consumer electronics; heating, ventilation and air conditioning (HVAC) systems and refrigeration equipment; architectural materials, and electrical appliances, including home appliances. Component parts that are believed to contain PFAS compounds include coated wire, data and power cables, printed circuit boards; hoses; gaskets; seals; hydraulic components; polyurethane foams (as a blowing agent); membranes (such as water filtration membranes); coatings on bearings; and composite materials. In short, the universe of articles and component parts that may contain a PFAS compound is enormous.

Complex Supply Chains Make Information Gathering Difficult and Time Intensive

Modern supply chains are complex, extensive and multi-national in scope. They can include small, medium and large suppliers all providing component parts that are used in a single product, and they often entail multiple tiers of suppliers -- from material suppliers, to component manufacturers, to suppliers of complex sub-assemblies that are ultimately assembled into the final manufactured article. Navigating these supply chains to identify which components of a manufactured article could contain a PFAS compound, the specific identities of any PFAS compounds used, and the quantities of any PFAS compounds that might be present in a component is a highly complicated and time-consuming process. Under the Proposed Rule,

³ See 86 Fed. Reg. at 33,939 (June 28, 2021). See also 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.

⁴ EPA estimates the number of manufacturers and importers of PFAS substances to total approximately 250. See 86 Fed. Reg. at 33,939.

⁵ Ebnasajjad, Sina. (2021). Introduction to Thermoplastic Fluoropolymers at p. 57. 10.1016/B978-0-12-819123-1.00005-7.

the difficulty of this task would be multiplied by the need to collect this information retrospectively, since 2011, for a structurally-defined universe of chemistry that likely exceeds more than 1,000 individual compounds across millions of components.

The complexity of this task increases exponentially for complex articles and for manufacturers with diverse and extensive product lines. For example, some NAM members would have to assess and query their supply chains for information on components for more than 1,000 different products. The overwhelming majority of manufacturers expected that their suppliers would be unable or unwilling to supply some or all of the required information, and those who might fare better indicated that collecting the information the Proposed Rule specifies would take up to 18 months to complete. Many companies indicated that these information-gathering activities would cost in the hundreds of thousands of dollars to complete and about ten percent of manufacturing companies surveyed estimated that the costs of collecting the required information would exceed \$1 million. Navigating supply chains to identify and quantify the presence of specific PFAS compounds in component parts of articles is a complicated and largely uncharted task – especially for manufacturers of complex articles and manufacturers with extensive product offerings. And the information resulting from these extensive efforts is likely to be incomplete and impossible to verify.

RECOMMENDED CHANGES TO THE PROPOSED RULE

In light of the challenges outlined above and in order to ensure that the Section 8(a)(7) rule focuses reporting obligations on the respondents most likely to have actionable information, EPA should limit reporting to the manufacture and import of *chemical substances* and exclude *articles* from the scope of the Section 8(a)(7) rule.

This would be consistent with EPA's longstanding practice under TSCA.⁶ Notably, when EPA established a blanket exemption from the premanufacture notification (PMN) and review requirements for substances imported as part of articles, the Agency explained this decision by acknowledging that it would be "enormously difficult" for importers of articles to ascertain the identity of each substance present in an imported article.⁷ The same considerations apply with respect to the Section 8(a)(7) rule: it would be enormously difficult for importers of articles to ascertain whether those articles contain one of more than a thousand specific compounds covered by EPA's structural definition. Moreover, EPA has not demonstrated how requiring reporting for articles under Section 8(a)(7) is "necessary" or even additive to the information EPA will receive from manufacturers and importers of PFAS *chemical substances*.⁸ Consequently, the NAM encourages EPA to focus on chemical manufacturing and importation reporting requirements and exclude articles from the scope of the Section 8(a)(7) rule.

To the extent EPA sees value in attempting to include reporting requirements for some articles, where information is available, the following modifications to the Proposed Rule are needed to avoid "unnecessary or duplicative" reporting and focus on "those persons likely to

⁶ See, e.g., 40 CFR § 710.27 (import of a substance as part of an article is excluded from reporting for the Inventory); 40 CFR § 720.22(b)(1) (import of a new substance as part of an article is excluded from premanufacture notification (PMN) reporting); 40 CFR § 711.10(b) (import of a substance as part of an article is excluded from reporting under the Chemical Data Reporting (CDR) rule).

⁷ See 48 Fed. Reg. 21,699, 21,726 (May 13, 1983) (final PMN rule).

⁸ 15 U.S.C. § 2607(a)(5) (EPA shall not require reporting which is "unnecessary or duplicative").

have information relevant to effective implementation” of the statute.

Adopt a Phased Approach to Reporting

As discussed above, navigating supply chains to identify and quantify the potential presence of PFAS compounds in articles and their component parts over a 10-plus year period is an enormously complicated and difficult task. Indeed, the NAM survey results indicate that importers of articles and components will need 18 months, or more, to thoroughly interrogate their supply chains to obtain what information might be available. Therefore, if EPA determines that it is necessary and appropriate to require reporting on certain articles under the Section 8(a)(7) rule, the effective date of any such reporting obligations should be delayed by at least 18 months, to allow importers of articles and article components time to query their supply chains. Furthermore, EPA should consider bifurcating its rulemaking effort to require reporting by chemical manufacturers and importers in “Phase 1” before finalizing regulations to require reporting for any articles in “Phase 2”. The information received from Phase 1 reporting could allow EPA to more carefully tailor the reporting requirements for articles, to focus on those articles or categories of articles that utilize the greatest volume of PFAS compounds or that present the greatest potential for exposure.

Focus the “Look Back” Period on Chemical Substances, not Articles

When available, current information on the use and presence of PFAS compounds in articles could be of value to EPA in assessing potential risks and risk mitigation measures that could be implemented in the future. However, it is much less clear how incomplete and/or unreliable information on the historical presence of PFAS compounds in imported articles and components would be of practical utility to the Agency. Articles that were imported in 2011 have long ago dispersed into commerce and, in many instances, will have reached the end of their useful lives and been recycled or disposed of. Consequently, historical data on imported articles, to the extent it is available, provides very little actionable information to EPA with respect to current exposures and risks. In that sense, attempting to reconstruct historical information on imported articles differs substantially from obtaining historical information on facilities that manufactured PFAS *chemical substances* or imported them into the US.

Manufacturers and importers of chemical products are likely to have much more reliable records regarding the chemical composition of those products as compared to manufacturers and importers of articles. Thus, historical information provided by manufacturers and importers of PFAS *chemical substances* may allow EPA to pinpoint with a high degree of confidence locations where large volumes of PFAS chemicals were manufactured or processed in the past. These locations could potentially be significant sources of exposure (for example, as a result of historical site contamination). Thus, information on past manufacture and import of PFAS *chemical substances* could provide valuable insights to drive EPA’s current risk assessment and mitigation efforts. It is difficult to envision how information on imported articles that have long ago been widely dispersed in commerce and likely disposed of or recycled can provide similar value for EPA. Moreover, due to changes in product designs and offerings over time, information on components used in articles from 2011 may have little if any relevance to articles currently in commerce.

Thus, to ensure that the information EPA receives on articles has practical utility for risk assessment and mitigation purposes, EPA should require reporting on manufacturing and processing of PFAS *chemical substances* for the ten-year “look back,” but **not** expand that “look

back” reporting to articles. Particularly if combined with the “phase-in” suggested above, this approach should allow manufacturers and importers of articles to provide advance notice to their supply chains of the types of information that will need to be collected – which should serve to enhance the reliability and utility of the information article manufacturers and importers report to EPA.

Establish Exemptions for Impurities and *De Minimis* Presence

Consistent with other TSCA reporting rules, EPA should exempt from reporting under Section 8(a)(7) any PFAS substance that is present in an article only as an impurity.⁹ As a practical matter, it is highly unlikely that the importer of an article will possess, or be able to obtain, information on the existence or identities of substances that may be present in the article only unintentionally, as an impurity. Similarly, the potential for exposure to an impurity contained in a component of an article is likely to be negligible. Thus, requiring reporting on such substances is likely to have little, if any, utility for EPA. Pursuant to Section 8(a)(5), EPA should not require such unreliable and unnecessary reporting.

Similarly, EPA should establish a *de minimis* level, such that reporting will not be required for any PFAS substance that is present in an article at a level of 0.1% (by weight) or less. This level is consistent with the threshold established in EPA’s export notification regulations under TSCA Section 12 for substances subject to regulation under other sections of TSCA that are known or suspected carcinogens. Although being subject the Section 8(a)(7) rule will **not** trigger export notification requirements, the export notification regulations provide a useful analogous benchmark for requiring reporting under Section 8(a)(7).

Clarify Required Reporting for Health and Safety Information

The Proposed Rule would require respondents to provide EPA with all existing “environmental and health effects information” on a reportable PFAS substance. This term is defined in the Proposed Rule to include “any information that bears on the effects of a chemical substance on health or the environment.”¹⁰ The Proposed Rule also indicates that this term includes *already-published* studies.

Requiring the submission of *already-published* data is inherently duplicative and imposes an unnecessary reporting burden on respondents, since published data are already available to EPA. TSCA Section 8(a)(5) directs the Agency to avoid requiring duplicative and unnecessary reporting, and EPA should modify the Proposed Rule to only require reporting of *unpublished* health and safety data.

Similarly, the proposed definition of “environmental and health effects information” seems impossibly broad, since almost any type of information on a substance (including information such as sales data) could potentially “bear on” the effect of that substance on health or the environment. Additionally, in the preamble to the Proposed Rule EPA explains that the requirement to provide all “environmental and health effects information,” is intended to

⁹ See, e.g., 40 CFR § 720.30(h)(1) (manufacture [and import] of a new chemical substance as an impurity is excluded from PMN reporting); 40 CFR § 711.10(c) (manufacture [and import] of a substance as an impurity is excluded from CDR reporting).

¹⁰ 86 Fed. Reg. at 33,936.

encompass “adverse effects reports” as well as studies. If this provision is included in the final rule, EPA should clarify that adverse effects reports for articles must be submitted under the rule only if those reports specifically identify a PFAS compound in the article as the source of the alleged adverse effect. Therefore, to avoid duplicative and confusing reporting, EPA should more carefully tailor the types of health and environmental data that should be submitted under the Section 8(a)(7) rule. Specifically, the NAM recommends that EPA require reporting on “health and safety studies” as that term has been defined and interpreted under Section 8(d).¹¹

Clarify Methods of Demonstrating Required Diligence

Under the Proposed Rule, manufacturers and importers must provide required items of information to the extent the information is “known to or reasonably ascertainable” by them.¹² EPA explains that some degree of supply chain outreach may be necessary to establish whether information is “reasonably ascertainable” by a manufacturer or importer. According to the Agency:

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.¹³

As discussed previously, modern supply chains are complex, extensive, multi-tiered and multi-national in scope. Interrogating these supply chains to identify whether components of a manufactured article may contain any PFAS compounds and the specific identities and quantities of any PFAS compounds present is highly complicated, enormously burdensome and unlikely to yield information that is reliable or actionable. To establish certainty and consistency in the information that is reported under the Section 8(a)(7) rule, EPA should clarify that inquiries made to immediate suppliers of articles and component parts are ordinarily sufficient to establish whether an item of required information regarding the article or component part is “known to or reasonably ascertainable” by the manufacturer or importer, and interrogations of multiple tiers of suppliers are not necessary.¹⁴ Similarly, EPA should give clear direction for circumstances where the records do not exist or components may have been purchased from distributors or other parties without knowledge of specific chemical compositions of the articles.

¹¹ See 40 CFR §716.3.

¹² 86 Fed. Reg. at 33,928.

¹³ *Id.*

¹⁴ 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.

Conclusion

The NAM supports EPA's efforts to identify, assess, and respond to the potential risks that may be associated with certain individual PFAS compounds in the US and believes that TSCA Section 8(a)(7) provides EPA with a valuable tool to collect the information needed to pursue those objectives. To ensure that the Section 8(a)(7) rule focuses reporting obligations and on respondents most likely to have actionable information, the Proposed Rule should:

- Require reporting by manufacturers and importers of chemical substances and exclude *articles* from the scope of the rule.
- To the extent EPA desires to extend the reporting requirement to some articles for which data are available, the reporting requirements for articles should be adjusted by:
 - Phasing in the requirements, to allow importers and manufacturers of component parts or articles sufficient direction and time to obtain reliable and responsive information from their supply chains;
 - Requiring reporting on chemical manufacturing and processing for the ten-year “look back,” but not expanding that requirement to articles;
 - Establishing exemptions for PFAS compounds potentially present in articles only as an unintentional impurity or only at *de minimis* levels;
 - Clarifying what types of adverse effects information should be submitted for articles and clarifying that only unpublished health and safety studies should be added to the data-in call; and
 - Providing guidance on specific steps that importers and manufacturers of articles can take to demonstrate what information is not “known to or reasonably ascertainable” by them.

The NAM appreciates this opportunity to provide comments on the critically important TSCA Section 8(a)(7) rule and welcomes the opportunity to work collaboratively with EPA and other stakeholders to ensure that the rule can be successfully implemented in a manner that is practicable and protective of human health and the environment.

Sincerely,



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