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Michal Freedhoff, PhD
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, NW, (7410M)
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Attention: EPA–HQ–OPPT–2020–0549; FRL–7902–04-OCSPP

Re: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment

Dear Assistant Administrator Freedhoff:

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits these comments on the Environmental Protection Agency's ("EPA" or "the Agency") *Federal Register* notice titled "TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment" ("the proposed rule" or "proposal").[1] AFPM is the leading trade association representing the makers of the fuels that keep us moving, the petrochemicals that are the essential building blocks for modern life, and the midstream companies that get our feedstocks and products where they need to go. AFPM members are committed to sustainably and efficiently manufacturing the fuels and petrochemicals that growing global populations and economies need to thrive.

AFPM supports EPA's decision to take a step back and review the potential impact of its original proposal to collect information on perfluoroalkyl and polyfluoroalkyl substances ("PFAS") under the Toxic Substances Control Act ("TSCA") Sec. 8(a)(7), especially on small businesses that are not familiar with or have never been subject to TSCA. AFPM also commends the Agency for its recognition that burdens associated with determining whether a business is affected by a regulatory proposal can be substantial.

AFPM also applauds EPA's efforts to form a Small Business Advocacy Review ("SBAR") Panel, develop an Initial Regulatory Flexibility Analysis ("IRFA"), and update its Economic Analysis. AFPM agrees that the cost burden to industry, much of which will be borne by small businesses, is significantly more than previously thought. AFPM strongly supports a *de minimis* exemption, as well as exemptions for byproducts, intermediates, impurities, and R&D substances. AFPM firmly believes that these exemptions will greatly reduce the cost burden to industry and especially to small- and medium-sized businesses, while still resulting in sufficient information to characterize potential exposures.

[1] *See* 87 *Fed. Reg.* 72439, "TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment" , Docket No. EPA–HQ–OPPT–2020–0549; FRL–7902–04-OCSPP, published November 25, 2022, at https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0122.

EPA needs to recognize that TSCA risk evaluations do not need to account for every molecule of a particular substance.

In its original proposal, EPA sought to require all businesses to report every conceivable situation that could have resulted in the production or import of just about any fluorinated alkyl substance, including minute amounts of unintentional byproducts and inert polymers. The Agency states that the information is necessary to conduct risk screening and potential risk evaluations for high priority substances. In essence, the original proposal abandoned the tiered, targeted, and risk-based approach to information collection that has been used successfully by the Agency for decades.

The statutory language in TSCA carefully lays out a framework for a regulatory approach to risk evaluation and management, and provides EPA with the tools and authority to regulate chemicals in commerce. That is the whole point of TSCA: to effectively regulate chemicals in commerce. There is nothing in the statute that speaks of perfect information, like that suggested in EPA's IRFA, where the Agency claims that "rational decision making cannot occur" without "perfect information."[2] On the contrary, EPA has been successfully evaluating the risk of chemical substances using a tiered, targeted, and risk-based approach for decades under a variety of different regulatory and voluntary programs.

The TSCA statute talks about tiered and targeted approaches, using toxicity information to inform the level of detail for exposure analysis and vice versa. The statute specifically mentions the use of sentinel exposures, which means that Congress never intended for EPA to account for every PFAS molecule.[3] AFPM strongly urges EPA to abandon its originally proposed approach and resume its traditional tiered, targeted, and risk-based approach to information collection that the Agency has used for decades.

EPA should establish a definitive list of substances that will be subject to reporting.

Originally, EPA proposed a vague, structural approach to defining whether a molecule is a PFAS. It is unrealistic for EPA to expect American companies that do not intentionally manufacture PFAS (*e.g.*, importers of articles containing trace amounts of PFAS or manufacturers of products with impurities) to determine whether their article or substance should be reported based on such a loose and imprecise definition. This is especially true for small businesses and other companies that have not had much experience with TSCA regulations. As a precaution, companies will report and avoid potential noncompliance actions even in situations where the substance may not fit EPA's definition of a PFAS molecule. EPA will still have to determine whether the reported information is pertinent to PFAS.

In its revised economic impact analysis, EPA states that one of the most significant costs associated with the proposed rule is determining whether a company is subject to it. EPA has already determined a list of substances that fits its criteria for PFAS and is comprised of chemicals actually sold in commercial amounts. That list should be the basis of the regulation because EPA has not demonstrated a need for information on low-volume substances. Using its existing list of substances known to be in commerce and implementing exemptions like *de minimis* amounts, R&D substances, and other traditional exemptions under Section 8(a), would simplify the determination of whether a company is subject to the rule and reduce the overall cost burden.

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[2] *See Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*, Market Failure section on Page 22, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, November 2022.

[3] *See* TSCA Sec. 6(b)(F)(ii)

EPA should provide the same exemptions under Section 8(a)(7) as it does for other reporting under Section 8(a).

TSCA Section 8(a) gives EPA broad rulemaking authority to require manufacturers (including importers) and processors of chemical substances to maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates. Specifically, Section 8(a)(7) authorizes EPA to collect manufacturing and use information on PFAS. In the original proposal, EPA departs from its well-established history of exemptions for byproducts, non-isolated intermediates, R&D substances, and impurities generally provided under 40 CFR §§ 711.10 and 720.30. There is nothing in the NDAA that suggests EPA should abandon those historical exemptions.

The Agency expresses its belief that Congress intended to create a whole, new "stand-alone" section of TSCA through the National Defense Authorization Act ("NDAA") for Fiscal Year 2020 that excludes the exemptions traditionally applied in this context.[4] EPA offers no explanation of why it is reasonable to depart from these longstanding principles and fails to cite any legislative history or other justification for this change in position. If Congress intended to bypass the existing tools for implementing Section 8(a) of TSCA, it would have created a whole new subparagraph much in the same way it did for asbestos, lead, and formaldehyde. Instead, Congress amended Section 8(a) with the intent that the Agency would collect information using TSCA reporting authority that was already well-established, including longstanding exemptions and interpretations under 40 CFR §§ 711.10 and 720.30. In fact, Section 8(a)(7) explicitly references Section 8(a)(2), indicating that Section 8(a)(7) is not, as the agency claims, a stand-alone section.

EPA should exclude articles from reporting under Section 8(a)(7).

EPA proposes to require articles that may contain PFAS to be reported. EPA states that the term "article" is not explicitly defined in the statute.[5] EPA's rationale is muddled in that it assumes because the statute does not "define articles as a category of substances exclusive of chemical substances," then "chemical substances" must necessarily include articles. Congress added PFAS to the existing 8(a) reporting regime as part of the NDAA in 2020. There is no mention in the NDAA that EPA should treat articles containing PFAS differently from articles that contain other chemical substances. At no other time has EPA used this line of reasoning to include articles in record-keeping and reporting under Section 8(a). In fact, EPA has avoided the inclusion of articles because it would inundate the Agency with information that is unlikely to enhance its understanding of a substance's risk. Had Congress wanted EPA to depart from its standard reporting exclusions, it would have explicitly said so like it did for lead, asbestos, and formaldehyde.

If EPA includes articles, the universe of industries and materials subject to reporting will become untenable. Everything from non-stick kitchen items, water-repellant outdoor clothing, shoes and camping equipment, carpeting, curling irons, solar panels, tennis racket strings, dental fillings, ski bindings, windshield wipers, plumbing tape, water treatment membranes, dialysis membranes, insulated computer cables, OLED televisions and computer monitors, surgical implants, and a large number of other products will have to be reported. Subjecting all of these everyday products to reporting will not provide any added protection of human health and the environment and will mislead the public regarding the safety of those products. Since supply chains for many products can span several different countries, compliance with these new reporting requirements will be extremely difficult, if possible at all.

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[4] *See* https://www.congress.gov/116/plaws/publ92/PLAW-116publ92.pdf.

[5] "Article" is defined in 40 CFR Subpart A - General Reporting and Recordkeeping Provisions for Section 8(a) Information-Gathering Rules under § 704.3.

To illustrate, a foreign supplier of tennis racket strings uses a perfluorinated polymer to enable the strings to maintain their overall grid pattern and not require constant adjustment by the tennis player. Those strings are imported by an American tennis racket manufacturer to enable the American company to sell the racket pre-strung. The foreign supplier of strings is not likely to divulge such competitive information to the American importer, confounding that company's ability to comply. EPA does not have the authority to require that information from a foreign manufacturer, which makes the idea of joint submissions moot under these circumstances.

The inclusion of articles by EPA would vastly expand current reporting and create an incredibly burdensome reporting requirement on American manufacturers, many of which would be small to medium in size, but would not provide any additional protection of human health or the environment. While EPA states that the "reasonable inquiry/reporting standard" is the same cited in other sections of TSCA, never has this standard been applied to so many industries and consumer goods at once, while simultaneously omitting any *de minimis* threshold that reasonably limits the scope of inquiry. A *de minimis* exemption avoids an unreasonable burden on American manufacturers and inundating EPA with voluminous information that does not further the statute's goal to appropriately characterize PFAS exposure or risk. EPA should exclude articles from reporting under Section 8(a)(7).

EPA should establish a *de minimis* exemption to reduce unnecessary reporting burdens and focus on information that has practical utility.

Unlike other TSCA reporting rules, such as Chemical Data Reporting ("CDR") rules and Preliminary Assessment and Information Reporting ("PAIR") rules, EPA did not specify a *de minimis* threshold for reporting under the proposed rule. Without such a threshold EPA will receive information on miniscule amounts of impurities and byproducts, which will not improve the Agency's understanding of overall risk from PFAS and make it difficult for the Agency to discern more meaningful information. Moreover, without a *de minimis* threshold the reporting burden on industry is greatly increased and companies are likely to over-report or report preliminary data out of an abundance of caution, than not report and face the possibility of a noncompliance action. TSCA fines for noncompliance can be up to $41,056 per day, so it would be in a company's best interest to take all measures and ensure that they are in compliance.[6] For example, if a restaurant ordered a replacement non-stick frying pan from an overseas internet distributor five years ago and does not report that information to EPA, under this proposed rule that restaurant would be out of compliance and subject to a fine for every day until the restaurant fulfills its reporting obligation.

EPA should establish a *de minimis* exemption consistent with other parts of 40 CFR and use the same 25,000 pound per year threshold as it does for submissions under the CDR rules.

Due diligence should be considered met in cases where the requested information is not readily available or forthcoming.

Most companies only have production and use information that covers the previous 5 years, which follows current practices under the TSCA CDR rules. For polymers, companies typically do not retain or report information under CDR because most polymers are exempt. It is unlikely that companies will have detailed production and use information that goes back to 2011. In the case of articles and formulated mixtures, it is unrealistic to expect suppliers to hand over proprietary business information on ingredients and materials. Safety Data Sheets do not list chemical constituents below 0.1% and inquiries to manufacturers are unlikely to produce information with practical utility. The NDAA only stipulates when EPA is required to issue rules; it does not specify the parameters for due diligence. AFPM strongly urges

[6] This is the current maximum penalty found in 40 CFR §19.4. See https://www.law.cornell.edu/cfr/text/40/19.4.

EPA to consider existing records and internal inquiries of current personnel and inquiries to suppliers as meeting a company's obligations of due diligence under Section 8(a)(7), including in cases where the information is not readily available or forthcoming.

Confidential Business Information ("CBI") from an original claimant should be protected from disclosure even if a chemical name or other confidential information has been submitted later without a CBI claim.

A legitimate CBI claim under TSCA should be treated as an agreement between the original submitter (claimant) and the Agency. Other actors reporting under TSCA Sec. 8(a) should not affect that agreement. For instance, where a customer discloses the generic name and accession number for a chemical supplied by another company, that customer is not going to know the specific identity, nor will it be able to assert or substantiate a claim for confidentiality of that specific chemical identity. Under this proposed rule, EPA will take away the confidentiality claim of the supplier and disclose the specific chemical identity. This is a breach of the original agreement for protection of CBI between the original claimant and the Agency. In cases where CBI is either inadvertently disclosed by another party or included in a future submission under Section 5 (Bona Fide Intent Notices and Premanufacture Notices) or Section 8 (chemical reporting) but not claimed as confidential, EPA must still honor the CBI claim with the original claimant.

EPA should notify original CBI claimants of all disclosures and allow sufficient time to respond to inquiries or threats of disclosure.

Sec. 14(g)(A) is clear that if the Agency discloses information under Sec. 14(d), it is required to notify claimants via certified mail or through another method that ensures that the notification is received and the date of receipt. Due to consistent technical problems and reliability issues, the Central Data Exchange does not meet the requirement for ensuring receipt. AFPM urges EPA to include provisions for notification of the CBI claimant prior to release of CBI in non-emergency situations and notification in a reasonable time frame after disclosure during an emergency. This will allow companies to monitor for further disclosures after EPA releases the information to a particular party.

Conclusion

As originally set forth, this proposed rule sets American companies up to fail. AFPM acknowledges that EPA must propose a rule to collect information on PFAS manufacturing. EPA has limited discretion on what types of information it needs to enhance its understanding of overall PFAS risks and how it should go about collecting that information, but that discretion does not extend to turning its back on longstanding exemptions necessary to make the program function efficiently. If EPA establishes a *de minimis* threshold, exempts byproducts and impurities, and excludes articles, the Agency will be able to focus its attention on the information and factors most likely to affect risk. If EPA tries to collect PFAS information in a manner outlined in the original proposed rule, it will be inundated with useless information and create a large burden and compliance quagmire for many American manufacturers.

Sincerely,

Senior Petrochemical Advisor
American Fuel & Petrochemical Manufacturers