July 28, 2021

Docket EPA-HQ-OPPT-2020-0549
Docket Center
US Environmental Protection Agency
WJC West Building
1301 Constitution Avenue, NW
Washington, DC 204660

Re: TSCA Section 8(a)(7) reporting and recordkeeping requirements for perfluoroalkyl and polyfluoroalkyl substances, Proposed Rule, 86 *Federal Register* 33926 (June 28, 2021)

To Whom It May Concern:

The American Chemistry Council (ACC) and its members are committed to enhancing the quantity and quality of data and information provided to the Environmental Protection Agency (EPA) on per- and polyfluoroalkyl substances (PFAS) in commerce. ACC supports EPA's commitment to strengthen chemical management in the US and to the collection of information to support the Agency's mission to protect the health and safety of the public and environment. Additionally, ACC appreciates that EPA has provided a structural definition of PFAS in its 8(a) reporting proposal. However, we are deeply concerned about the proposed PFAS reporting requirements and submit these preliminary comments on the information collection provisions of the proposal. The proposal represents an unprecedented request for information - both in terms of the amount and type of data requested and the number of years subject to reporting - and goes well beyond the language of the National Defense Authorization Act (NDAA) for Fiscal Year 2020[1] and the information described in Section 8(a)(2) of the Toxic Substances Control Act (TSCA).

After our initial review of the proposed reporting requirements and the supporting economic analysis, ACC has identified the following significant concerns -

- Identification of an expansive list of more than 1,300 substances subject to reporting,
- Inclusion of reporting for manufactured and imported articles containing PFAS,

[1] Public Law 116-92, Section 7351.

- Requirement for the reporting of historical data that has not been subject to prior reporting or is likely unavailable, and
- An unrealistic timeline for reporting.

Although we have identified additional concerns in the proposal, we have highlighted these issues because of their potential impact on the burden associated with the proposed reporting requirement. As outlined below, EPA has significantly underestimated the reporting burden, and associated cost, of the proposal by making inappropriate extrapolations to the reporting of Chemical Data Reporting (CDR) data for manufacturers, by failing to provide estimates for the burden for reporting of articles containing identified PFAS, and by failing to take into account all expected collateral burdens that this proposed rule would trigger.

Identification of Substances Subject to Reporting

The proposal suggests that EPA has identified 1,364 substances that may be subject to reporting under the proposal – including 669 substances on the active TSCA Chemical Substance Inventory and 516 substances that have been subject to applications for a low volume exemption (LVE) under TSCA Section 5. [2] The Agency notes, however, that the lists provided in the Section 705.5 of the proposed regulations are "not a comprehensive list of all substances that meet the rule's definition"[3] and that manufacturers will be required to determine whether additional substances are subject to reporting.

Such uncertainty about which substances are included significantly increases the burden of reporting by requiring entities to determine whether substances meet the definition included in the proposal. EPA already possesses the information to provide a complete list of manufactured PFAS, per the requirements of the NDAA and existing definitions in the TSCA regulations. It is essential that EPA include a complete list of substances, rather than identify only a partial list and leave it to the reporting entities to ensure that they have identified every substance subject to reporting. In addition, with the potential inclusion of articles containing PFAS, durable goods manufacturers and importers (many of whom are small to medium enterprises) do not have the resources to assess and characterize the contents of fabricated parts or components against an uncertain list of chemical substances.

Beyond the uncertainty about the substances subject to reporting, EPA's analysis underestimates the reporting burden associated with the proposal. According to the draft Economic Analysis, the Agency assumes only 3.9 PFAS per site (5.5 PFAS per firm), based on an

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[2] The *Federal Register* notice identifies 1,154 substances, including 414 substances with a CAS Registry Number, 224 substances with an Accession Number, and 516 with a low-volume exemption (LVE) case number.

[3] 86 *Federal Register* 33930.

analysis of 2016 CDR data.[4] However, the requirements for reporting for CDR are very different from the requirements outlined in the proposed rule. CDR reporting is limited to companies manufacturing 25,000 pounds or more of a substance per site for commercial purposes,[5] while EPA is proposing to require reporting for any detectable amount of a substance defined as a PFAS regardless of whether it is a commercial product. Some of the substances subject to reporting under this proposed rule are not reportable under CDR. The proposed inclusion of byproducts, non-isolated intermediates, TSCA R&D exempt substances, and impurities, which are exempt from TSCA notification under 40 CFR 720.30, will drastically increase the number of substances subject to reporting under the proposal – dramatically increasing the reporting burden.

Rather than require reporting for all identified PFAS produced at a manufacturing facility, ACC urges EPA to focus on those PFAS that are manufactured for commerce at a site in quantities above 2,500 pounds (the lower reporting threshold for CDR reporting) within the principle reporting year.[6] This will significantly reduce the reporting burden, while still providing EPA with data on those substances with the greatest potential to impact public health. Focusing on PFAS produced in larger quantities also will reduce the need for companies to dedicate significant engineering resources to estimate historic production and releases.

Exemption for Substances listed in 40 CFR 720.30

As noted above, the proposal for reporting of PFAS manufacturing should include a corresponding exemption for substances listed in 40 CFR 720.30 which are typically exempt from TSCA The failure to include this exemption in the proposed rule or to clearly demarcate what is in scope and what is excluded will create a multitude of problems for industry and for the Agency. Lack of a threshold, *de minimis* concentration, or other exclusion substantially increases the burden – and in an as yet unqualified manner - by requiring manufacturers to consider a wider universe of substances and to generate information related to byproducts and impurities present in minute quantities that have not been subject to a prior reporting requirement, in some cases has not been subject to prior TSCA Inventory listing, or may not be known to the manufacturer. As suggested above, reporting for PFAS should be limited to those intentionally manufactured for commerce in quantities of 2,500 pounds or more at a single

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4 USEPA. Economic analysis for the proposed TSCA Section 8(a) reporting and recordkeeping requirements for perfluoroalkyl and polyfluoroalkyl substances. Economic and Policy Analysis Branch. (May 2021 Draft)

5 The reporting threshold is 2,500 pounds for any person who manufactures a chemical substance that is the subject to rules proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4) or 6, orders issued under TSCA sections 4, 5(e), or 5(f), or relief that has been granted under a civil action under TSCA sections 5 or 7.

6 Additionally, EPA should make very clear that only chemical processes are in scope for this rule and that non-chemical processes, such as refrigeration and fire suppressant systems, present on a chemical plant site are not in scope.

facility annually, consistent with the threshold for CDR reporting for substances that are the subject of a TSCA action.[7]

Inclusion of Reporting of Articles containing PFAS

Despite the specific reference in Section 7351 of NDAA to a person "who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance," the Agency has indicated in the preamble of the proposal that "articles containing PFAS . . . are included in the scope of reportable chemical substances."[8] At the same time, the preamble notes that "EPA acknowledges that some article manufacturers, including article importers, may not have such information." For the following reasons, ACC urges EPA to clarify that manufacturers (and importers) of articles containing PFAS are not subject to the reporting requirements –

- The statute authorizes only reporting by manufacturers of the chemical substance EPA has defined as PFAS. It does not authorize a reporting requirement on manufacturers of anything else, including articles containing PFAS.

- The current definition of "chemical substance" cannot and has never been interpreted to include articles that contain the regulated chemical substance. The preamble incorrectly reasons that since TSCA does not expressly exclude an "article" from being a "chemical substance," it can be one.[9] This reasoning fails to recognize that the term "article" has been defined in the regulations implementing Section (8) of the statute,[10] such that there is a clear distinction between "article" and "chemical substance."

- The example provided in the draft reporting proposal – an article with a surface coating – has been exempt from TSCA Inventory requirements under the Article

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7 At a minimum, ACC recommends aligning the proposed rule with the Preliminary Assessment Information Rule (40 CFR Part 712) which exempts from reporting - persons who manufactured or imported the chemical substance solely for R&D, or only as a byproduct exempt from PMN reporting, a non-isolated intermediate, or an impurity.

8 86 *Federal Register* 33930

9 Ibid.

10 *Article* means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design. (40 CFR Section 704.3).

Exemption as well as the CDR. It is therefore unreasonable for the EPA to now require reporting under this new rule.

If EPA intends to require reporting by manufacturers and importers of articles that contain PFAS, the number of entities that would be subject to this reporting rule will increase by thousands. Reference to Tables 3, 4 and 5 of proposed Section 705.15 indicate how many industries use PFAS in articles they manufacture, and the many functions this broad and diverse category of chemicals perform. Even if the requirement were limited to articles with a surface coating containing PFAS, the number of firms required to conduct reasonable inquiry, and potentially subject to reporting, would be dramatically increased. Many of these firms do not have experience with the CDR reporting system and would incur higher costs in reporting the information to EPA than those projected in the draft Economic Analysis.

With respect to imported articles, obtaining information on articles potentially containing PFAS will likely be even more difficult than from article manufacturers because the importers will be even less familiar with the attributes and composition of the articles they import. In fact, EPA acknowledges that an importer of an article "may not have knowledge" of the presence of a covered substance even after they have conducted their due diligence. EPA appears so unsure of the implications of its proposal to require reporting of identified PFAS contained in articles that it has not attempted to estimate the potential cost burden of such reporting or even the number of firms affected by the proposal.[11] Given the high level of uncertainty surrounding articles, it is unclear how including articles with their increased level of unknown information will "improve the Agency's knowledge of various products which may contain PFAS, their categories of use, production volumes, and exposure data."[12]

Reporting of Data not Historically Collected or Likely Unavailable

While many of the data elements to be reported under the current proposal are consistent with those under CDR, several proposed data elements are not required for CDR reporting and have not been collected historically. The economic burden associated with this significantly expanded reporting scope has not been quantified. Even for data reported to CDR, facilities are only required to retain the records for 5 years from the close of the submission window. [13] Consequently, manufacturers subject to the proposed reporting requirement are unlikely to have much of the required data (if it was subject to CDR) for years prior to 2016. Creating, or recreating, these data elements will require significant effort that has not yet been estimated and likely will result in inaccurate engineering estimates of historical information. In

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[11] While the FR notice cites data from a November 2020 economic analysis (Reference 14), the May 2021 draft analysis indicates that the costs associated with reporting of imported articles are not included.

[12] 86 *Federal Register* 33930.

[13] https://www.epa.gov/chemical-data-reporting/other-issues#record

addition, some of these identified PFAS are polymers exempted from CDR reporting so the volumes have not been historically tracked. For polymers which have been exempt from CDR reporting, this would represent an extreme burden on industry to go back and calculate these volumes for the past 12 years.

To reduce the burden, and improve data accuracy, ACC urges EPA to require data elements related to uses, exposures, and environmental releases for the principal reporting year (2020 or 2021) only. Only reporting of basic manufacturing information, such as production volumes and disposal practices, should be required as far back as 2011, provided that the information is available without the need for recalculation or estimation.

Reporting on PFAS Use

Much of the information EPA would require to be reported under proposed Section 705.15(c) relates to how PFAS is used in the making of various products and how those products in turn are used by consumers and industrial purchasers. EPA must recognize that manufacturers of PFAS will know to whom it sells its product, but generally will not know how their product is ultimately used. Often the manufacturers will sell their products to distributors and wholesalers who in turn sell it to other companies that use the PFAS in downstream manufacturing operation. These distributors, wholesalers and downstream manufacturers may have some information on how the PFAS are used, what byproducts result, disposal methods, product recipes, and other information - but that is not information that they are likely to share with the upstream PFAS manufacturers since it is likely proprietary and commercially sensitive. Thus, EPA must have realistic expectations of the amount of useful information it will obtain from its Section 705.15(c) reporting requirements in that PFAS manufacturers will not know and will not be able to reasonably ascertain the requested information. EPA should consider deleting or greatly reducing the information it proposes to request regarding downstream usage of PFAS and its related by-products and disposal because, as proposed, EPA will not receive meaningful information.

Unrealistic Timeline

EPA proposes that persons who have manufactured a PFAS at any time since January 1, 2011, would report to EPA during a six-month submission period, which would begin six months following the effective date of the final rule. Such an extensive reporting period is unprecedented for the detailed and, in some ways, vague scope of information proposed for collection and reporting. Typical TSCA 8(a) reports require only a 1-year look-back. Given the broad scope of chemistries covered by the definition of PFAS, gathering all the available requested data for 10 years within the proposed 6-month period is unfeasible and would represent an overwhelming burden to many companies subject to reporting. Unlike many other regulatory burdens, this one is not easily susceptible to outsourcing given the intimate knowledge required of the underlying chemistries, processes, products, and markets. ACC

believes that a 1-year timeframe for data gathering followed by a 6-month submission period (total of 1.5 years).

Please do not hesitate to contact me at srisotto@amercianchemistry.com or at (202) 249-6727 if you have any questions on the information provided above.

Sincerely,

Steve Risotto

Stephen P. Risotto
Senior Director