December 29, 2025

EPA-HQ-OPPT-2020-0549
Office of Pollution Prevention and Toxics
Chemical Information, Prioritization, and
Toxics Release Inventory Division (7460M)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460
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Re: PFAS Data Reporting and Recordkeeping under the Toxic Substances Control Act (TSCA); Revision to Regulation, 90 Fed. Reg. 509023 (Nov. 13, 2025). 2025-19882.pdf

Dear Ms. Nelson:

Introduction – The Flexible Packaging Association (FPA) is seeking additional clarification on the TSCA PFAS Reporting and Recordkeeping Rule, with regard to its applicability to processors generally and to processors that import materials which they do not manufacture themselves but that may contain PFAS that are mixed in substrates and laminates and/or coatings and/inks that are applied in manufacturing flexible packaging. The proposed amendments also include an extension of the reporting time for affected reporters and revisions to the regulation to provide for a "0.1% de minimis exemption" for potentially affected reporters. FPA generally supports both of these proposed amendments to 40 CFR Section 705, but recommends that the "de minimis: be defined in a less restrictive manner, as discussed below.

Background– FPA represents flexible packaging manufacturers and suppliers to the industry in the United States. Flexible packaging is produced from paper, plastic, film, aluminum foil, or any combination of these materials, and includes bags, pouches, labels, liners, wraps, rollstock, and other flexible products. Food packaging represents 44%, or $19 billion, of flexible packaging's portfolio in the U.S. If you add beverages and pet food, this rises to 52% or $22.4 billion. Flexible packaging represents $42.9 billion in annual sales; is the second largest, and fastest growing segment of the domestic packaging industry; and employs approximately 85,000 workers in the United States. FPA and its

members are dedicated to the protection and preservation of food products and the reduction of food insecurity, foodborne illnesses, and food waste, as well as the protection of their employees.

FPA DISCUSSION AND REQUESTS FOR CLARIFICATION

Background for the TSCA PFAS Reporting Rule – Pursuant to TSCA section 8(a)(7) PFAS reporting rule, EPA issued a TSCA PFAS electronic reporting rule at 88 FR 70,516 (Oct. 11, 2023), 2023-22094.pdf (eff. Nov. 11, 2023), the effective date of which has been extended and would be extended further by this rulemaking. The regulation requires annual reporting of manufacturing and importation of "PFAS in articles" in any year since January 1, 2011, including PFAS uses, production volumes, disposal, exposures, and hazards. Affected compounds are identified at https://comptox.epa.gov/dashboard.[1] The preamble of the 2011 regulation contained a clarification regarding the exclusion of PFAS in mixtures that are processed,[2] but it lacked a *de minimis* reporting exemption (see discussion of comparison with TRI 100-pound exemption at page 70,526/col 1), and/or threshold, and it also eliminated the otherwise applicable reporting exemptions for articles, impurities, and by-products. The regulation was codified in 40 CFR part 705.

The proposed revisions will further extend the deadline for reporting until October 13, 2026, for manufacturers and importers of articles containing listed PFAS. Small businesses reporting data solely on importing PFAS contained in articles would have until April 13, 2027, to submit reports.

1. ***FPA Requests Confirmation that Processors that Use Materials that Contain PFAS (Which They Themselves Do Not Manufacture) are Excluded from the Reporting Requirement, and FPA Recommends that EPA Codify the Exclusion of Processors in this Rulemaking.***

TSCA section 8(a)(7) only refers to manufacturers and expanding the rule to processors would be pursuant to EPA's separate rulemaking authority at TSCA section

[1] Also see Public List of TSCA PFAS for 8(a)(7) Rule (xlsx).
[2] See *id.* at 70519/3 ("Although EPA received several public comments about extending the rule to cover processors (see Unit IV.), TSCA section 8(a)(7) only refers to manufacturers and expanding the rule to processors would be pursuant to EPA's separate rulemaking authority at TSCA section 8(a)(1), which the Agency is not pursuing at this time.")

8(a)(1), which the Agency stated in the 2023 rule that it was not pursuing at this time. **2025-19882.pdf)** See 88 FR 20,519/col.3.

> *"However, persons who have only processed, distributed in commerce, used, and/or disposed of PFAS are not required to report under this rule, unless they also have manufactured PFAS for a commercial purpose. Id.*

However, on page 50925/2 of the proposed revision rule, EPA seemingly includes processing in its description of the National Defense Authorization Act's adoption of Section 8(a)(7), which unless read very carefully, appears to contradict the original preamble. Moreover, the propensity to describe processing and mixing in the context "manufacturing" PFAS (or manufacturing articles that contain PFAS) throughout all of these related Section 8(a)(7) rulemakings, as for example in the definition of "manufacture for commercial purposes" in § 705.3, further confuses the applicability of the reporting rule. We find this to particularly to be the case with regard to manufactured articles that may contain PFAS from mixing "imported" substrates (i.e., webs and laminate materials to which inks and coatings are applied). The rulemakings for the regulation, for example, use the words mixing and processing, to denote steps in the manufacture of PFAS and PFAS-containing articles, which while perhaps unavoidable, could be greatly clarified if the regulation*, itself*, contained a statement regarding the exclusion of processors from the reporting requirement.

Simply because of its importance to the scope of the regulation, FPA urges EPA to use the occasion of finalizing the proposed revisions of the PFAS recordkeeping and reporting rule to codify the agency's statements that processors, distributors, users and or disposers of PFAS-containing materials are not required to report under this rule--unless they manufactured the PFAS containing material and/or article. FPA suggests that words to this effect should be added to 40 CFR § 705.1(a) of the regulation.

2. ***FPA Requests Further Clarification that Materials that Members "Import" Articles that Include Materials Containing PFAS, and Which are Then Mixed to Create Coatings and Inks or Laminates and Substrates, and Then Processed in the United States Also Are Excluded from the TSCA Section 8(a)(7) PFAS Reporting Rule.***

FPA's membership includes companies (some multi-national), that may routinely – or from time-to-time – *import* articles that contain PFAS from suppliers and their own plants outside the United States that they mix in substrates, laminates, coatings and/or inks to manufacture flexible packaging. An "article" is defined in 40 CFR § 705.3, as

> *"a manufactured item which (1) if formed to a specific shape or design during manufacture (2) has end use function(s) depending in whole or in part upon its shape or design during end use; and (3) 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 flued and particles are not considered articles regardless of shape or design."*

It is FPA's understanding that these facilities and/or companies would not be required to report to EPA PFAS in these articles pursuant to this regulation because "mixing" the article with coatings and inks is neither "manufacturing" itself, nor results in a change of chemical composition during its end use or only changes of composition which have no commercial purpose separate from that of the article or that results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles. In other words, if a material containing PFAS such as an ink or coating (i.e.an "article") is imported and processed but not manufactured, the processor need not report the PFAS in the article that it applies or mixes with other inks or coatings in making packaging. Otherwise, the definition of an "imported article" would seem to gobble up the exclusion for processors of materials containing PFAS. FPA seeks confirmation of its understanding of the exclusion of these PFAS-containing imported articles from the TSCA PFAS Reporting Rule.

Beyond the legal liability were someone not to report under the TSCA reporting rule when the regulation becomes effective, there are practical and economic issues were articles that are imported and processed not be excluded. First, it may not be known when an article is imported whether is contains PFAS unless it contains an SDS or REACH notification (and most do not). Second, the quantity of the reportable PFAS will be impossible to know without testing each shipment. That would require expensive testing and analysis, which few flexible packagers could avail themselves internally or from outside testing professionals. Further, it does not appear that Congress or EPA intended to include processors that import materials ((*i.e. articles")* containing PFAS, unknown to the purchaser. However, the November 2025 proposed revisions to add a "*de minimis* exclusion" to the rule could be interpreted or applied to expand the scope of the rule's coverage to articles that contain more than 0.1 percent PFAS, pursuant to the regulation when finalized.

3. ***While a "De Minimis" Exemption is Needed for Administration of the Rule, the Proposed 0.1 % is Confusing, and Needs to Be Increased so that it Can Be Measured with Accuracy.***

Background - In its proposed November 2025 rule, the agency stated that "(t)he purpose of this rule is to better understand the PFAS manufactured (including imported) in the United States for commercial purposes, to the extent the information is known to or reasonably ascertainable by regulated entities." https://www.federalregister.gov/d/2025-19882/p-49 EPA chose the 0.1 % *de minimis* value based on its analogous use in Safety Data Sheet (SDS) or the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) notification levels, as well as the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (29 CFR 1910.1200), which sets cut-offs for the minimum concentration of a chemical that triggers requirements for an SDS. The cut-off level of 0.1% is generally applied to chemicals classified as "health hazards" and a chemical is classified as a health hazard if it poses certain hazardous effects. https://www.federalregister.gov/d/2025-19882/p-53. The Agency also considered the use of the OSHA Hazard Communication's 1% de minimis exclusion, but declined to adopt it because "PFAS are typically present at low concentrations in mixtures, so a 1% *de minimis* threshold may remove otherwise reportable information from the scope of the rule. In part, this rulemaking is designed to identify and address available information gaps involving PFAS, so EPA believes that applying a lower, uniform 0.1% *de minimis* concentration threshold for all reportable PFAS helps address information gaps where information exists and still alleviates burden by providing a *de minimis* threshold." *Id*.

FPA supports a *de minimis* exclusion from the TSCA PFAS recordkeeping and reporting rule, but it does not support the use of the use of a 0.1% de minimis value because the information is unlikely to known or reasonably ascertainable because it is unlikely that import records are available over the past ten years for such materials -- particularly the PFAS species to be reported over the 10-to-11-year reporting period. In this regard, FPA also has three additional concerns:

First, if an imported substance and/or article does not include a REACH or comparable notice that it contains 0.1% or greater PFAS, may an importer conclude that it is not reportable? "In other words, what does reasonably ascertainable mean." Second, if only certain records are available, is the importer allowed to utilize available records to estimate PFAS, and is it obligated to state via the CDX reporting rule why other records may not be available? Third, if the record does not indicate the species of PFAS – and may well

include PFAS that are not reportable under this regulation[3] – may the reporting entity make assumptions about the proportion of reportable PFAS that the article contains? And is the CDX reporting tool able to accommodate this information, or is it sufficient that the reporter retains such records (and if so, for how many years)?

It appears from the rulemaking that there may still be a responsibility for the reporter of imports to measure whether greater than 0.1 % of an imported article contains reportable PFAS. As the Small Business Administration Committee members made abundantly clear in the SER Panel on this rulemaking, 0.1 % of the volume of a substance could be difficult to measure accurately in our laboratories where our members mix coatings and inks--whether the value applies to any single PFAS or to all the PFAS in the material (per the proposed testing protocol. FPA believes that finalizing a *de minimis value* as equal to, exceeding 1 percent or even 0.5%, would allow it to be administered more easily, and is fully consistent with the "(t)he purpose of this rule is to better understand the PFAS manufactured (including imported) in the United States for commercial purposes, to the extent the information is known to or reasonably ascertainable by regulated entities."

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In closing, FPA greatly appreciates the opportunity to share its concerns and questions with the agency. If you would like to discuss these issues or need other clarifications regarding our concerns, please feel free to contact me by phone or email.

Respectfully submitted,

Kyla Fisher,
Director of Regulatory Affairs kfisher@flexpack.com

[3] For instance, the most common PFAS used in inks and coatings is PTFE, and it does not carry the same OSHA/GHS hazards as other PFAS. The important PRFE is defined as reportable, but because there is no GHS hazard, some information may not be reasonably able to be obtained in our members' views.