

ALERT

EPA's Mandatory PFAS Reporting Rule Under TSCA Includes Thousands of Products, No Exemptions for Impurities or Imported Articles

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On September 28, 2023, the U.S. Environmental Protection Agency (EPA) issued a final rule to require reporting under Section 8(a)(7) of the Toxic Substances Control Act (TSCA) for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS). Generally, the reporting requirement applies if you have manufactured or imported PFAS for a commercial purpose in any year since January 1, 2011, alone or in any type of industrial or consumer product subject to EPA's authority.

Reports are due 18 months following the effective date of this rule, except for small importers of items that qualify as "articles,"¹ whose reports are due 24 months from the effective date of this rule. The final rule was published in the Federal Register on October 11, 2023. The effective date of the rule is November 13, 2023. The reporting period will run from November 12, 2024 to May 8, 2025. Small businesses that import articles have an additional six months beyond that, with reports due November 10, 2025.

The TSCA PFAS Reporting Rule – Overview

WHO: The TSCA Section 8(a)(7) PFAS reporting requirement applies to manufacturers (including importers) both small and large that have manufactured PFAS in any year since January 1, 2011.

WHAT: EPA will make a list of reportable PFAS with Chemical Abstracts Service Registry Numbers (CASRN) available on the CompTox Chemicals Dashboard. However, reporting is also required

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for PFAS that do not have CASRNs if they meet the definition in the rule.

WHERE: These reporting obligations will be codified at 40 CFR Part 705.

WHEN: Reporting forms are due 18 months following the effective date of the rule, except for small importers of articles, whose reports are due 24 months from the effective date of the rule.

By way of background, in the National Defense Authorization Act for Fiscal Year 2020 (NDAA 2020), Congress inserted Section 8(a)(7) into TSCA which calls on EPA to issue an information collection rule on PFAS. Initially, EPA took the position that it had no authority to apply the traditional exemptions from reporting that are used to focus information collection and make the cost reasonable. The administrative record quickly filled with public comments explaining to EPA that it has the authority to issue exemptions and why exemptions were needed. Just last March, EPA issued an economic impact assessment which predicted that this single reporting rule alone will cost U.S. businesses \$875 million dollars even after exemptions were considered. Even though EPA is no longer taking the position it lacks the authority to issue exemptions, the final rule has only a single exemption for the narrow categories of imported municipal solid waste streams slated for disposal and non-commercial imports by a federal agency.

As a result, many companies that have been unaffected by the new TSCA – perhaps your own – will be now. You may have heard us say more than once that TSCA is not only the domain of chemical manufacturers. This could not be truer than in relation to this new rule. In fact, the types of products and product sectors that will have to report are simply too numerous to list here.

Manufacturers (including importers) both small and large of PFAS in any year since January 1, 2011, must submit information to EPA regarding PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects. Reporting applies to well over 1,000 kinds of PFAS in neat form, in mixtures, when contained within or as part of imported articles, if present as impurities, and when generated as a byproduct. Domestically produced articles are not subject to reporting – but the companies that make them should be on the alert to report any PFAS ingredients they import or inadvertently generate.

As noted above, importing municipal solid waste streams for the purpose of disposal or destruction and non-commercial imports by a federal agency are not within scope of this rule's reporting requirements. The scope of reporting is otherwise constrained only by the overall jurisdiction EPA has under TSCA, which serves to exclude chemicals regulated by the U.S. Food and Drug Administration (FDA); any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act; and ammunition (shot shells, cartridges, and components of shot shells and cartridges). This rule will enable EPA to better characterize the sources and quantities of manufactured PFAS in the United States in virtually any other type of product.

EPA is predicting industry will spend approximately 11.6 million hours complying with this rule, with an associated cost of \$800-\$843 million. EPA's cost for administering the rule is expected to be \$1.6 million.

TSCA PFAS Reporting Decision Tree: Do I Need to Report?

Is your use of PFAS limited to:

1. Importing municipal solid waste streams for the purpose of disposal or destruction of non-commercial imports by a federal agency?
2. Chemicals in products regulated by FDA such as a drug, cosmetic, medical device, food, or food packaging?
3. Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide?
4. Tobacco or any tobacco product?
5. Any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act?
6. Ammunition (shot shells, cartridges, and components of shot shells and cartridges)?
7. Processing of PFAS that is domestically-sourced to manufacture an article? If you answered yes to any item above, your company is not subject to reporting under the TSCA PFAS rule. If your use is not listed above, you should further evaluate your need to report.

Here are some important takeaways for understanding the rules associated with these reports:

Reporting Threshold: As finalized, there is no *de minimis* threshold for reporting.

Virtually No Exemptions: Imported articles, R&D chemicals, impurities, and byproducts are subject to reporting. Municipal solid waste imports and non-commercial federal agency imports are exempt.

Mixtures: The rule requires reporting on each PFAS in a mixture.

PFAS Definition: EPA modified the definition of reportable PFAS to remove the R group requirements in the first substructure (originally proposed as R-(CF₂)-CF(R')R'', where both the CF₂ and CF moieties are saturated carbons). The removal of the R group requirement from the proposed definition expands the universe of PFAS to include additional substances of potential concern because they are likely to be persistent. The final definition includes fluoropolymers regardless of molecular weight and gases but does not include substances that only have a single fluorinated carbon, or unsaturated fluorinated moieties (e.g., fluorinated aromatic rings and olefins). EPA will make a list of reportable PFAS with CASRNs available on the CompTox Chemicals Dashboard. However, reporting is also required for PFAS that do not have CASRNs if they meet the definition in the rule.

Standard for Reporting: Information is reportable if it is “known or reasonably ascertainable.” EPA plans to issue new guidance for companies in this area. To comply with this reporting standard, companies must evaluate what they know about the products they manufacture and/or import, as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. The level of effort and the time it takes to exercise the necessary due diligence and gather the required information will vary, depending on the size of the company and the complexity of its supply chain. Companies are expected to conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). Beyond these internal inquiries, EPA expects companies may have to contact suppliers or others to understand their import or production of PFAS. EPA's reporting guidance is here.

No New Data or CASRN Required: This rule does not require reporting companies to generate new test data or obtain a CASRN or other identifier for a substance without such a number for the purpose of complying with this rule.

Required Forms and Information: EPA has developed a shorter form for article importers that do not know or cannot reasonably ascertain all of the information on the longer standard form. EPA is providing a similar accommodation for manufacturers of R&D substances in quantities below 10 kilograms annually. Any information concerning health and environmental effects must be reported using OECD-harmonized templates, where such templates exist for the type of data. OECD templates are accessible to the public online on the OECD website. All information must be submitted electronically, via EPA's Central Data Exchange (CDX). See Table 1 below for specific data elements.

Joint Submissions: EPA is enabling joint submissions for PFAS manufacturers (including importers) to work with suppliers who want to protect the identity of their ingredients. This option is only available if the CASRN or the specific identifier (i.e., Accession number or LVE number) is not known or reasonably ascertainable to the submitter, and a secondary submitter (who would provide such information) is known. This accommodation does not apply to importers of articles who do not know information such as CASRN, Accession Number, and/or LVE number. The shortened reporting form should be used in those cases.

Avoiding Duplicative Reporting: EPA is limiting the requirement for reporting “duplicative” information if a PFAS manufacturer has previously submitted the requested information to EPA for that same PFAS in that same year through Chemical Data Reporting (CDR), Toxics Release Inventory (TRI), Greenhouse Gas Reporting Program (GHGRP), or TSCA Sections 8(d) and 8(e), or is also reporting a PFAS byproduct on its own reporting form. If a reporter submitted environmental or health effects data pursuant to a TSCA Section 4 test order or voluntarily, in conjunction with EPA's National PFAS Testing Strategy, the information does not have to be reported under this rule.

Confidential Business Information (CBI): Companies must understand what information can and cannot be claimed as CBI. The final rule provides the following examples of information that can be claimed as CBI, consistent with TSCA Section 14: specific chemical identities that are not on the public Inventory, company

identifier, and production volumes. TSCA Section 14(b) limits the extent to which information from studies that bears on the effects of a PFAS on human health or the environment may be claimed CBI. In addition, information under this rule that may not be asserted as CBI includes:

- Specific chemical identity if the chemical is on the public (non-confidential) Inventory or reported as non-confidential in an LVE;
- All generic chemical names;
- For any PFAS that are on the public (non-confidential) Inventory, the chemical's CASRN;
- For PFAS that are on the confidential Inventory, the Inventory Accession Number cannot be claimed as CBI (but the underlying chemical identity can be claimed as CBI);
- LVE numbers;
- The following categories of use information: industrial processing and use type, sector, and functional categories; whether a chemical is in a consumer and/or commercial product; the consumer/commercial product categories and functional categories; and its presence in products for children; or
- Any blank response or a response that the information is "not known or reasonably ascertainable."

Only confidentiality claims made and substantiated through EPA's (forthcoming) PFAS reporting tool will be considered properly asserted. In other words, EPA does not intend to honor prior CBI claims from other TSCA submissions. These will need to be renewed with each report.

This information collection rule offers industry a lot to digest. It illustrates the sizable authority that EPA has under TSCA. The industry cost of reporting is unprecedented and steep, yet this exercise may be an opportunity for industry to emphasize the important distinctions among different types of PFAS, such as relative production and use levels in commerce, cases that present inaccessible or low exposures, critical uses, the acknowledged differences in ability to persist in the environment, and the enormous range in their hazard and exposure profiles.

Since the 2016 Lautenberg amendments breathed new life into EPA's authority to regulate chemicals that have been around for years, the agency has been testing the range of this new authority. EPA has long administered TSCA information collection rules with moderation. That is no longer the case. The normal exemption and small business consideration guardrails are off in this reporting rule. EPA has raised the level of attention on what corporate environmental, health, and safety (EHS) programs must know about PFAS in their product portfolios. Based on our experience, this mandatory exercise will take all the time that EPA provides. We recommend starting now! It is not too early to begin developing procedures for compliance determinations, outreach to suppliers, CBI determinations, and other aspects of this rule. For questions or to discuss a compliance strategy, please contact Martha Marrapese, Sara Beth Watson, or Tracy Heinzman.

Table 1: Specific PFAS Reporting Data Needs Regular Reporting § 705.15

Streamlined Reporting for Certain Article Importers² and 10 kg R&D § 705.18

1. Company and plant site information of the submitter, authorized official, and technical contact.
 2. NAICS code, Dun & Bradstreet (D&B) number, other site identifiers for each site.
 3. Trade name, specific chemical name and associated CASRN, Accession number, LVE number, generic name, and molecular structure, as applicable. *If specific chemical identity is not known, due diligence to identify a joint submitter is necessary.*
 4. For joint submissions, contact information for the supplier, a trade name or other designation for the chemical substance, and a copy of the request to the supplier or other entity.
 5. Selected code designations for the categories of industrial processing and use, industrial sector(s), and function.
 6. Up to ten commercial and consumer product code designations, functional purpose, and whether the product is intended for children (14 years or less).
 7. For each consumer and commercial product category, a range for the estimated typical maximum concentration, by weight, per year.
 8. For each PFAS at each site, whether the imported PFAS is physically present at the site, site-limited, or recycled on-site.
 9. The physical form(s) of the PFAS as it is sent off-site from each site. If the PFAS is site-limited, each physical form of the PFAS at the time it is reacted on-site to produce a different chemical is needed.
 10. The total amount of PFAS manufactured (including imported) per year, amounts for each category of use, and separated reporting for the amount domestically manufactured or imported per site.
 11. For each reported combination of industrial processing, use, sector, and function, the estimated percentage, rounded off to the closest 10 percent, of total production volume of each PFAS.
 12. For each reported consumer and commercial product category, the estimated percentage, rounded off to the closest 10 percent, of the site's total production volume.
 13. The volume directly exported of each PFAS domestically manufactured or imported at each site.
 14. Each byproduct produced from the manufacture, processing, use, or disposal of a PFAS, if it is released to the environment and in what quantity.
 15. All existing information concerning the environmental and health effects of each substance or mixture.
 16. The number of workers exposed, type of activity, daily and annual exposure duration estimates for each activity, maximum exposure and duration.
 17. Releases to air, water, and land, the manner or method of disposal of each substance or mixture, and any change in such manner or method.
1. For imported articles and R&D 10 kg.:

1. Company and plant site information of the submitter, authorized official, and technical contact.
 2. NAICS code, D&B number, other site identifiers for each site.
 3. To the extent known, trade name, specific chemical name and associated CASRN, Accession number, LVE number, generic name, and molecular structure as applicable. *If specific chemical identity information is not known, provide a generic name or description.*
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2. For imported articles only:
 1. Selected code designations for the categories of industrial processing and use, industrial sector (s), and function.
 2. Up to ten commercial and consumer product category code designations, functional purpose, and whether the product is intended for children.
 3. For each consumer and commercial product category, a range for the estimated typical maximum concentration, by weight, per year.
 4. Whether the PFAS in the article is ever physically present at the reporting site.
 5. Import volume of the article and the unit of measurement (e.g., quantity of the imported article, pounds, tons).
 6. Any other information the article importer wishes to provide.
 3. For R&D 10 kg only:
 1. The total annual volume (in pounds) of each PFAS domestically manufactured or imported at each site. Manufacturing and import volumes must be separately reported.
 2. Whether any imported R&D PFAS is ever physically present at the reporting site.
 3. Option to report any additional information to EPA that is requested under § 705.15 on the PFAS, including as supplemental attachments.

¹ An “article” is 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.

² Streamlined reporting may be used if the article importer does not know nor can reasonably ascertain information requested under § 705.15, beyond what is listed in § 705.18.