

UPDATES

U.S. EPA Issues New Expansive Reporting Obligations for PFAS: What Manufacturers and Importers Need to Know

October 30, 2023

On October 11, 2023, the U.S. Environmental Protection Agency (EPA) published a [final rule](#) under the Toxic Substances Control Act (TSCA) Section 8(a)(7) requiring most covered businesses to submit a one-time report by May 8, 2025, detailing their manufacture or import of an expansive list of per- and polyfluoroalkylated substances (PFAS) since 2011.¹ Companies of all sizes that have manufactured or imported PFAS in the United States, including as part of a manufactured product, will need to consider this new reporting obligation. Specifically:

- Any business that has manufactured PFAS domestically or has imported any PFAS since 2011 through the end of 2022, including as part of a manufactured product or article, must submit this one-time report to EPA, subject to only limited exemptions. The rule covers at least 1,462 distinct PFAS compounds.
- The reporting obligation does not extend to distributors, processors, users, or retailers.
- Exemptions are more limited than in EPA's other chemical reporting programs, with no exemptions for small businesses and low volumes.

The broad scope of PFAS subject to reporting makes this rule a potentially extreme burden on companies that will need to review records dating back over 10 years.

Manufacturers and Importers Required to Report. Companies must file a report if they qualify as a “manufacturer,” which expressly includes importers for the purpose of the rule.² Manufacturers and importers of raw chemicals and chemical components that may be classified as PFAS are obviously regulated entities.

Under the rule, EPA has defined PFAS to “includ[e] at least one of these three structures:

- $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF [compounds] are saturated carbons;
- $R-CF_2-OCF_2-R'$, where R and R' can either be F , O , or saturated carbons; and
- $CF_3-C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons.”³

This definition in the final rule is expanded from the scope under the proposed rule. As noted above,

EPA has identified at least 1,462 substances and mixtures that are PFAS that would potentially be subject to reporting.⁴ However, this new definition could expand PFAS covered to encompass thousands more substances.

Importers of finished articles are also subject to reporting requirements because they contain PFAS that are defined as for “consumer use.” “ ‘Consumer use’ means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) when sold to or made available to consumers for their use.”⁵ The expanded definition and scope of the rule to include finished articles implicate even broader reporting requirements than anticipated under the proposed rule.

Limited Exemptions From Reporting. There are no express exemptions or exceptions to this rule. Small-sized business manufacturers are not exempt from the PFAS reporting requirement, unlike under TSCA Section 8(a)(1). In addition, chemicals that are subject to a low-volume exemption under TSCA Section 8(b) must still be reported.

However, manufacturers that have previously submitted information under the Chemical Data Reporting (CDR) rule would not be required to report duplicative information to EPA.⁶ Data elements that may have already been reported by CDR would include physical state of the chemical, use type, product category, maximum concentration in the product, and additional data. The rule also does not separately mandate that all PFAS be reported every four years under the CDR rule, which already requires manufacturers and importers of certain chemicals to report information on chemical use and production.

Importantly, the rule does not require retailers and distributors of PFAS and PFAS-containing articles to report PFAS-related activities. So, if a retailer sells a product that contains PFAS and does not report, it would not violate the rule if it is not the manufacturer or importer.

Obligation to Ascertain Imported Product Contents. Regulated industries could face substantial administrative cost and burden when complying with the one-time reporting requirement. Indeed, EPA revised its cost estimates from \$10.8 million in the draft Economic Analysis for the proposed rule to \$843 million and \$800 million under a 3% and 7% discount rate, respectively, under the final rule.⁷ Challenges may arise for article importers if they are unsure whether their imported articles contained one of the identified 1,462 PFAS compounds. However, they have a reasonable duty to inquire as to whether the imported articles contain PFAS, as manufacturers or importers must report information “to the extent they know or can reasonably ascertain.”⁸ In its Supplementary Information for the rule, EPA states that

‘Known to or reasonably ascertainable by’ is defined to include ‘all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.’ This reporting standard requires reporting entities to evaluate their current level of knowledge of their manufactured products (including imports), as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control.⁹

This standard does not specify what inquiry is sufficient but could suggest a broad duty to gather and evaluate information. Article importers, for example, are asked to “share with EPA the information they already have (or can reasonably determine) on their manufactured and imported PFAS,”¹⁰ which indicates that they may be required to identify and collect information from suppliers involved across the supply chain. EPA encourages manufacturers to consider whether a “reasonable estimate” of data is not

ascertainable, which “may rely, for example, on approaches such as mass balance calculations, emissions factors, or best engineering judgment.”¹¹ EPA indicates that if requested information is beyond the scope of what can be known or reasonably ascertainable, manufacturers or importers may indicate such information is “Not Known or Reasonably Ascertainable”¹² in certain circumstances. However, because the requirements for what level of inquiry to conduct to meet the due diligence requirement are not entirely clear, covered entities should retain documentation of their efforts to collect reasonably ascertainable information.

Process and Timeline for Reporting. The one-time report requires regulated entities to submit information including PFAS chemical composition, disposal processes and methods, and production volume, among other requirements. Depending on what type of manufacturer a reporting entity is classified as, they may have different reporting options. Article importers, for example, have the option to submit a streamlined reporting form if they do not know nor can reasonably ascertain the information requested.¹³ The streamlined reporting option requests chemical identity, processing and use information, production volume, and any additional information that the manufacturer may have (such as a safety data sheet).¹⁴ Article importers must report the volume of the imported article, or alternatively, the imported production volume, rather than the volume of PFAS the article contains.

Different reporting timelines apply depending on the entity type.

- The submission period for manufacturers and importers of PFAS in general and manufacturers of PFAS that are solely research and development substances manufactured in volumes no greater than 10 kilograms per year lasts from November 12, 2024, through May 8, 2025.
- For article importers that are also small manufacturers,¹⁵ the reporting period lasts from November 12, 2024, through November 10, 2025.¹⁶

Similar to other requirements under TSCA, EPA requires submitters to use the Central Data Exchange, the agency’s electronic reporting portal, to submit reports. Civil and criminal penalties may apply for a failure to report, as TSCA Section 15(3) makes it unlawful for a person to fail or refuse to submit information.

Backdrop for New PFAS Reporting Rule. Congress directed EPA to issue the rule in the National Defense Authorization Act (NDAA) of 2020, which amended TSCA Section 8(a)(7) to require any person who has manufactured a PFAS substance to report their manufacturing activities (defined to include importing) since January 1, 2011. The NDAA added PFAS to the list of toxic chemicals covered by the Toxics Release Inventory (TRI) under the Emergency Planning and Community Right-to-Know Act and thus provided a framework for adding PFAS to TRI reporting on an annual basis. Through its new reporting rule, EPA aims to identify PFAS sources and quantities comprehensively in the United States for the first time.

On a broad scale, through its PFAS Strategic Roadmap,¹⁷ EPA has advanced three central directives:

- to invest in research and development to increase knowledge of the effects of PFAS
- to restrict PFAS from entering air, land, and water resources at levels that would cause adverse impact to human health or the environment
- to remediate PFAS contamination; this latest action requiring reporting fits into EPA’s aim to

develop tools to measure and understand PFAS

Next Steps. Companies that are potentially affected under the rule should consider whether they are covered as a manufacturer of PFAS, including whether they might qualify as an importer of PFAS in articles intended for consumer use. If a company might be covered under the rule, it should begin evaluating the scope of information it will need to report over the 11-year reporting period, which includes information that is “known or reasonably ascertainable by” the company, as well as which reporting options the company can use. Given the wide range of information that companies are required to provide under the rule and the possible steps companies may be required to take to report “reasonably ascertainable” information, companies should seek the advice of legal counsel to evaluate how the new rule’s reporting obligations may apply to their business. Companies should also be aware of measures necessary to comply with PFAS reporting requirements in certain states as well as content requirements limiting PFAS in certain products, that may differ from EPA’s final rule.

¹[40 CFR Part 705.10.](#)

²[40 CFR Part 705.1.](#)

³[40 CFR Part 705.3.](#)

⁴[Supplementary Information, III.A.1.](#)

⁵[40 CFR Part 705.3.](#)

⁶[40 CFR Part 705.22.](#)

⁷[Supplementary Information, I.E.](#), referencing the Initial Regulatory Flexibility Analysis and Notice of Data Availability in the Economic Analysis for the final rule.

⁸[40 CFR Part 705.15.](#)

⁹[Supplementary Information, III.C.](#)

¹⁰[Summary of Comments and Other Public Input and EPA’s Response, IV.B.2.](#)

¹¹[Supplementary Information, III.C.](#)

¹²*Id.*; [Summary of Comments and Other Public Input and EPA’s Response, IV.B.2.](#)

¹³[40 CFR Part 705.18\(a\).](#)

¹⁴[Supplementary Information, III.C.](#); [40 CFR Part 705.18\(a\)\(4\).](#)

¹⁵Small manufacturers means either (1) “A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$120 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lbs), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under paragraph (2) of this definition. (2) [] A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$12 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).” [40 CFR Part 704.3.](#)

¹⁶[40 CFR Part 705.20.](#)

¹⁷https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

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