

EPA Adopts PFAS Reporting Requirements Applicable to Article Importers and Chemical Manufacturers

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AUTHORS

Ryan Carra, Nessa Coppinger, Mark Duvall, Russ LaMotte, Robert Denney

The U.S. Environmental Protection Agency (EPA) has [finalized](#) a one-time reporting rule regarding the manufacture (including import) of per- and polyfluoroalkyl substances (PFAS). Despite heavy industry opposition, obligated companies will include importers of articles that contain any amount of PFAS. The rule does not incorporate exemptions typically applied in other Toxic Substances Control Act (TSCA) rules (e.g., byproducts, impurities, most research and development (R&D)). The rule also does not incorporate a de minimis volume threshold. For most companies, reports will be due by May 8, 2025. Reports must cover in-scope activities in each calendar year from 2011 through 2022.

Background

In December 2019, Congress directed EPA to adopt a PFAS reporting rule by adding Section 8(a)(7) to TSCA. That section required EPA to promulgate the rule by January 1, 2023. EPA [proposed the rule](#) in June 2021. At the time, EPA estimated the rule would result in industry compliance costs of approximately \$10.8 million. After adverse industry comments on the proposed rule, EPA issued an [Initial Regulatory Flexibility Analysis](#) (IRFA) last year that updated the compliance cost estimate to over \$875 million, an 80-fold increase. In the IRFA, EPA hinted at potential major changes to the rule as proposed, including limiting the scope of PFAS covered by the rule to a finite list and incorporating an annual reporting threshold. EPA published the final rule in the Federal Register on October 11, 2023, over nine months after the statutory deadline. The final rule does not include many of the changes that EPA considered in the IRFA. The final rule is estimated to cost the private sector \$843 million.

PFAS Definition

EPA has expanded its definition of PFAS relative to the proposed rule. The final definition includes any chemical substance that contains at least one of the following substructures:

1. $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons
2. $R-CF_2OCF_2-R'$, where R and R' can either be F , O , or saturated carbons
3. $CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons.

According to EPA, the finalized definition covers 1,462 known TSCA chemical substances, relative to 1,364 under the proposed definition. EPA stated it would issue a list of chemical substances that fall under the structural definition, drawn from the TSCA Inventory, Low Volume Exemptions (LVEs), and EPA's CompTox Chemicals Dashboard. A substance that is not on the list but still meets the TSCA "chemical substance" definition and contains one of the above substructures will still be regarded as a PFAS for purposes of the reporting rule.

The preamble to the rule also confirms that fluoropolymers that meet the rule's definition are subject to the rule.

Scope of Activities Covered by the Rule

Manufacture (including import) of any PFAS during calendar years 2011 through 2022 is in the scope of the rule. The import of articles containing PFAS in any amount during the same period is also in scope. This includes PFAS present in mixtures or articles even as byproducts or impurities. PFAS manufactured (including imported) solely for test marketing or R&D for commercial purposes are also in scope.

Companies that only processed, distributed, used, or disposed of PFAS during the reporting period are not required to report. EPA has also excluded certain imports of municipal solid waste streams from the scope.

Reporting Standard

Like other TSCA Section 8 rules, this rule only requires reporting of information "known to or reasonably ascertainable by" the submitter. Thus, this is not a "strict liability" rule.

EPA provides guidance in the preamble on the level of due diligence anticipated by this standard and also released reporting instructions and a Small Entity Compliance guide that provide further detail. Given the challenges that article importers face in identifying PFAS in supply chains, and given that the rule extends back to a time period well before most PFAS were reported or reportable in the supply chain, the precise boundaries of this standard will require careful attention by companies that are potentially within the scope of the rule.

Reportable Information

For manufacturers (including importers) of PFAS – which includes mixtures containing one or more PFAS – the following information must be reported.

- ◆ **Company and plant site information.** Companies must identify company and plant site information for each site at which a reportable chemical substance is manufactured.
- ◆ **Chemical-specific information.** Companies must identify the PFAS they manufacture, although in certain circumstances, companies may provide a generic name or description of the PFAS.
- ◆ **Categories of use and concentration ranges.** For each calendar year from 2011 to 2022, companies must report on the certain commercial and consumer categories of use for each PFAS they manufactured. They must also report on certain concentration ranges specified by EPA.
- ◆ **Manufactured amounts.** For each calendar year from 2011 to 2022, and for each PFAS reported, companies must provide certain production volume data.
- ◆ **Byproduct reporting.** For each byproduct produced from the manufacture, processing, use, or disposal of a PFAS, companies must provide certain information about the byproduct (e.g., chemical identity, volume, releases).
- ◆ **Environmental and health effects.** Companies must, for example, provide all information concerning the environmental and health effects of each reported PFAS in its possession or control (not limited to studies conducted or published during the reporting period).
- ◆ **Worker exposure data.** Companies must provide certain information regarding the number of individuals exposed to PFAS in their places of employment and the duration of the exposure.

- ◆ **Disposal data.** Companies must provide certain information about the disposal of the PFAS reported (e.g., method of disposal, volume).

EPA promulgated streamlined reporting obligations for importers of articles containing PFAS and for manufacturers (including importers) of R&D substances below 10 kilograms.

Timing and Method of Reports

For most companies required to report, the reports will be due by May 8, 2025. The reporting window will open on November 12, 2024. For small manufacturers whose only reportable activity involves the import of articles, reports will be due by November 10, 2025. All reports must be submitted through EPA's CDX portal.

Confidential Business Information (CBI) Claims

Any CBI claims must be asserted within the CDX portal at the time the information is submitted. All CBI claims must also be substantiated at the time of submission, except for certain information that is exempt from substantiation requirements (e.g., production volume information). CBI claims may not be asserted for certain information.

Recordkeeping Requirement

Each company required to report must maintain records documenting any information reported to EPA. The records must be maintained for five years after that company's reporting deadline.

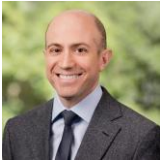
Commentary

The PFAS reporting rule resembles the Chemical Data Reporting rule (CDR) in many ways but differs in others. Unlike with CDR, there is no threshold; chemicals not on the TSCA Inventory are included; articles, byproducts, and impurities are not exempt; full reporting is required for 12 calendar years at once; and the information to be provided has rarely been part of the normal business records kept by companies.

EPA has provided a full year for gathering information required by the rule, and some companies are likely to need much or all of that time. To meet the "known to" standard of knowledge, they must check with all relevant internal stakeholders. To meet the "reasonably ascertainable by" standard, a key question, particularly for article importers, will be the extent to which they must check with suppliers. It will be important for companies to create and maintain records of their efforts to obtain information, even if unsuccessful.

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AUTHORS



Ryan Carra

Principal, Washington, DC
rcarra@bdlaw.com
+1.202.789.6059



Mark Duvall

Principal, Washington, DC
mduvall@bdlaw.com
+1.202.789.6090



Robert Denney

Associate
rdenney@bdlaw.com



Nessa Coppinger

Principal, Washington, DC
ncoppinger@bdlaw.com
+1.202.789.6053



Russ LaMotte

Principal, Washington, DC
rlamotte@bdlaw.com
+1.202.789.6080

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