

TSCA PFAS Reporting Rule

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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-(CF₂)-CF(R')R'', where both the CF₂ and CF moieties are saturated carbons
2. R-CF₂OCF₂-R', where R and R' can either be F, O, or saturated carbons
3. CF₃C(CF₃)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 has also issued four non-exhaustive lists of chemical substances that fall under the structural definition. The first list (the CompTox List) is drawn from the TSCA Inventory, Low Volume Exemptions (LVEs), and other lists on EPA's CompTox Chemicals Dashboard. This list contains over 11,000 chemicals since the rule's PFAS definition is not limited to known TSCA chemical substances. The list does not include polymers or UVCBs (chemicals of unknown or variable composition, complex reaction products, and biological materials) which may be covered by the rule.

The second list (the Public TSCA List) differs from the first in that it is only drawn from substances on the TSCA Inventory or submitted under LVEs. Moreover, this second list is comprised of two spreadsheets – the first sheet contains such in-scope substances without confidentiality claims (identified by chemical name, and CAS Number or LVE Number), while the second list contains such in-scope substances whose specific identities are confidential (identified by generic name, and TSCA Accession Number or LVE Number). Unlike the CompTox List, the Public TSCA List does not seem to specifically exclude polymers or UVCBs and it only contains around 1,200 chemicals.

The third and fourth lists are posted on EPA’s Substance Registry Services (SRS) portal. The first SRS list (the Generic SRS List) is similar to the generic sheet on the Public TSCA List in that it displays in-scope PFAS that are subject to confidentiality claims and that are either on the TSCA Inventory or have been submitted under LVEs. Both the Generic SRS List and the generic sheet on the Public TSCA List contain about 600 chemicals each, though the former contains some additional identifying information (e.g., flags for if the substance is regulated under other TSCA programs). The other SRS list (the Non-Confidential SRS List) is similar to the CompTox List in that both appear to be drawn from like sources, though the lists are formatted differently (e.g., the CompTox List shows structural formulas while the Non-Confidential SRS List does not). However, the Non-Confidential SRS List contains about 1,000 more substances than the CompTox List. This is because the Non-Confidential SRS List contains some substances that were excluded from the CompTox List, such as polymers.

These four lists of in-scope PFAS are not exhaustive, meaning that a substance that is not on any of the lists 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.

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.

Key Resources

Key resources for understanding the rule that have been released by EPA include:

- ◆ [Preamble to the PFAS Reporting Rule](#) (pages 70516-48 of the *Federal Register* notice)
- ◆ [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#)

- ◆ [Small Entity Compliance Guidance for the TSCA PFAS Data Call](#)
- ◆ [Response to Comments on the PFAS Reporting Rule](#)
- ◆ [Economic Analysis for the Final Rule](#)
- ◆ [Slides from EPA’s January 2024 Webinar on the PFAS Reporting Rule](#) (note that EPA indicated during this webinar that it plans to release an FAQ document on the rule in the coming months)
- ◆ EPA’s four non-exhaustive lists of in-scope PFAS, which include the:
 - ◆ [CompTox List](#)
 - ◆ [Public TSCA List](#)
 - ◆ [Generic SRS List](#)
 - ◆ [Non-Confidential SRS List](#)

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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