

Regulatory Alert

Global Environmental and Chemical Regulations, Policies, and Standards

Alert 28



Toxic Substances Control Act Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

Region: USA

WHY IS THIS ALERT IMPORTANT?

If your company manufactures and/or imports Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS), whether on its own, in mixtures or in articles into the United States (US) in any year since 1 January 2011, you are obliged to submit certain information to the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA). Information regarding PFAS uses, production volumes, disposal, exposures, and hazards are required to be reported. Whilst the reporting deadline is 8 May 2025 for companies, small companies (see 'Applicability' section for definition) have an additional six months (until 10 November 2025) to submit their reports to the EPA.

This regulatory alert will outline the scope, and key reporting and recordkeeping requirements for companies that have manufactured and/or imported any PFAS since 2011, as specified in the [Final Rule](#). Penalties for non-compliance with the rule include fines and/or imprisonment. Each separate violation of the requirements outlined in the rule would be subject to a maximum \$46,989 per day.

INTENDED AUDIENCE

This Regulatory Alert is intended for IAEG members that manufacture and/or import into the US PFAS in any year since 2011.

EXECUTIVE SUMMARY

PFAS, which are a large family of man-made substances used in a variety of products and industrial applications, have been gaining significant attention globally that can be attributed to their persistence and toxicity to human and ecological health. To address these substances, on 11 October 2023, the US EPA published a Final Rule, which provides reporting and recordkeeping requirements for companies that have manufactured and/or imported PFAS since 1 January 2011. With this rule, "EPA is finalizing its obligations under TSCA section 8(a)(7), as amended by the [National Defense Authorization Act for Fiscal Year 2020](#) (FY 2020 NDAA) and creating a more comprehensive database of previously manufactured PFAS to improve the Agency's understanding of PFAS in commerce and support actions to address PFAS exposure and contamination." The reporting period commences on 12 November 2024 and ends on 8 May 2025 for all companies except for small companies for which the submission deadline is 10 November 2025.

The requirements for the Final Rule apply to companies that manufacture or import PFAS (including PFAS in mixtures) or import articles containing PFAS. Companies that have only processed, distributed, used, or disposed of PFAS are excluded. Also, PFAS used for non-commercial research and development (R&D) work are excluded. Exemptions apply for the manufacture and import of ammunition, but exemptions do not apply for small companies, low volume (a minimum threshold amount, *de minimis*, for reporting does not apply), R&D for commercial purposes, impurities, and by-products.

BACKGROUND ON REGULATION

TSCA Section 8(a) concerns rules authorized by the EPA to maintain certain records and submit such reports as specified under the rule. Generally, these rules, such as the Chemical Data Reporting (CDR), require entities other than small companies, who manufacture (including import) or process a chemical substance, to maintain and submit certain records to the EPA, as required by the EPA Administrator. However, unlike the CDR program, the PFAS Reporting and Recordkeeping Rule under TSCA Section 8(a)(7) neither exempts small businesses nor imported articles from compliance with this rule. Additionally, this PFAS Rule does not exclude a *de minimis* amount of chemical substance to trigger reporting obligations.

The EPA was required to promulgate the PFAS Rule under TSCA Section 8(a)(7) as amended by the FY 2020 NDAA. The aim of the rule is to collect information about chemical identity, uses, volumes made and processed, by-products, health and environmental effects, worker exposure, and disposal. This information will help the EPA to better characterize and understand the sources and quantities of PFAS manufactured and imported in the US.

The [Proposed Rule](#) for Reporting and Recordkeeping of PFAS was published on 28 June 2021. The finalization of this rule was one of the key actions from the EPA's [PFAS Strategic Roadmap](#) that was announced on 18 October 2021. Some key changes were made to the rule following its finalization by the EPA, including:

- » expanding the scope of PFAS through the revised structural definition (see 'Applicability' section – points 2 and 3 were added)
- » extending the reporting submission period to one year rather than six months

APPLICABILITY

The Final Rule applies to all companies, including small companies (see below for definition), that have manufactured and/or imported PFAS into the US in any year since 1 January 2011. PFAS either on their own or in mixtures and in articles that meet at least one of the following three structures, are covered under the Final Rule:

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

The EPA has published two PFAS lists that meet the above definition (at least one of the three structures) and thus reportable under the Rule:

- » [CompTox Chemicals Dashboard PFAS List](#) – 11,409 substances; does not include polymers or Unknown or variable compositions, complex reaction products, and biological materials (UVCBs); updated on 6 November 2023
- » [SRS PFAS List](#) – 12,696 substances; updated on 29 November 2023

These PFAS lists are non-exhaustive – any PFAS that meet the definition of one of the three structures will be subject to reporting. Fluoropolymers that meet the above definition are in scope as well.

Small companies are defined as manufacturers and/or importers whose i) total annual sales, when combined with those of its parent company, are less than \$120 million, and the annual production volume of a chemical substance

is less than 100,000 pounds, or ii) total annual sales, when combined with those of its parent company, are less than \$12 million.

The rule applies to a wide range of activities – a non-exhaustive list is provided in § 705.15 of the Final Rule. Exclusions/exemptions to reporting include:

- » companies that have only processed, distributed, used, or disposed of PFAS
- » ammunition
- » chemicals in products regulated by the Federal Drug Agency such as a drug, cosmetic, medical device, food, or food packaging
- » pesticides

PFAS used for R&D, impurities, and by-products are all subject to reporting. Additionally, there is no *de minimis* threshold for reporting – i.e., low-volume exemptions do not apply.

RELEVANT DATES

- » Effective: 13 November 2023
- » Reporting submission period (except for small companies): 12 November 2024 to 8 May 2025
- » Reporting submission period (only applicable for small companies): 12 November 2024 to 10 November 2025

REGULATORY OBLIGATIONS

All companies, including small companies, that have manufactured and/or imported PFAS into the US in any year since 1 January 2011 are required to report certain information to the EPA during the submission period specified above. All reports must be submitted to the EPA's [Central Data Exchange \(CDX\)](#). For information regarding the CDX registration process, refer to the [CDX User Guide](#).

Reporting information

According to § 705.15 of the Final Rule, PFAS manufacturers or importers to the US are required to submit information, including:

- » company and plant site information
- » chemical identifiers, such as the common/trade name of the PFAS, and CAS number
- » categories of use and concentration ranges
- » manufactured/imported amount
- » by-product reporting
- » environmental and health effects
- » worker exposure data
- » disposal data

Streamlined reporting, a shorter reporting form (information requirements detailed under § 705.18 of the Final Rule), may be used if i) a PFAS-containing article importer does not know or cannot reasonably ascertain information requested under § 705.15, or ii) a company manufactures or imports R&D substances (e.g., PFAS) in

quantities below 10 kilograms annually. For the streamlined reporting, applicable manufacturers and importers to the US are required to submit information, including:

- » company and plant site information
- » chemical identifiers, such as the common/trade name of the PFAS
- » categories of use and estimated maximum concentration
- » manufactured/imported amount

If a company does not know or cannot reasonably make estimates for the necessary information, they may indicate such information as “Not Known or Reasonably Ascertainable (NKRA).”

For further information, see the EPA’s guidance documents on the [Assessing and Managing Chemicals under TSCA webpage](#) – “Instructions for Reporting PFAS Under TSCA Section 8(a)(7)” and “Small Entity Compliance Guidance”.

Known to or reasonably ascertainable information

The PFAS Rule requires companies to submit *known to or reasonably ascertainable information* to the EPA. This means “all information in a person’s possession or control, including all information that a reasonable person similarly situated might be expected to possess, control, or know.” Companies must make reasonable efforts to gather the necessary information. This may include making internal inquiries (within the company) and contacting suppliers to find out if PFAS is contained in the products they manufactured or imported. However, the EPA has clarified that no new testing or surveys are required.

Confidential Business Information (CBI)

In line with TSCA Section 14, companies may claim the following information as CBI:

- » chemical identifiers, such as the chemical substance name and CAS number, that are not on the [public \(non-confidential\) TSCA inventory](#)
- » company identifier
- » production volume/amount

Exceptions for information considered to be CBI include:

- » chemical identifiers for PFAS on the public (non-confidential) TSCA inventory
- » generic chemical names
- » Low Volume Exemption numbers
- » the Inventory Accession Number on the confidential TSCA Inventory (underlying chemical identity can be claimed as CBI)
- » when a response is left blank or designated as not known or reasonably ascertainable

Prior CBI claims from other TSCA submissions also need to be renewed as part of the PFAS reporting under the Final Rule.

Duplicative reporting and joint submissions

The EPA permits duplicative reporting and joint submissions under certain circumstances. If a company that is subject to the Final Rule previously submitted the requested information to the EPA for that same PFAS in that

same year, duplicative information does not need to be submitted again. The EPA allows for companies subject to the Final Rule to submit joint submissions with their suppliers who want to protect the identity of the PFAS-containing products.

Recordkeeping

Companies must retain relevant records, such as the information reported to the EPA, for a period of five years beginning on the last day of the submission period.

RISKS TO AEROSPACE AND DEFENSE

Penalties for non-compliance with the Final Rule include fines and/or imprisonment. Small companies may also be subject to these penalties. Each separate violation of the reporting requirements would be subject to a maximum \$46,989 per day. Penalties may be issued for failing to:

- » report information by the deadline
- » maintain records of the information for reporting for a period of five years beginning on the last day of the submission period
- » allow inspections to assure compliance (according to TSCA Section 11)
- » respond to a request for information from the EPA
- » providing false or misleading information

Companies must submit all known or reasonably ascertainable information and be able to demonstrate that they have made reasonable efforts to do so. Failure to do so may result in penalties.

USEFUL LINK

[Final Rule](#)

[Assessing and Managing Chemicals under TSCA \(EPA webpage on the Rule\)](#)

[EPA's Central Data Exchange \(CDX\) portal](#)

[CompTox Chemicals Dashboard PFAS List](#)

[SRS PFAS List](#)

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