EPA TSCA PFAS Reporting Rule

On October 11, 2023, the U.S. Environmental Protection Agency (EPA) released printed in the *Federal Register* a copy of its one-time Toxic Substances Control Act (TSCA) reporting rule for facilities that manufacture (including import) or have manufactured (including imported) a per- or polyfluoroalkyl substance (PFAS) for commercial purposes in any year between January 1, 2011 – December 31, 2022. The reporting rule is required by the National Defense Authorization Act for Fiscal Year 2020, and is an outgrowth of EPA's June 28, 2021 proposed rule (86 Fed. Reg. 33926). The reporting rule requires entities to report PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects associated with PFAS.

- **What is it?**

  A one-time EPA reporting rule to collect information on the manufacture (including import) of a PFAS in any calendar year since January 1, 2011.

- **Am I subject to the rule if I don't currently manufacture (or import) or didn't previously manufacture (or import) a PFAS for a commercial purpose?**

  A site is subject to reporting if it manufactured (including imported) a PFAS for a commercial purpose at any time between January 1, 2011 – December 31, 2022. EPA broadly interprets "manufactured for a commercial purpose" to apply to a PFAS present (1) in an imported article, (2) as an impurity in an imported article or a manufactured or imported substance (including a mixture), and (3) in a coincidentally-manufactured or imported byproduct. However, non-commercial research and development (R&D) activities such as scientific experimentation, research, or analysis are not subject to reporting unless the activity is for eventual commercial purposes.

- **How is a PFAS Defined?**

  EPA expanded the definition of a PFAS for reporting purposes from the single, structural definition in its proposed rule. For purposes of the final reporting rule, a PFAS is defined as any chemical substance or mixture containing a chemical substance that structurally contains at least one of the following three substances:

  (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; or
  (3) $CF_3C(CF_3)$R'R'', where R' and R"" can either be F or saturated carbons.

  EPA identifies at least 1,364 substances on both the TSCA Inventory and Low-Volume Exemption claims that meet these structural definitions. However, the reporting rule applies to any substance meeting the structural definition of a PFAS, regardless of whether it is present on the TSCA Inventory.

- **Do I need to perform sampling and testing to determine the presence and quantity of a PFAS in a material?**

  No. Sampling and testing are not required. Entities may rely on existing information/data or, if not available, reasonable estimates of a PFAS may be reported.

- **Do I need to query up-stream suppliers of imported substances, articles and mixtures to ascertain whether a PFAS was present therein at any time since January 1, 2011?**

  Likely not. The reporting of a PFAS along with the other data elements on the reporting forms are premised on a "known to or reasonably ascertainable by" standard, the same reporting standard as in the Chemical Data Reporting rule. "Known to or reasonably ascertainable by" is defined as "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." There are two components to this standard, a "known to" component and a "reasonably ascertainable" component.

  - Under the "known to" component, a submitter must ascertain what it knows about the chemical substance it manufactures (or imports), without confining the inquiry to what is known to managerial and supervisory employees. This component requires a reasonable inquiry within the full scope of the organization.

  - The "reasonably ascertainable" component may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. However, EPA notes that if particular information cannot be derived or reasonably estimated without conducting customer surveys (*i.e.*, without sending a comprehensive set of identical questions to multiple customers), it would not be considered "reasonably ascertainable" to the submitter.

  If an entity is subject to reporting, but some data elements are not "known to or reasonably ascertainable by" the submitter, the submitter may select "NKRA" ("not known to or reasonably ascertainable") for that information.

- **When is the reporting period?**

  The final rule sets a one-year information collection period following the "effective date" of the rule (the effective date is 30 days after it is published in the *Federal Register*), followed by a six-month reporting period. For entities meeting the definition of a "small manufacturer" and only reporting on imported articles, the reporting period is extended an additional six months. Assuming the rule is published in the *Federal Register* in October 2023, the information collection period will close sometime in November 2024, followed by a reporting period closing in May 2025 (and closing in November 2025 for a small manufacturer reporting only on imported articles). Reports must be submitted through EPA's electronic Central Data Exchange (CDX) – which many companies already use for other EPA reporting programs.

- **What are the reporting forms, and which one do I use?**

  There are two possible forms to use: a "standard" form and a "streamlined" form. The streamlined form is only, available for (1) importers of articles, and (2) manufacturers of R&D substances for commercial purposes in quantities below 10 kilograms per year if they do not know nor can reasonably ascertain information beyond the data elements contained on the streamlined form.

- **What are the required data elements?**

  The required data elements are dependent on whether the streamlined or standard form must be completed for the reportable PFAS. Attachment 1 provides the data elements for the streamlined form, and Attachment 2 provides the data elements for the standard form, based on a review of EPA's pre-publication copy of the final rule. EPA has prepared a detailed data elements document for the rule, which will be available in the rulemaking docket once the final rule is published in the *Federal Register*.

  In addition, certain data elements set forth in 40 C.F.R. § 705.27 and previously reported to EPA under other reporting programs (*e.g.*, Chemical Data Reporting, Greenhouse Gas Reporting, and Toxic Release Inventory Reporting) need not be re-reported.

- **What are the record retention requirements?**

  Records must be maintained for five years from the close of the reporting period.

- **May certain information be claimed as confidential business information (CBI)?**

  Yes, 40 C.F.R. § 705.30 specifies the CBI procedures, including which data elements cannot be claimed as such.