

EPA's Long Arm Reach: PFAS TSCA Rule

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On October 11, 2023, the U.S. Environmental Protection Agency (EPA) issued a [final rule](#) to require reporting under Section 8(a)(7) of the Toxic Substances Control Act (TSCA) for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS). The rule aims to gather comprehensive data on PFAS, a large group of synthetic chemicals that have been linked to various health and environmental concerns.

This broad reporting rule under TSCA will impact all U.S.-based manufacturers, which, as explained below, includes companies that do not, in fact, manufacture but only import PFAS as a component of an article. Companies subject to the rule are required to report not only current and historical PFAS chemical identity, but also their uses, production volumes, byproducts, environmental and health effects, and their manner and method of disposal. Subject companies must also report exposure to PFAS by employees and contractors and certain information related to PFAS-containing articles.

The EPA's new rule is likely to have significant impacts across multiple industries, as manufacturers will be forced to exercise reasonable levels of due diligence to gather detailed PFAS information related to their use directly or with respect to materials being used in their manufacturing operations. Notably, there is no small business exemption from the reporting requirements as there have been with other rules promulgated under Section 8(a) of TSCA.

Key Provisions

Mandatory Reporting

The rule requires any entity that has manufactured or imported PFAS or PFAS-containing articles since January 1, 2011, to electronically submit detailed reports to the EPA. There are several methods of reporting PFAS information, including streamlined forms for small businesses and researchers who either import PFAS as part of an article only or manufacture small quantities solely for research and development purposes.

Extensive Data

Regardless of the form of report, PFAS reporting must include extensive data monitoring that extends to the specific PFAS substance, its uses, production volumes, byproducts, disposal methods, potential exposures, and existing health and environmental hazard data.

Retroactive Scope

Importantly, the rule seeks to gather historical data from 2011 on, with the goal of providing valuable insights into past PFAS usage and potential environmental burdens.

Phased Deadlines

The relatively good news is that manufacturers have 18 months (or 24 months for small entities) from the effective date of the rule (November 13, 2023) to submit their initial reports. Therefore, as it currently stands, the two relevant dates to track for reporting purposes are May 8, 2025, and (for small manufacturers) November 10, 2025. Reports must be submitted electronically through the EPA's Central Data Exchange System, and future periodic reporting may also be required. To comply with the reporting deadlines, manufacturers should determine whether the rule applies to them, and—if so—immediately begin taking steps to comply.

Who Does the TSCA Rule Apply To?

The rule mandates reporting and recordkeeping obligations for manufacturers and importers of PFAS, marking a significant step towards understanding the scope and potential risks associated with these chemicals. The final rule requires any entity or person that has manufactured PFAS for a commercial purpose in any year since January 1, 2011, to submit PFAS uses, production volumes, byproducts, disposal methods, known exposures, and existing information on environmental or health effects to the EPA. The Rule covers chemical manufacturers, importers, and companies that incorporate PFAS (whether manufactured or imported) into their products. The rule does not apply to persons and entities that process, distribute, or use PFAS but do not manufacture or import these substances. However, the EPA has indicated that it may promulgate a similar rule for businesses engaged in those activities under Section 8(a)(1) of TSCA.

TSCA section 8(f) sets forth the scope of “manufacturing” which is limited to entities manufacturing for a commercial purpose. The term “‘manufacture for commercial purposes’ includes the import, production, or manufacturing of a chemical substance or mixture containing a chemical substance with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer.” (emphasis added). EPA has by rule expanded this definition to also include the “coincidental manufacture of byproducts and impurities that are produced during the manufacture, processing, use, or disposal of another chemical substance or mixture.” This rule makes clear that the EPA intends to cast the widest net possible to gather data about the manufacturing of PFAS and their effects.

What Information Needs To Be Reported?

Companies subject to the rule must submit detailed reports, on a site-by-site basis, to the EPA covering various aspects of PFAS. The reporting requirements also extend to entities that have imported articles containing covered PFAS chemicals into the United States, as well as to PFAS-containing byproducts and impurities produced during the manufacturing process. The reporting rule does not establish any de minimis thresholds or minimum production volumes. If an entity has manufactured in (or imported into) the United States PFAS or an article containing PFAS, then it is required to report the following:

Chemical Identity

Specific chemical identity of each PFAS manufactured or imported, including Chemical Abstracts Service (CAS) registry number, must be reported if available. If the specific identity is unknown, reports should provide other identifying information, such as structural formula or commercial name.

Production Volume and Uses

Reports must disclose quantity of PFAS manufactured or imported, their applications, and production volumes of each PFAS manufactured or imported since January 1, 2011. This includes information on whether the PFAS was used in articles (products) and, if so, a description of the types of articles. Additionally, if known, reporting companies must disclose the number of articles containing the PFAS that were manufactured or imported.

Byproducts and Disposal

Reports require descriptive information about byproducts generated during PFAS production and their disposal, including (i) a description of any byproducts formed during the manufacture of the PFAS, and (ii) the methods used to dispose of the PFAS and its byproducts.

Worker Exposure

Data on potential worker exposure to the PFAS during its manufacture, processing, and use, and known or potential releases of the PFAS to the environment during any stage of its lifecycle, must be reported.

Environmental and Health Effects

Reports require available information on the potential environmental and human health impacts of the reported PFAS, including (i) any existing studies or data on the health or environmental effects of the PFAS, and (ii) any information on potential known risks associated with exposure to the PFAS.

Next Steps

Although there is some uncertainty about the new rule, it is very clear that the broad scope of PFAS subject to reporting will place an extreme burden on any company that will need to review records dating back more than 10 years. Companies are encouraged to determine as soon as possible if the rule applies to their business operations, as compliance is likely to be time-consuming and resource-intensive. The EPA estimates that the compliance costs alone across all affected industries are likely to be between \$800 million and \$843 million.

If a company determines that it is subject to the reporting rule, it should immediately begin evaluating the scope of information it will need to report over the 11-year reporting period (including information that is “known or reasonably ascertainable by” the company), as well as which reporting options may be available to the company. The final PFAS TSCA Reporting Rule contains robust provisions regarding the type and form of information that must be submitted. 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 determine and report what is “reasonably ascertainable” information, companies should seek the advice of legal counsel to evaluate if and how the new rule’s reporting obligations may apply to their business.

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