Updates



Back in 2023, the U.S. Environmental Protection Agency (EPA) issued a sweeping information-gathering rule under the Toxic Substances Control Act (TSCA) requiring manufacturers (including importers) to report on perand polyfluoroalkyl substances (PFAS) in their products.

The rule requires that manufacturers, including importers of PFAS and PFAS compounds in consumer products in any year from 2011 to 2022, submit detailed information regarding the manufacture, processing, use, disposal, and environmental and health effects of these substances. In our October 2023 Update, we provided an overview of the new TSCA reporting rule. The following is an in-depth analysis of who is required to report, the reporting standard (including the due diligence a manufacturer will need to complete to adequately report), what information can be protected as confidential business information, and potential penalties for failure to report.

Who Must Report

Under 40 CFR 705, the reporting obligation falls to the "person who manufactured (including imported)" a chemical substance that is a PFAS. This obligation extends to manufacturers who import and use materials containing PFAS in their products. If a company manufactures its product in the United States and then sells the product, it must report. However, in its 2024 Reporting Instructions, the EPA suggests that, in the case of chemical substances or products that are manufactured by one person on behalf of another, the manufacturer is the person who actually produces the chemical substance or manufacturers the product—not the seller or brand owner of the product. See Reporting Instructions at 2.1.1.

If a company imports a foreign manufactured product (that is, the company is the import broker/importer of record) and then sells a product, that company will need to file a report. But even if the company is not the import broker, the company may still need to file a report. 40 CFR 704.3 broadly defines "importer," so the way in which shared reporting obligations are divided falls to the parties. However, if no one reports, the EPA could hold all parties liable for the failure to file the required report.

Regulated entities that import articles containing PFAS may use a streamlined article import form, which does not require all the information on the standard form. The form also allows production volume to be reported as the total weight of the imported articles or as the quantity of articles that are imported, rather than the weight of the PFAS.

If a company imports PFAS in an article and domestically manufactures PFAS, the company could use the streamlined import form for the imported article and the standard form for the other PFAS; alternatively, the company could include the information for the imported articles on the standard form, which would result in one form for all PFAS produced and imported by the site.

Reporting Requirements: Overview

Companies subject to the rule must report information on activities conducted since January 1, 2011, through 2022. This one-time reporting event covers a broad range of elements, including:

- 1. **Chemical substance identification.** Using the agency's Substance Registry Services to report the chemical substance identification information, consisting of the currently correct Chemical Abstracts Index Name and the correct corresponding Chemical Abstracts Service Registry Number.
- 2. **Manufacturing information.** Detailed data on production volumes, including domestically manufactured and imported quantities.
- 3. **Processing and use information.** Information on industrial processing and use, consumer and commercial use, and specific categories of use.
- 4. **Byproducts and disposal.** Reporting of byproducts generated during manufacturing, processing, use, or disposal, along with disposal methods and release quantities.
- 5. **Environmental and health effects.** Submission of all known or reasonably ascertainable information concerning the environmental and health effects of PFAS.

Reporting Standard: Information Known or Reasonably Ascertainable

Companies are only required to report "information known or reasonably ascertainable" to the company. As described in the Reporting Instructions, this means "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." To meet

this standard, regulated entities must evaluate their current level of knowledge for their manufactured products (including imports) and evaluate whether there is additional information that a reasonable person who is similarly situated would be expected to know, possess, or control.

Practically speaking, companies that are required to report should do the following:

- Conduct a reasonable inquiry within the organization (and not just rely on the information that is known to managerial or supervisory employees). This may require inquiries outside the organization to fill gaps.
- If information cannot be derived or reasonably estimated without conducting further customer surveys (*i.e.*, without sending a comprehensive set of identical questions to multiple customers), it would not be "reasonably ascertainable."
- If the actual data is not available, companies can make "reasonable estimates."

The rule does not require a company to actually test its products, but if the company has information that PFAS compounds are or may be present, it must report that information. If the company has actual data, the company must report that information.

If companies do not know and cannot estimate certain data elements, except for production volumes, they may indicate that such information is "Not Known or Reasonably Ascertainable" (NKRA). However, NKRA designation should only be used when the information is truly not reasonably ascertainable or is unattainable (*e.g.*, when the appropriate recordkeeping period has lapsed and a past record is no longer available).

Confidential Business Information (CBI) Claims

Submitters may claim certain information as confidential, but such claims must be substantiated at the time of submission. The EPA has outlined specific substantiation questions that must be answered to support CBI claims. Failure to substantiate claims may result in the information being made public.

CBI claims apply to:

- The company, site, and technical contact identity.
- Chemical substance information listed on the confidential portion of the TSCA Inventory.
- Maximum concentration of the PFAS in the product.
- Production/import volume information.
- Byproduct information.
- Worker exposure information.

However, the following information may not be claimed as CBI:

- Specific chemical identity if the chemical is listed on the public TSCA Inventory.
- Generic chemical names.
- Whether a PFAS chemical is present in a consumer/commercial product, the consumer/commercial product categories and functional categories, and PFAS presence in products for children.
- Any blank or NKRA designation in the report.
- General information on health and safety studies.

Submission Deadlines

The deadline for reporting is May 8, 2025, but small manufacturers, as defined by 40 CFR 704.3, have an additional six months, which end on November 10, 2025. Reports must be submitted via the "TSCA section

8(a)(7) PFAS data call rule" service through EPA's Central Data Exchange. EPA has indicated that this reporting tool should be available in November 2024.

Special Provisions for Joint Submissions

Joint submissions are required when a company (a foreign supplier, for example) will not disclose certain chemical substance identifiers due to confidentiality concerns. In that case, the importer would ask the supplier about the confidential chemical substance to provide the EPA the correct chemical identity. The primary submitter (the importer or manufacturer of the unknown PFAS) must then provide the necessary information for completing the joint submission.

Potential Penalties

Companies should not avoid reporting. Failure to file the report is a violation of TSCA sections 8(a) and 15 and could subject companies to significant penalties. See 40 CFR 705.1. The current TSCA penalties are approximately \$48,000 per day.

Conclusion

The TSCA Section 8(a)(7) reporting requirements for PFAS are comprehensive and demand meticulous attention to detail. Manufacturers and importers must ensure accurate and timely submission of data to comply with the EPA's mandates. By understanding the key elements and procedural requirements, companies can navigate the complexities of this reporting rule.

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