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Product Importers: Are You Ready for the New PFAS Reporting Requirements Under the Toxic Substances Control Act?

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In this article, the authors detail the data collection and documentation requirements under a new per- and polyfluoroalkyl substances (PFAS) rule issued by the U.S. Environmental Protection Agency that are needed for reporting known and reasonably ascertainable information on a compound-by-compound basis.

The U.S. Environmental Protection Agency (EPA) published a far-reaching and important final rule (Rule) on October 11, 2023, requiring comprehensive reporting of per- and polyfluoroalkyl substances (PFAS) manufactured and imported in the United States under the Toxic Substances Control Act (TSCA).[1]

Promulgated under Section 8(a)(7) of TSCA,[2] the Rule is mandated by Section 7351 the National Defense Authorization Act for fiscal year (FY) 2020 (2020 NDAA) titled "PFAS Data Call." This simple section amended Section 8(a) of TSCA to add an entirely new subsection (7).

Specifically, Congress ordered the EPA to promulgate a rule to collect categories of PFAS data for every year from January 1, 2011, through 2022, corresponding to recordkeeping requirements related to preexisting categories for chemical substances subject to TSCA reporting outlined in subsections (A) through (G) of Section 2607(a)(2).

The Rule applies not only to traditional chemical manufacturers but to all importers of products (Product Importers) that may contain one or more PFAS compounds. PFAS are used in a large number of product categories, such as electronics, wires and cables, pipes, cooking and bakeware, textiles, automotive applications, toys,

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water- and stain-resistant clothing, cleaning supplies, dental floss, toilet paper, paints, varnishes, carpets, and many other industrial and consumer products, so the potential universe of regulated parties is vast. There are no exemptions for low levels or small amounts of PFAS use. Exemptions are provided for PFAS used in certain types of products regulated by other agencies and programs, such as food additives and medical devices. These exemptions involve specifically defined terms that should be evaluated on a case-by-case basis.

The Rule requires the EPA to collect a wide range of data on each PFAS, compound by compound, contained in an imported product for each year from 2011 through 2022, including:

- The covered common or trade name, chemical identity, and molecular structure of each chemical substance or mixture;
- Categories or proposed categories of use for each substance or mixture;
- Total amount of each substance or mixture manufactured or processed, amounts manufactured or processed for each category of use, and reasonable estimates of the respective proposed amounts;
- Descriptions of by-products resulting from the manufacture, processing, use, or disposal of each substance or mixture;
- All existing information concerning the environmental and health effects of each substance or mixture;
- The number of individuals exposed—and reasonable estimates on the number of individuals who will be exposed—to each substance or mixture in their places of work and the duration of their exposure; and
- The manner or method of disposal of each substance or mixture, along with any change in such manner or method.

In its Response to Public Comments,[3] the EPA confirmed that the Rule is intended to apply to Product Importers and its discretion was somewhat limited by Congress and distinct from the rulemaking authority contained in TSCA Section 8(a)(1). For many Product Importers, this will be an entirely new process giving rise to many questions, some of which are answered in the EPA's recently published Frequently Asked Questions[4] and Instructions for Reporting PFAS Under TSCA Section 8(a)(7) (Reporting Instructions).[5]

What if We Don't Know What PFAS Compounds Are in Our Company's Imported Products?

The EPA requires all manufacturers (including importers) to report all known and reasonably ascertainable information about PFAS in their products. The EPA encourages parties to evaluate their current level of knowledge, review their records, and even reach out to suppliers if reasonable. The EPA will accept a joint submission if a supplier will not divulge the fluorinated materials in its product or Chemical Abstracts Service (CAS) Registry Number. If a company has no known or reasonably ascertainable (NKRA) information, it will not be covered by the Rule or required reporting. However, the EPA has confirmed that incomplete information is not a basis for failing to report.[6] In all circumstances, entities are encouraged to keep good records of their efforts to obtain known and reasonably ascertainable required information.

What Should Companies Do if There Has Been a Merger or Acquisition During the Lookback Period?

The EPA encourages companies to follow the guidance offered under its Chemical Data Reporting (CDR) rule, specifically, its Reporting After Changes to Company Ownership or Legal Identity fact sheet,[7] if there has been a merger or if a company is no longer in business.[8] If the information is NKRA, the EPA has indicated it does not need to be reported. A company may want to seek additional guidance from the EPA based on its specific circumstances.

Similarly, the CDR provides guidance for how a company should handle the scenario if the company only has records going back for a specific period of time because it was previously part of another company but not for the entire lookback period. The EPA has indicated that it will evaluate the company's compliance on the basis of what a similarly situated person would have possessed, controlled, or known under the circumstances. In any of these scenarios, the company should maintain good records of the efforts it made to identify the known and reasonably ascertainable required information.

How Does Our Company Demonstrate Our Search Efforts?

Companies that need to comply with the TSCA 8(a)(7) reporting requirements should develop a standard operating procedure detailing the protocol for how they will attempt to collect and gather the information being requested by the EPA, along with robust procedures for documenting their due diligence efforts. While each Product Importer's plan will be based on the specific nature of its business, it is important to have a detailed plan that includes, as a minimum, the topics identified by the EPA in the Reporting Instructions Section 4.2. These include marketing studies, sales reports, customer surveys, supplier notifications, safety data sheets, and Dun & Bradstreet reports.

The EPA clarified that companies do not need to test or sample their products in order to comply with the requirements of TSCA.[9] In order to evaluate potential environmental and health effects, the EPA expects companies to consult safety data sheets, third-party studies that have previously been submitted to the EPA, and trade association reports.[10] This information need only be listed with an indication of when the reports were previously submitted to the EPA and to which office. Manufacturers (including importers) do not need to conduct science literature reports.

If a company has any confidential business information (CBI) included in its submission, it must assert a CBI claim at the time of reporting. If a CBI claim was previously asserted, it simply needs to be reasserted, and the company can report the chemical's TSCA Accession Number and generic name instead.[11]

Should Our Company Submit an Estimate?

The EPA also provided some guidance on whether a company should submit a reasonable estimate or claim that the information is NKRA. The basis for making the determination whether to provide an estimate or assert NKRA would be what a person similarly situated could be expected to possess, control, or know.[12] The company will need to make inquiries of its subsidiaries, general partnerships, and employees. The EPA encourages companies to review Chapter 4.2 in the Reporting Instructions. The EPA will review

NKRA claims, which need to be carefully and closely documented, particularly if a company could have provided reasonable estimates on the basis of mass balance calculations, emissions factors, or best engineering judgment.[13]

In Table 4-1 of the Reporting Instructions, the EPA provides illustrations of when it will consider information to be known or reasonably ascertainable, as well as when it might be willing to accept an NKRA claim. For example, if a company has data on its products for three seasons in a year but not the fourth, the EPA would likely accept a report on the basis of the three seasons of known data, but it would not accept a claim of NKRA when partial responsive information exists and is known to a company.

Similarly, if the company could not get information from its major supplier but could obtain information from 10 of its minor suppliers and was willing to survey those entities, the EPA would accept this data. It would not accept a claim of NKRA if the company failed to obtain the information from its minor suppliers.

How Long Must I Keep Records?

The records should be retained for five years, beginning on the last day of the information submission period.[14]

What Will the EPA Do with the Reports?

Public Availability

The EPA's stated purpose behind much of chemical regulation—in addition to fulfilling statutory obligations—is to increase public accessibility to nonconfidential chemical data wherever possible. To that end, under TSCA, the EPA seeks to characterize the sources and quantities of manufactured PFAS in the United States to further its goals of enhancing understanding of chemical hazards and exposures to better assess risks to human health and the environment, supporting risk reduction efforts and informing efforts to encourage industry to switch to safer chemicals. The EPA's ChemView program[15] provides public access to some data submitted to the agency under TSCA. Although Section 8(a)(7) reporting is not currently listed in ChemView, it is possible that the EPA may

add nonconfidential information reported under Section 8(a)(7) to ChemView or otherwise share the underlying data in the future.

Confidentiality

To prevent potential public disclosure by the EPA of reported data under Section 8(a)(7), manufacturers (including importers) must assert CBI claims at the time of reporting. It is critical that reporting entities follow the stringent CBI procedures set forth in 40 C.F.R. § 705.30 or they may forfeit the claim. These procedures include satisfying the requirements for substantiation, generic chemical names, reporter certification, and the EPA's review of specified CBI claims within 90 days after receipt of the claim. All substantiation claims must include written responses to five detailed questions, with an additional four questions required to assert a claim of confidentiality for the specific chemical identity of a chemical substance.[16] As clearly stated in the Reporting Instructions[17] and Frequently Asked Question No. 52, entities may make CBI claims only through the Rule's electronic reporting tool; the EPA will not consider CBI claims made elsewhere. Accordingly, for each piece of confidential data being reported, the CBI box must be checked in the reporting tool, which will then trigger the requirement to provide substantiation.

Additionally, CBI claims with respect to information previously submitted under TSCA Section 8(a)(7) are bifurcated based on whether the information was submitted *before or after* the 2016 TSCA amendments:

- For CBI information submitted before the 2016 TSCA amendments, the reporter must reassert and resubstantiate the claim in accordance with 40 C.F.R. § 705.30 or forgo the claim.[18]
- For CBI information submitted after the 2016 TSCA amendments, the reporter must provide the EPA with details regarding when, how, and under which title and/or statutory authority the reporter submitted the CBI claim, along with a certification to demonstrate that the previous CBI claim adequately covers the current claim. However, if the prior CBI claim does not satisfy the current substantiation requirements, the reporter must submit a new CBI claim consist with the current substantiation requirements.[19]

Will Plaintiffs Use Data Reported to the EPA in PFAS Litigation?

We anticipate that plaintiffs alleging property and personal damages related to alleged PFAS contamination will likely use nonconfidential data reported to the EPA under Section 8(a)(7) in support of their claims. At a minimum, plaintiffs will likely be able to use aggregated nonconfidential data in PFAS lawsuits. Plaintiffs could present redacted reports to juries, and courts could conduct in camera review of confidential versions.

Taking an analogue from a recent federal class action complaint currently pending in California, plaintiffs used a third-party nongovernment agency's Freedom of Information Act[20] request to obtain nonconfidential data that PFAS was allegedly contained in BIC's razors, based on reporting that the company submitted to the Maine Department of Environmental Protection[21] under the state's PFAS reporting law.[22]

The plaintiffs' theory is that no reasonable consumer would believe that PFAS were in the razors unless the company disclosed the presence of PFAS (it is alleged they did not). The plaintiffs allege several causes of action under California law, including violations of the state's unfair competition law based on fraudulent acts and practices, false advertising law, and the Consumer Legal Remedies Act, as well as common law fraud, unjust enrichment, and negligent failure to warn. The class action lawsuit is seeking compensatory damages, punitive damages, and injunctive relief. Although this case is at the early stages and based on state law, it illustrates the potential use for and ramifications of the release of PFAS data that the EPA is requesting under Section 8(a)(7) of TSCA. However, it remains to be seen whether the EPA's format for TSCA Section 8(a)(7) will provide sufficient information for plaintiffs to link specific PFAS compounds to particular products in the same way the Maine reporting does.

Unique Challenges for Product Importers

The EPA has recognized that Product Importers likely will not have all of the information that a product manufacturer would possess. Accordingly, it adopted special provisions to allow streamlined reporting[23] or more detailed reporting through a joint submission

between the manufacturer/supplier when, for example, the import is a mixture and the manufacturer refuses to reveal the chemical identity of a confidential component of the mixture.[24]

For the streamlined form, a company will still be required to search for relevant data and answer all of the questions, but it will be allowed to provide estimates or ranges for certain numerical data requests (maximum concentrations and production volumes). In each case, in addition to known or reasonably ascertainable information about each PFAS compound, the streamlined form also seeks information about how the PFAS compound is used, which includes the choice "Processing-incorporation into article." The streamlined form also requests information on industrial sectors, function category (how the PFAS is used in the article), product category, and whether the product is for commercial, consumer, or children's use. These are preset codes that will be available in a drop-down menu in the reporting tool. The lists of choices are found in the Reporting Instructions, Tables 4-7 (type of process or use operation), Table 4-8 (industrial sector), Table 4-9 (function categories), and Table 4-10 (product categories), with detailed explanations of each category found in Appendix D of the Reporting Instructions.

When it comes to identifying the imported production volume, in Section 4.7.2.2 of the Reporting Instructions, the EPA provides the following helpful suggestion:

> Product Importers reporting on the Product Importer form should report the volume of the article imported, rather than attempting to calculate the volume of the PFAS contained within the articles. You may choose to report the total weight of the PFAS-containing articles (e.g., in tons or pounds) or the quantity of the article imported (e.g., the number of vehicles). You must specify the unit of measurement for the reported production volume.[25]

If the importer subsequently exports some or all of the PFAS-containing products, it still must report the volume imported initially.

Conclusion

In summary, the 2023 TSCA one-time call for 10 years' worth of data under Section 8(a)(7) will be challenging to comply with

for most Product Importers. The investigation and recordkeeping requirements involve significant due diligence, and many case-by-case questions are likely to arise during the process. Given that reporting on a compound-by-compound basis by is due by May 8, 2025 (or November 10, 2025, for small entities), it is recommended that document collection and compliance measures begin to be implemented promptly.

Notes

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1. https://www.govinfo.gov/content/pkg/FR-2023-10-11/pdf/2023-22094.pdf.
2. 15 U.S.C. §2607(a)(7).
3. https://www.govinfo.gov/content/pkg/FR-2023-10-11/pdf/2023-22094.pdf.
4. https://www.epa.gov/system/files/documents/2024-05/tsca-8a7-faqs-may-2024.pdf.
5. https://www.epa.gov/system/files/documents/2024-05/tsca-8a7-reporting-instructions_may2024.pdf.
6. Frequently Asked Questions nos. 54-57.
7. https://www.epa.gov/sites/default/files/2015-05/documents/cdr_fact_sheet_company_changes.pdf.
8. Frequently Asked Questions nos. 25 and 26.
9. Frequently Asked Question no. 39.
10. Frequently Asked Questions nos. 49-51.
11. Frequently Asked Questions nos. 52 and 53.
12. 40 C.F.R. § 705.3.
13. Frequently Asked Question no. 57.
14. See 88 Fed. Reg. 70516, 70530 (Oct. 11, 2023); 40 C.F.R. § 705.25.
15. https://chemview.epa.gov/chemview.
16. See 40 C.F.R. § 705.30(e)(f).
17. Sections 4.4.1, 4.5.1, 4.7.1.1, 4.7.1.2, 4.8.1, 4.9.1, 4.10.1, 4.11.1 and 4.13.4.
18. See 40 C.F.R. § 705.35(a)(3)(iii).
19. See Preamble to Final Rule at Section E.
20. https://defendourhealth.org/wp-content/uploads/2024/03/Unknown.pdf.
21. https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/.

22. See Complaint, Butler v. BIC USA Inc., No. 4:24cv2955 (May 15, 2024 N.D. Cal.) (where allegations specifically cite the Maine reporting); "More 'Forever Chemicals' Reported in Products Sold in Maine," Defend Our Health (Mar. 5, 2024), https://defendourhealth.org/news/more-forever-chemicals-reported-in-products-sold-in-maine/.

23. 40 C.F.R. § 705.18; Reporting Instructions Section 2.2.

24. Reporting Instructions Sections 4.5.11 and 4.13.

25. P. 4-40.