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## **EPA Issues Final Rule Requiring Companies That Manufacture or Import Products Containing PFAS to Report Under TSCA**

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On October 11, 2023, the United States Environmental Protection Agency (“EPA”) issued a [final rule](#) requiring manufacturers and importers of per- and polyfluoroalkyl substances (“PFAS”) to submit a one-time report containing certain information to EPA under the Toxic Substances Control Act (“TSCA”). The final rule requires companies to report information that is known or reasonably ascertainable related to PFAS manufactured in or imported into the United States in any year since 2011. Importantly, the final rule requires companies that manufacture or import “articles” – defined broadly as manufactured items – to report the concentration of PFAS in, and the volume of, articles manufactured or imported. This broad definition will require most companies that import goods (including products and equipment) that contain PFAS to submit a report to EPA. EPA did not include many exceptions in the final rule. Therefore, most companies that manufacture or import products or equipment containing PFAS will be required to report those activities to EPA between now and May 8, 2025 (the reporting deadline). There is, at least, a short form for companies that import articles. The remainder of this alert addresses some important aspects of this new PFAS information reporting rule.

### **What was EPA’s authority for this new rule and why did EPA issue it?**

The final rule was prompted by passage of the National Defense Authorization Act for Fiscal Year 2020 (“NDAA”), which amended section 8 of TSCA to direct EPA to

promulgate a rule requiring “each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011, to submit to the Administrator a report” containing certain information. 15 U.S.C. § 2607(a)(7). The NDAA did not define PFAS for purposes of the TSCA reporting requirement. In the final rule EPA defined PFAS structurally, by reference to PFAS’ chemistry. EPA also plans to provide a list of known PFAS on its CompTox Chemicals Dashboard. EPA intends to use the new data to “support activities addressing PFAS under TSCA, as well as activities and programs under other environmental statutes.” EPA believes the additional data it receives will help the agency determine “whether additional risk assessment and management measures are needed.”

### **When do reporting obligations begin?**

The rule creates a one-time reporting obligation for entities that manufactured or imported PFAS for commercial use at any time since January 1, 2011. The reporting period begins on November 12, 2023, and is open until May 8, 2025. EPA granted an additional six months to entities that report exclusively as article importers (see below for additional detail on these companies) and qualify as small manufacturers. These companies must submit a report by November 10, 2025. To qualify as a small manufacturer (including importer) a company must meet one of two standards:

1. a manufacturer (including importer) with total annual sales, when combined with those of its parent company, less than \$120 million, and annual production or importation volume of a particular substance at any individual site owned or controlled by the company must not exceed 100,000 pounds; or
2. a manufacturer or importer with total annual sales, when combined with those of its parent company, less than \$12 million regardless of the quantity of substances produced or imported.

### **What are articles?**

The final rule defines an “article” as a manufactured item that:

1. is formed to a specific shape or design during manufacture;
2. has end use function(s) depending in whole or in part upon its shape or design during end use; and
3. has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

In the rule's preamble, EPA identified a wide range of articles that may contain PFAS, including "textiles, electronics, wires and cables, pipes, cooking and bakeware, sport articles, automotive products, toys, transportation equipment, and musical instruments . . . ." The definition of article and the description of articles in the rule's preamble demonstrates that EPA intended articles to include all manner of manufactured goods or finished products.

### **What does this rule mean for article importers?**

Unlike previous TSCA reporting rules that exclude importers of articles, importers of articles are not excluded from the new PFAS reporting requirements. Importers include any individual or entity that imports any "chemical substance as part of a mixture or article" into the United States. EPA is implementing a "streamlined form" for importers to use in reporting. The streamlined form still requires information regarding chemical identity, processing and use information, and production volume, as described in more detail below. When reporting production volume, importers can report the volume of imported article(s), either by weight or by number of articles (e.g., number of vehicles), instead of volume of PFAS, but must include, if ascertainable, PFAS concentration. Similar to the option for importers EPA implemented a streamlined reporting option for R&D substances generated in volumes under 10 kilograms per year.

### **What information is required on the streamlined reporting form option for article importers?**

The streamlined article importer form will require the following information to the extent it is known or reasonably ascertainable:

- company and site information
- chemical identity
- chemical identification number (i.e., CASRN)
- trade name or common name, if applicable
- representative molecular structure of the PFAS
- import production volume (e.g., quantity of the imported article – either by weight or by number of articles)
- industrial processing and use information
- consumer and commercial use information

Notably, unlike the general reporting form, the streamlined form does not require companies to report the number of workers reasonably likely to have been exposed to PFAS in imported articles.

For the one-time submission, companies must report to EPA for each “site” where PFAS are manufactured or imported. More than one plant may constitute a single site. For importers, the “site” is the “operating unit” in the company directly responsible for importing the PFAS; in some instances, this may be the company’s headquarters. If no “operating unit” or headquarters exist in the U.S., the reported “site” should be the address for the agent acting “on behalf of the importer” who is “authorized to accept service of process.”

### **What is your duty to gather and find information related to PFAS manufacturing and importation?**

Under the new rule, companies must report information known or reasonably ascertainable to them. This standard is the same standard used in the TSCA Chemical Data Reporting (CDR) rule and includes “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 comply, companies should not only evaluate current levels of knowledge regarding their manufactured products and imports, but also determine whether additional information exists that a similarly situated person would be expected to know. Examples of these types of information include “[1] files maintained by the manufacturer such as marketing studies, sales reports, or customer surveys; [2] information contained in standard references showing use information or concentrations of chemical substances in mixtures, such as a Safety Data Sheet (SDS) or a supplier notification; and [3] information from the CAS or from Dun & Bradstreet (D-U-N-S).”

Companies should evaluate information held at all levels of the company and not rely exclusively on information known to managers and supervisors. If necessary, organizations should inquire with entities (e.g., upstream suppliers, downstream users, employees, research and development (R&D) teams, and other agents of the manufacturer) outside the organization to gap-fill their knowledge.

Information that cannot be derived or reasonably estimated without conducting new customer surveys would not be “reasonably ascertainable.” Therefore, for the purposes of this rule, there is no need to conduct new surveys. However, if a company has existing survey data, it may be considered “known” to the organization and must be reported.

When actual data is not available, a company should determine if “reasonable estimates” of such information are ascertainable. Examples of reasonable estimates include mass balance calculations, emissions factors, and best engineering judgment. If

manufacturers cannot make reasonable estimates of certain data elements, they may indicate such a determination on their report with Not Known or Reasonably Ascertainable (“NKRA”). However, production volumes cannot be marked as NKRA, and NKRA designations cannot be claimed as Confidential Business Information (CBI) under TSCA § 14.

### **How does your company get started?**

Given the extensive scope of this new rule, companies should take time to work with their compliance, technical, and legal teams to understand how the rule impacts their specific operation. The requirement for companies to look back 12 years into their operations means there is likely considerable internal fact gathering needed to comply. With the potential need for internal research, beginning the road to compliance early will be an important first step. Consider these actions to prepare for reporting:

- Designate an individual(s) to lead the reporting work. Ideally, employees familiar with other EPA reporting obligations or with purchasing practices can lead this work. When questions arise, leads can coordinate with counsel.
- Familiarize appropriate personnel with the information required on reporting forms to locate where pertinent reporting information may be stored. This includes individuals and departments that are familiar with reportable information.
- Establish a timeline or other protocol for gathering information to document the processes for contacts and communications with internal and external sources of data.
- Inform appropriate employees and suppliers about the reporting requirement, so they can take the steps necessary to locate reportable data.
- Contact external sources that may be able to provide information and request specific data to populate the EPA reporting form.
- Initiate internal or external legal review of the reporting form before submitting it to EPA.

These measures will support compliance with the reporting requirements. It is important for companies to dedicate time to plan a route toward compliance. Preparing a path forward, sooner rather than later, will minimize roadblocks and avoid a rush on suppliers, vendors, and other supply chain holders of information as the reporting deadline approaches.

# EPA Encourages Inclusion of PFAS Monitoring in Discharge Permits

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In August 2023, EPA released a best management fact sheet called [Pollution Prevention Strategies for Industrial PFAS Discharges](#) which provides information to address NPDES discharges containing PFAS under the Clean Water Act. The fact sheet aims to help permit writers and pretreatment coordinators by providing best management practices and examples. Under EPA's new best management practices, EPA encourages permit writers and pretreatment coordinators to include PFAS monitoring limits when PFAS are present or suspected in discharges. The best management practices specifically note industrial operations such as airport operations, firefighting, chemical manufacturing, semiconductor manufacturing, chrome finishing, textile manufacturing, centralized waste treatment, landfill operations, and coatings manufacturing as industries to evaluate.

In December of last year, EPA released a [memorandum](#) to states that provides direction on how to use the Clean Water Act to monitor for PFAS discharges. EPA's goal was to reduce discharges of PFAS at the source and limit the amount of PFAS entering wastewater and stormwater systems. The memo recommends that states use the most current sampling and analysis methods in their NPDES programs to identify known or suspected sources of PFAS. It also recommends that states act using their pretreatment and permitting authorities to impose technology-based limits on sources of PFAS discharges. Recommendations in the memo also allow EPA to obtain information through monitoring of the sources and quantities of PFAS discharges, which inform other EPA efforts to address PFAS as part of its [PFAS Strategic Roadmap](#). The August 2023 best management practices fact sheet builds on last year's memo by providing additional resources to improve monitoring and reduce PFAS discharges.

The best management practices encourage permit writers and pretreatment coordinators to evaluate and include numeric discharge limits based on treatment technologies using granular activated carbon, ion exchange resins, or reverse osmosis if appropriate. When not applicable to a permit, it encourages pollution prevention practices instead.

It also provides draft permit language if PFAS are found in a facility's discharge that states:

“Within 6 months of the effective date of the permit, the facility shall provide an evaluation of whether the facility uses or has historically used any products containing PFAS, whether use of those products or legacy contamination reasonably can be reduced or eliminated, and a plan to implement those steps.”

The best management practices fact sheet also provides examples of state actions where pollution prevention initiatives have been successful including chrome plating PFAS analysis in Michigan and California, policy provisions in Colorado for site investigations, and metal finishing and aerospace PFAS discharge reductions in Vermont. Additionally, the best management practices fact sheet provides a guide to developing a facility-specific plan to monitor and implement PFAS reduction strategies.

Entities engaged in any of the industries listed in the fact sheet should evaluate their current permit cycles and permit requirements to prepare for additional information requests, and potential best management practice requirements, in future permit renewals. Regulated entities should also evaluate participation in state voluntary sampling programs to prepare for future requirements, with advice of counsel and technical consultants.