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Decoding PFAS:

A Comprehensive Study on TSCA Section 8(a)(7) Reporting and Recordkeeping

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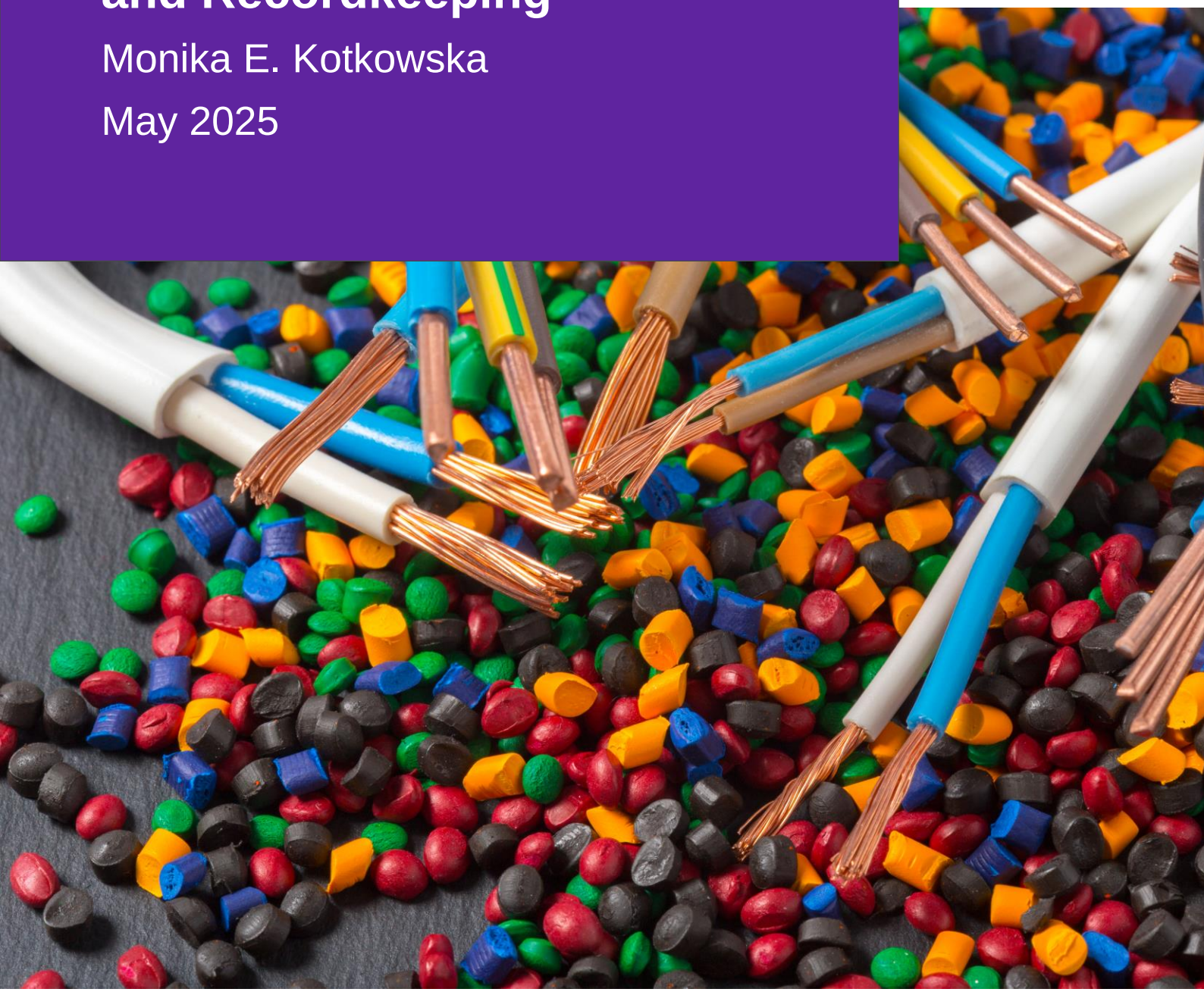
May 2025



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In Navigating Environmental Compliance and Market Regulations

The PFAS Reporting Rule signifies a critical step in addressing US environmental concerns related to PFAS. Manufacturers and importers must act promptly to comply with the reporting requirements. Adequate planning and understanding of the reporting framework will ensure a seamless process and adherence to regulatory timelines.

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Entities operating in Construction, Manufacturing i.e. Aerospace, Automotive, Heavy Equipment, Mining, Agriculture, Life Science, but also Wholesale Trade, Retail Trade, Waste Management and Remediation Services, and potentially other sectors, are subject to the regulatory standards imposed by the PFAS Reporting Rule.

This reporting obligation is comprehensive, requiring the submission of vital details, **including chemical identity, production volumes, byproducts, disposal methods, exposures, and existing information on health and environmental effects.**

In essence, this rule marks a pivotal step in fostering a comprehensive understanding of PFAS dynamics in **the United States.** It enables proactive measures to address exposure and contamination, facilitating more informed and effective decision-making processes within the regulatory framework.

Executive Summary

In response to mandates within the National Defense Authorization Act for Fiscal Year 2020, the U.S. Environmental Protection Agency (USEPA) has implemented robust reporting and recordkeeping standards under the Toxic Substances Control Act (TSCA) Section 8(a)(7) for per- and polyfluoroalkyl substances (PFAS). This regulatory framework, known as the PFAS Reporting Rule, compelling entities involved in the commercial manufacturing or import of PFAS from January 1, 2011, to December 31, 2022, to submit comprehensive data.

The primary objective of this initiative is to create an exhaustive database of previously manufactured PFAS, enhancing the Agency's comprehension of PFAS in commerce and supporting actions to address PFAS exposure and contamination. The data collected is expected to empower the EPA in determining the necessity for further risk assessment and management measures, potentially leading to more streamlined and cost-effective decision-making processes and contributing to more robust regulatory measures.

As of November 13, 2023, the final rule regarding TSCA Section 8(a)(7) PFAS reporting is officially in effect. However, in May 2025, the EPA issued an interim final rule extending the reporting deadlines. The updated reporting window for most manufacturers and importers will now begin on April 13, 2026 and close on October 13, 2026. Small businesses that are solely reporting data on importing PFAS contained in articles will have until April 13, 2027, to submit their reports.

These changes were made because the EPA required additional time to finalize and deploy the electronic reporting tool and to consider further public comments on certain aspects of the rule. The scope and detail of the reporting requirements remain unchanged: all manufacturers and importers of PFAS—including those importing articles containing PFAS—must report for any year between 2011 and 2022.

What are Per- and polyfluoroalkyl Substances (PFAS) and why are they a concern for the EPA?

PFAS, a family of over 15,000 synthetic chemicals, known as "forever chemicals," are widely used for their water and heat resistance in various products. Their persistent nature raises concerns about potential health risks, with evidence linking certain PFAS to adverse effects in humans and animals.

PFAS chemistry was discovered in the late 1930s. Since the 1950s, many products commonly used by consumers and industry have been manufactured with or from PFAS.

Referred to as **"forever chemicals"** due to their prolonged environmental persistence, PFAS have impacted over 2,300 sites in 49 states [2], **affecting the drinking water of approximately 200 million Americans** [3].

Recognizing the significant threat posed by these toxic and persistent substances, numerous states, manufacturers, and retailers are taking proactive measures to phase out the use of PFAS in various products and processes.

Per- and polyfluoroalkyl substances (PFAS) form a diverse family of fluorinated chemicals, numbering in the thousands, with applications in commercial use and the environment, each exhibiting unique properties. Over the years, the range of PFAS and their applications has significantly expanded. According to the U.S. Environmental Protection Agency's chemicals database (CompTox), the PFAS family encompasses nearly 15,000 chemical substances, with a primary classification into polymer and non polymer classes, as illustrated in Figure 1.

PFAS, introduced since the 1950s, is prevalent in industrial and consumer products, including firefighting foams, coatings for textiles and furniture, food contact substances, and the manufacturing of various chemicals and products. PFAS finds utility in textiles, electronics, wires, cables, pipes, cookware, bakeware, sports equipment, automotive products, toys, transportation equipment, and musical instruments, often imported into the United States as finished articles.

Throughout the entire lifecycle, manufacturing, processing, distribution, use, and disposal, PFAS may be released into the environment. There is evidence indicating potential links between exposure to specific PFAS in the environment and harmful health effects in humans and animals.

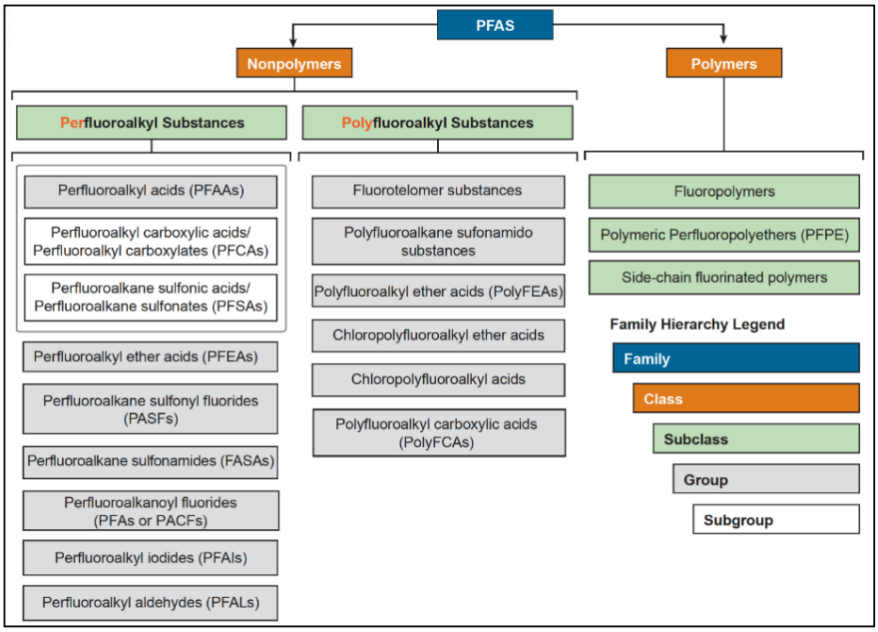


Figure 1. The PFAS Family [1].

Non polymers

Non polymer PFAS includes perfluoroalkyl and polyfluoroalkyl substances, each with various chemical structures.

- **Perfluoroalkyl substances**

Perfluoroalkyl substances are fully fluorinated (perfluoro-) alkane (carbon-chain) molecules. Their basic chemical structure is a chain of two or more carbon atoms with a charged functional group attached at one end. Common functional groups are carboxylates or sulfonates, but other forms are also detected in the environment. Figure 2 illustrated two examples of perfluoroalkyl substances: perfluorooctane sulfonate (PFOS) and perfluorooctane carboxylate, referred to as perfluorooctanoate (PFOA).

Studies indicates that the introduction of PFAS as substitutes for older, long-chain PFAS may have implications for human health. These newer, short-chain PFAS exhibit similar challenges in terms of breakdown, persistence in the environment, and high mobility, readily entering ground and surface waters. Despite these concerns, short-chain PFAS remain prevalent in various industries [4].

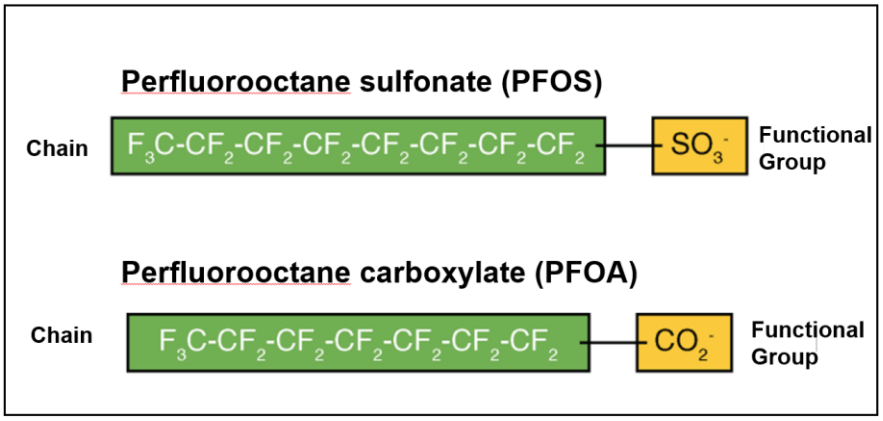


Figure 2. The tail and head structure of PFOS and PFOA [1].

- **Polyfluoroalkyl Substances**

Polyfluoroalkyl substances differ from perfluoroalkyl substances as they are not entirely fluorinated. Instead, they are aliphatic substances wherein all hydrogen atoms attached to at least one (but not all) carbon atom have been substituted with fluorine atoms. This results in the inclusion of the perfluoroalkyl moiety. Figure 3 provides an illustration of a polyfluoroalkyl substance, featuring two carbons in the tail that are not fully fluorinated, while the rest of the carbons are.

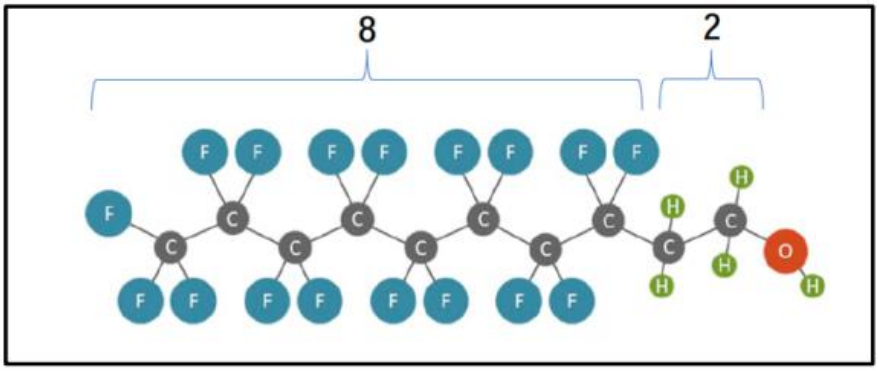


Figure 3. Example of a polyfluoroalkyl substance [1].

In various forms, per- and polyfluoroalkyl substances (PFAS) are prevalent in our environment, found in waterproof clothing, stain-resistant upholstery, carpets, nonstick cookware, and pizza boxes.

This extensive collection of synthetic organic chemicals, numbering in the thousands, has been produced for decades to endow various products with resistance to water, heat, and stains.

PFAS Polymers

Polymers are complex structures formed by linking numerous identical smaller molecules, called monomers, in a repetitive pattern. In the case of copolymers, formed from various monomer species, there might be variations in the ratio and connectivity of the monomer subunits.

Subcategories within the polymer classification include fluoropolymers, polymeric perfluoropolyethers (PFPE), and side-chain fluorinated polymers. Currently, certain polymer PFAS are believed to present a comparatively lower immediate risk to both human health and the environment when compared to specific non polymer PFAS. According to the publication of Barbara J Henry [5], many polymer PFAS, particularly high–molecular weight fluoropolymers, are insoluble and not bioavailable in the environment, making them less concerning for human and ecological health. Consequently, the primary chemicals of concern at environmental release sites are often non polymers.

Under TSCA 8(a)(7) regulations, reporting PFAS polymers as a single PFAS entity is mandatory. This reporting requirement emphasizes the need to consolidate information, treating the polymer as a unified PFAS entity despite potential complexities in its composition.

For thorough reporting, it is vital to include any known information about the structure and variability of the polymer in both the chemical description and molecular structure data fields. This ensures that the reporting not only captures the overall identity of the PFAS polymer but also its inherent structural nuances, contributing to a comprehensive understanding of its characteristics and potential environmental implications.

Figure 2 illustrated two examples of perfluoroalkyl substances: perfluorooctane sulfonate (PFOS) and perfluorooctane carboxylate, referred to as perfluorooctanoate (PFOA).

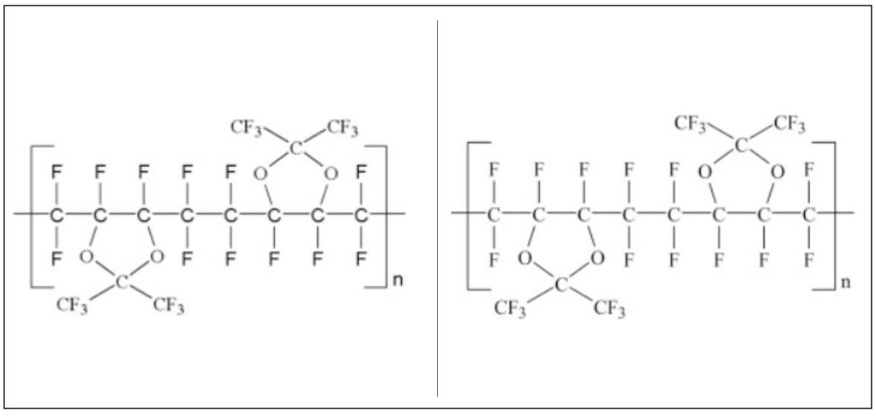


Figure 4. On the left Structure of Teflon® amorphous fluoropolymer and on the right Teflon® AF polymer [6].

Emerging Health and Environmental Concerns

A study found that over 98% of Americans have detectable PFAS levels. While blood levels have decreased since 2002, concerns arise with the phasing out of certain PFAS, posing potential exposure risks. The CDC's tracking shows links between PFAS exposure and health issues. Communities investigating PFAS in drinking water face challenges due to PFAS resilience, emphasizing the need for proactive measures in addressing contamination [11].

Awareness of Public Health Impacts

There is currently no remedy for PFAS exposure, and blood testing cannot offer a clinical diagnosis or definitively predict whether a person's health has been or will be impacted.

Awareness of the presence of Perfluoroalkyl acids (PFAAs) can be attributed to **occupational studies in the 1970s that found detections of some PFAS in the blood of exposed workers, and further studies in the 1990s that reported detections in the blood of the general human** [7].

A nationwide biomonitoring study, encompassing over 98% of U.S. participants, has revealed detectable levels of PFAS in their bodies. Concurrently, the Centers for Disease Control and Prevention (CDC) has systematically tracked blood PFAS levels in the U.S. population through The National Health and Nutrition Examination Survey (NHANES) from 1999 to 2018. This initiative, focused on assessing the health and nutrition status of both adults and children in the United States, indicates a noteworthy decline in blood PFAS levels since 2002. Figure 5 illustrates the outcomes of this extensive data analysis, showcasing a remarkable decrease of over 85% in blood PFOS levels and more than 70% in PFOA levels between 1999-2000 and 2017-2018 [1].

While this decline is a positive trend, concerns arise with the phasing out and substitution of PFOS and PFOA, as it prompts potential exposure to other PFAS within the population. This is particularly concerning given the growing scientific consensus on the toxicity of certain PFAS to human health. These substances have been associated with a range of health issues, including decreased antibody response, diminished fetal and infant growth, and an increased risk of kidney cancer. Additionally, evidence suggests a correlation between PFAS exposure and an elevated risk of breast cancer, testicular cancer, and other health-related concerns. Vigilance and ongoing research are crucial to understand and address the potential health implications of PFAS exposure.

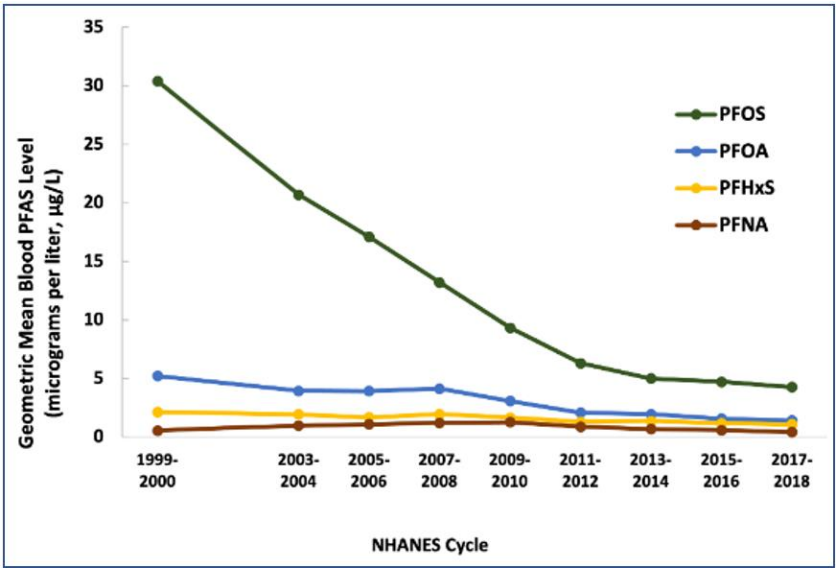


Figure 5. Blood Levels of the PFAS in People in the United States Over Time [8].

In addition to food, occupational exposures, and other less-explored pathways, drinking water stands out as a significant avenue of human exposure to PFAS. Specifically, **PFAS can infiltrate wastewater treatment plants (WTPs)** similar to other contaminants, entering through residential and industrial waste. However, due to their resistance to typical treatment methods, PFAS often persist through wastewater treatment, subsequently re-entering the waterways that serve as sources for drinking water. Given that PFAS can be present in the solid waste produced by WTPs, known as sludge, its utilization in agriculture contributes to the pollution of soil and food with PFAS [11].

Understanding Different Levels of PFAS Contamination

Across the United States, numerous communities are actively investigating PFAS levels in their drinking water, reflecting a growing concern. The persistent nature of PFAS poses a significant challenge for environmental management and remediation efforts, as these substances resist easy degradation and cycle through the environment. Incineration facilities and wastewater treatment plants inadvertently contribute to PFAS release into the air and agricultural biosolids [9][10].

Major environmental contributor to PFAS contamination is the use of firefighting aqueous film-forming foam (AFFF), extensively employed at airports, military sites, chemical plants, and facilities with above ground petroleum storage tanks. The widespread use of AFFF in fire departments for training and emergencies further exacerbates PFAS dispersion. Notably, PFAS contamination extends beyond industrial sites to impact landfills, where infiltration into groundwater is a growing concern.

Figure 6 illustrates the intricate pathways of PFAS transport and distribution. These pathways include direct sources like industrial emissions and secondary sources such as water treatment plant outflows and incineration facilities. All these sources contribute to the contamination of drinking water. Once released into the environment, PFAS disperses through the water cycle, impacting drinking water through both surface and groundwater. Thorough investigation and proactive measures are imperative to address the concerns arising from PFAS contamination in diverse environmental settings [11].

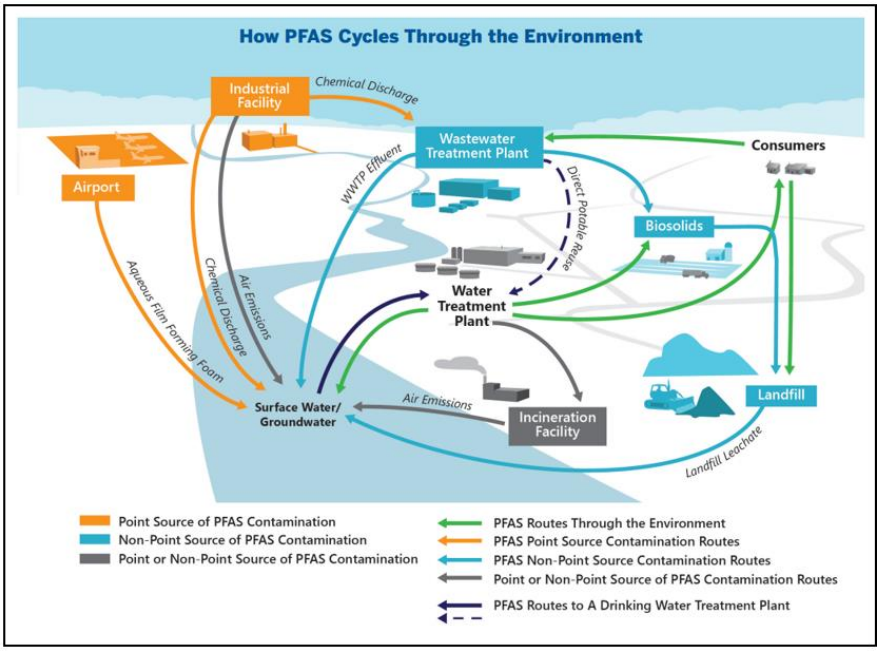


Figure 6. PFAS transport through the environment [11].

Environmental Impact of PFAS Polymer Production

PFAS polymer production is linked to the release of "climate super-pollutants," such as HCFC-22 and HFC-23. These substances possess extraordinary warming potential, surpassing carbon dioxide by significant margins. HCFC-22 is 5,280 times more potent, while HFC-23 is 10,800 times more potent, both measured over a twenty-year timescale [12].

The emissions from a single PFAS polymer manufacturing plant, particularly of these two compounds, are substantial, equivalent to the annual carbon dioxide pollution from 750,000 passenger cars [13]. Moreover, HCFC-22's emissions have an additional adverse impact—depleting the health-protective stratospheric ozone layer. This underscores the environmental implications and emphasizes the urgency for sustainable practices in PFAS polymer production to mitigate these significant climate-related concerns [14].

On December 20, 2019, the National Defense Authorization Act (NDAA) was officially introduced regulatory measures that automatically incorporate per- and polyfluoroalkyl substances (PFAS) or PFAS classes into the Toxics Release Inventory (TRI) as reportable chemicals.

Simultaneously, the updated reporting mandates for PFAS under the Toxic Substances Control Act (TSCA) demand extensive data disclosure, encompassing a broader range of chemicals compared to the reporting guidelines in the Toxics Release Inventory (TRI). **Key distinctions exist between TSCA and TRI reporting requirements, including variations in the PFAS covered, triggering actions, reporting periods, and other provisions outlined in each rule**.

TSCA Section 8(a)(7) PFAS Reporting and Recordkeeping

In response to the evolving landscape of environmental regulations, the Environmental Protection Agency (EPA) has revised and proposed changes to the reporting requirements for per- and polyfluoroalkyl substances (PFAS).

Regulatory Insight on PFAS Reporting Mandate

On October 11, 2023, the U.S. Environmental Protection Agency (EPA) implemented a pivotal Final Rule, mandating stringent reporting and recordkeeping obligations for entities engaged in the manufacturing or importing of per- and polyfluoroalkyl substances (PFAS) since January 1, 2011. Effectively starting November 13, 2023, companies involved in the production, processing, or importation of PFAS substances or mixtures are compelled to furnish the EPA with comprehensive data. This encompasses a spectrum of information, ranging from chemical identities to potential environmental and health ramifications.

The genesis of this rule lies in the EPA's commitment to meeting its obligations under the Toxic Substances Control Act (TSCA) section 8(a)(7), as amended by the National Defense Authorization Act for Fiscal Year 2020 (FY 2020 NDAA). The primary objective is to establish an all-encompassing database of previously manufactured PFAS, thereby augmenting the EPA's understanding of PFAS in commercial circulation. This database is pivotal for informed decision-making and executing strategies to address PFAS exposure and contamination comprehensively.

Understanding TSCA Section 8(a)(7) applicability

As of November 13, 2023, entities engaged in the production, manufacturing, or importation of PFAS within the customs territory of the United States for commercial purposes between January 1, 2011, and December 31, 2022, fall under the classification of "manufacturers" as per the rule. These entities are mandated to **submit a one-time report** to the Environmental Protection Agency (EPA) via EPA's Central Data Exchange (CDX), providing comprehensive details on PFAS usage, production volumes, byproducts, disposal methods, exposures, and existing knowledge regarding environmental or health effects.

EPA defines "manufacture for commercial purposes" to manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, among other things, the “manufacture” of any amount of a chemical substance or mixture:

- for commercial distribution, including for test marketing, or

The rule's applicability is broad, encompassing all entities, regardless of size. **A de minimis exemption for reporting small PFAS quantities, has not been accepted**. According to TSCA section 8(a)(7), entities are required to report PFAS usage regardless of its concentration in products.

The understanding of PFAS is constantly evolving, shaped by ongoing research and varying definitions across regulatory bodies, operational criteria, and the intended scope of included chemicals. As of now, there is no universally accepted definition of PFAS. The specific definition may differ based on the regulatory framework and the criteria employed in different contexts.

- for use by the manufacturer, including use for product research and development or as an intermediate.

The term also encompasses substances produced coincidentally during the manufacturing, processing, use, or disposal of another substance or mixture, including byproducts separated from the other substance or mixture, and impurities remaining in that substance or mixture. Even byproducts and impurities lacking separate commercial value are considered to be produced for the purpose of obtaining a commercial advantage, as they are integral to the manufacturing of a chemical substance for commercial purposes.

A diverse range of industries, as shown in Figure 7, may be affected. This includes various sectors, and there's a possibility that other entities not explicitly mentioned could also fall under regulatory oversight.

Figure 7. Examples of industries affected by the TSCA section 8(a)(7) requirements.

Structural Definition of Reportable PFAS

To determine your obligation to report each PFAS chemical substance domestically manufactured (including importation) into the United States from 2011 to 2022, your company must assess whether your chemical substance meet the definition of PFAS substances accordingly to the TSCA section 8(a)(7) reporting rule.

In defining 'PFAS' under this rule, EPA adopts a structural definition, encompassing at least one of these three structures:

- R-(CF2)-CF(R′)R″, featuring saturated carbons in both the CF2 and CF moieties;
- R–CF2OCF2-R′, where R and R′ can be F, O, or saturated carbons; and
- CF3C(CF3)R′R″, where R′ and R″ can be F or saturated carbons.

The EPA, in establishing the TSCA section 8(a)(7) reporting rule, has opted for a structural definition rather than relying on a specific list of identified substances. This decision is based on the recognition that a confined list may inadvertently exclude substances of significance to the Agency's interests.

TSCA 8(a)(7) PFAS Chemicals

EPA offers a list of substances meeting this definition, compiled from the Inventory, Low-Volume Exemptions (LVEs), and the CompTox Chemicals Dashboard. This comprehensive list is accessible on the CompTox Chemicals Dashboard. **It is crucial to note that this list is non-exhaustive**. Any substance falling under the definition of a 'chemical substance' under TSCA, even if not on

The **CompTox Chemicals Dashboard**, developed by the U.S. EPA, is **a free**, powerful tool providing **public access to information about over a million chemicals**. It supports EPA's research using new approach methods (NAMs) by integrating advancements in various sciences.

The Dashboard helps prioritize chemicals based on potential health risks and uses computational toxicology to evaluate thousands of chemicals quickly and cost-effectively. It's a widely used resource offering data on chemical properties, environmental impact, hazard, exposure, and bioactivity.

this list but manufactured for commercial purposes since 2011, is subject to this rule. Also, fluoropolymers that meet the above definition are in scope.

While the definition of a chemical substance typically excludes mixtures, PFAS, recognized as a chemical substance, can be found within mixtures. As a result, this rule mandates the reporting of each PFAS chemical substance, even when it is part of a mixture. It's important to note that components of a mixture that do not align with the structural definition of PFAS are not required to be reported under this rule.

What is a reporting process?

After a manufacturer (including importer) establishes that their products fall under TSCA reporting requirements, the next step is to determine the appropriate reporting process. Figure 8 illustrates a decision logic diagram developed by the EPA to guide manufacturers (including importers) in deciding whether to report using the standard form or if they may be eligible for streamlined reporting. The subsequent subsections provide detailed explanations for each question.

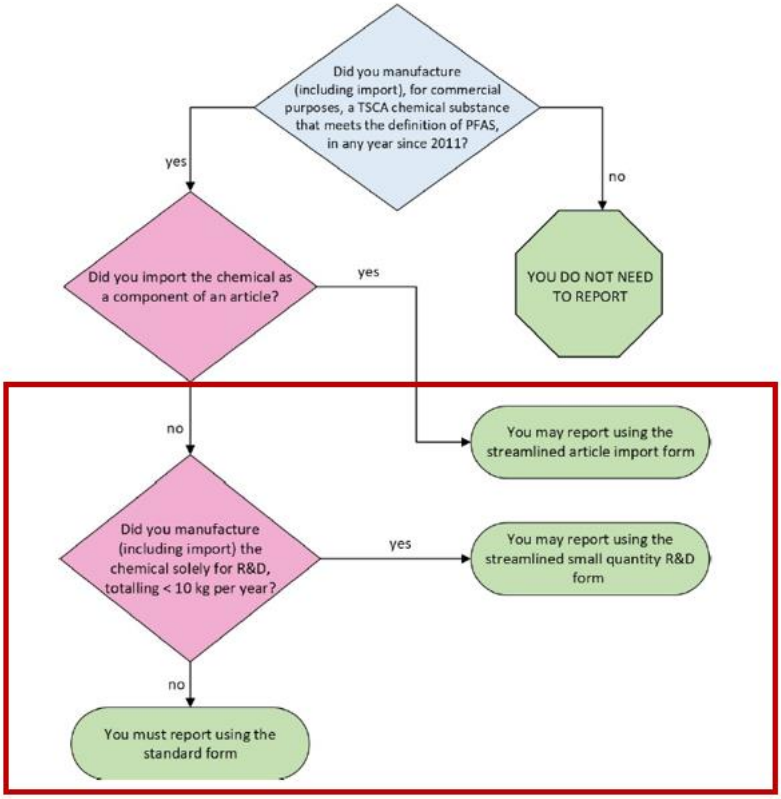


Figure 8. Decision Logic Diagram for Evaluating Step II [15].

Note that knowingly providing false or misleading information or concealing required information may be punishable by fine or imprisonment or both under TSCA section 16(b)(1).

Streamlined Article Import Form

- **Importing an article containing reportable PFAS**

If a company imports an article containing PFAS, it may be subject to the streamlined Article Import form. This simplified form, unlike the standard form, only

The EPA has introduced a **streamlined reporting form** for **importers**, **simplifying the process** while still requiring information on chemical identity, processing, use, and production volume. Importers can report the volume of imported articles by weight or number, with a mandatory inclusion of PFAS concentration if ascertainable.

This streamlined option also applies to **R&D substances in volumes under 10 kilograms per year**. Notably, unlike the general reporting form, it doesn't mandate the reporting of the number of workers exposed to PFAS in imported articles.

requires completion of Part I and specific fields in Part II Sections A, B, and C for importing articles. Importers, often unaware of the PFAS quantity within the articles, can report the production volume as either the total weight of imported articles or the quantity of articles imported, instead of the PFAS weight.

To assist in determining whether a company falls under the definition of importing an article, the EPA has provided a 'Imported Articles' factsheet, accessible here: Imported Articles Factsheet.

- **Reportable PFAS in Quantities Below 10 kg per Year Exclusively for Research and Development (R&D)**

Individuals manufacturing (including importing) PFAS in small quantities exclusively for research or commercial analysis purposes may report using the streamlined small quantity R&D form. This simplified form necessitates reporting only chemical substance identification information, domestic manufacturing and imported volumes, indication of whether the substance was imported but never on-site, and an optional additional information field.

What information need to be reported?

This section outlines the reporting requirements for substances falling under the category of per- or poly-fluoroalkyl substances (PFAS) that meet the Toxic Substances Control Act (TSCA) definition. The reporting obligation applies to all PFAS manufactured (including imported) for commercial purposes within the customs territory of the United States between January 1, 2011, and December 31, 2022. Entities involved in the manufacturing or importation of these substances are mandated to submit a one-time report.

To facilitate the reporting process, Tables 1 and 2 have been developed to guide reporters on the specific information required based on the different Parts and Sections of the TSCA Section 8(a)(7) Reporting form [16].

Table 1 delineates the essential data scope required for submission in Parts I A-B and Part II A-C of the Section 8(a)(7) Reporting form. This delineation serves as a crucial component of the streamlined Reporting Form, offering a concise overview of the required information.

Conversely, Table 2 provides a framework for the necessary data in Part II D-G. It is imperative for reporters to meticulously include the specified details to meet comprehensive reporting obligations. It is important to note that the information outlined in Table 2 is not integrated into the streamlined Reporting Form, emphasizing the need for careful consideration and separate inclusion during the reporting process.

Section	Section Name	General content	Types of requested data
Part I Section A	Parent Company Information	Information about your parent company	Information on U.S. parent(s) company: • Full name, • Address, • DUNS number associated with each parent company.
Part I Section B	Site Information	Information about each site at which a reportable chemical substance is manufactured	Information about site: • Name, • DUNS number, • Detailed address, • NAICS code(s). Assert a claim of confidentiality for site company, or technical contact information
Part II Section A	Chemical Substance Identification	The chemical substance identification information CA Index Name and CASRN must be reported separately for each reportable PFAS at your site	• Confidentiality of Chemical Substance Information • CASRN, TSCA Accession number, or LVE number, • ID Code, • Chemical Name, Trade Name or Common Name, • Generic Chemical Name or Description, • Molecular Structure, • Physical Form.
Part II Section B	The categories of use of each such substance or mixture	The processing or use information	• Industrial Processing and Use, • Type of Process or Use Operation, • Industrial Sectors, • Function Category, • Consumer and Commercial Use, • Product Category, • Functional Use for Consumer and/or Commercial Products, • Consumer and/or Commercial Use, • Use in Product(s) Intended for Use by Children, • Maximum Concentration Code.

Part II Section C	Manufacturing, Processing, and Use Information	The manufacturing information associated with each reported PFAS.	• Confidentiality of Manufacturing Information,
			• Reporting Manufacturing Information:
			  • Manufactured/Imported Production Volume,
			  • Volume Directly Exported,
			  • Percentage of Production Volume,
			  • Recycled Volume.

Table 1. Streamlined Reporting Form - Parts I A-B and Part II A-C [16].

Section	Section Name	General content	Category of data
Part II Section D	A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture	Information about all byproducts that are chemical substances, resulting from the manufacture, processing, use, or disposal of the PFAS. Information to be reported for each byproduct for each year.	• Confidentiality of Byproduct Information, • Byproduct Name or Description, • Byproduct Generic Chemical Name and Chemical ID, • Byproduct Source and Release.

Part II Section E	All existing information concerning the environmental and health effects of such substance or mixture	All information concerning the environmental and health effects of the substance or mixture that is known to or reasonably ascertainable.	• Confidentiality of Environmental and Health Effects Information,
			• Upload attachments:
			  • OECD Harmonized Environmental and Health Effects
			  • Study Report,
			  • Supporting Information,
			  • Analytical/Test Methods,
			  • Other i.e. SDS, preliminary studies, OSHA medical screening etc.

Part II Section F	The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure	Information associated with workers' exposure to the PFAS.	• Confidentiality of Worker Exposure Information, • Worker Activity Descriptions, • Number of Workers Exposed at the Manufacturing Site, for each Industrial Process and Use, for each Commercial Use, • Maximum Duration of Exposure for Manufacturing Workers, for Industrial Workers, for Commercial Workers.
Part II Section G	The manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method	contains information associated with the disposal of the PFAS.	• Confidentiality of Disposal Information, • Manner or Method of Disposal, • Changes in Disposal Methods, • Release Quantity, • Incineration Quantity and Temperature.

Table 2. Table 2: Additional Data Requirements - Part II D-G [16].

Reporting Challenges and Solutions

In specific situations, companies involved in the manufacturing or importing of per- or poly-fluoroalkyl substances (PFAS) may be aware of their involvement in production processes but lack specific knowledge about the identity of the PFAS being used. This commonly occurs when suppliers withhold chemical identities for confidentiality reasons or when companies are unaware of the chemical composition of reaction products or byproducts.

Manufacturers that don't use PFAS in their processes can provide statements supported by documents like Full Material Disclosure (FMD) and Safety Data Sheets (SDS), especially when the product type is known to contain PFAS.

If a manufacturer, including importers, lacks actual data to report to the Environmental Protection Agency (EPA), they should explore the possibility of making 'reasonable estimates' for the required information. 'Reasonable estimates' can involve techniques such as mass balance calculations, emissions factors, or

For reporters unfamiliar with submitting information via EPA's CDX, **EPA has provided helpful guidance documents.** Additionally, user support regarding any technical questions related to EPA's CDX is available through a dedicated:

- help desk
- chat,
- email (helpdesk@epacdx.net),
- toll-free line

  (888-890-1995), or for international callers, (970) 494-5500.

relying on best engineering judgment to establish a basis for compliance with TSCA reporting requirements.

In cases when certain data elements remain unknown or are challenging to estimate, manufacturers may declare such information as "Not Known or Reasonably Ascertainable" (NKRA), emphasizing the importance of accurate reporting only when data are genuinely unattainable or not reasonably ascertainable. This approach ensures transparency and compliance while navigating the complexities of PFAS reporting. *The 'Not Known or Reasonably Ascertainable' (NKRA) designation cannot be claimed for confidential information.

How to submit PFAS data?

All reporting sites are required to electronically submit PFAS data using the web-based reporting tool within EPA's Central Data Exchange (CDX) system, as specified in section 8(a)(7). Before submitting data, reporters must register with EPA's CDX and provide the company name on whose behalf they are submitting. Please note that EPA does not accept paper submissions or electronic media (diskette, CD-ROM, etc.) for any section 8(a)(7) submission.

All records documenting information submitted to EPA must be retained for a period of five years from the reporting deadline.

Compliance Timetable

In May 2025, the EPA announced an interim final rule further extending the reporting period for TSCA Section 8(a)(7) PFAS reporting. The key changes are:

- The **data submission period will now open on April 13, 2026**, instead of July 11, 2025.
- **Most reporters** will be required to complete all reporting **by October 13, 2026.**
- **Small businesses** reporting data solely on importing PFAS contained in articles will have **until April 13, 2027**, to submit reports.

The EPA attributed this additional delay to the need for more time to finalize and test the electronic reporting application, as well as to consider further public comments on the rule. This extension ensures that all stakeholders have adequate time to prepare and submit the required data.

Small manufacturers, as defined in 40 CFR 704.3, reporting exclusively as article importers, are now eligible for an even longer extension under the new timeline.

"**Small manufacturer**" refers to a manufacturer, including an importer, meeting either of the following criteria:

(1) Total annual sales, when combined with those of its parent company, are less than $120 million, and the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lbs); or

(2) Total annual sales, when combined with those of its parent company, are less than $12 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

The EPA Central Data Exchange (CDX) portal is now scheduled to open for PFAS reporting on **April 13, 2026**. The deadline for data submission is set for **October 13, 2026** for most manufacturers and importers.

Small manufacturers reporting exclusively as article importers have until **April 13, 2027** to submit their reports.

This updated timeline ensures a structured and phased approach for entities to fulfill their reporting obligations, allowing ample preparation and compliance with the specified deadlines.

"Small manufacturers" are not exempt from reporting but are given additional time to comply, recognizing the unique challenges they may face in gathering and submitting PFAS data.

According to the EPA's May 2025 interim final rule:

Small manufacturers reporting exclusively as article importers will now have until April 13, 2027 to submit their reports. This represents a substantial extension from the original timeline, giving these entities nearly 36 months from the effective date of the rule to submit the required information.

This extended deadline for small manufacturers who are article importers acknowledges the unique challenges these entities may face in gathering and reporting PFAS data, particularly given their size and potentially limited resources. The additional time is intended to ensure these businesses can thoroughly compile and accurately report the required information without undue burden.

Exemptions

In compliance with the Toxic Substances Control Act (TSCA) 8(a)(7), various exemptions have been established to delineate scenarios where reporting obligations do not apply. Below is a detailed overview of these exemptions, complemented by an additional clarification:

1. **PFAS Substances Not Meeting the Definition:**

Exemptions apply to PFAS substances that do not meet the PFAS definition outlined in the rule.

2. **Exclusion under TSCA Section 3(2)(B):**

This rule does not mandate reporting on activities that are excluded from the definition of "chemical substance" in TSCA section 3(2)(B). Thus, any activities falling under this exclusion are not subject to reporting requirements.

3. **Entities Inactive Since 2011:**

Entities that have not engaged in manufacturing (including importing) activities since 2011 are exempt from reporting obligations.

4. **Exemption for Municipal Solid Waste (MSW) Importers:**

Importers of municipal solid wastes (MSW) for disposal or destruction are exempt from reporting requirements. This exemption is grounded in the practical challenge of determining PFAS presence in MSW streams, as per 40 CFR 705.15.

5. **Exemption for Non-Commercial Research and Development (R&D) Activities:**

Activities not defined as "manufacture for a commercial purpose" are exempt. This includes common non-commercial R&D activities such as scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research organizations. (Note: Exemption does not apply if the activity is intended for eventual commercial purposes.)

6. **Exemption for FDA-Regulated Products:**

Chemicals present in products regulated by the FDA, such as drugs, cosmetics, medical devices, food, or food packaging, as well as pesticides, are exempt from reporting requirements.

7. **Exemption for Ammunition:**

PFAS substances used in ammunition are exempt from reporting obligations.

8. **Exemption for Non-Commercial R&D Work:**

PFAS used specifically for non-commercial R&D purposes are excluded from reporting requirements.

It is essential to comprehend these exemptions thoroughly to ensure compliance with TSCA 8(a)(7) and recognize instances where reporting obligations do not apply.

Collection, Due Diligence, and Reporting

As the countdown to TSCA 8(a)(7) Reporting Rule compliance ticks away, companies must proactively engage in a comprehensive preparation process.

Typically, reporting involves **collaborating with suppliers** to have them confirm whether their substances comply with regulations**.**

This process requires constant updates as regulatory lists evolve, placing an additional burden on both companies and their suppliers. The resulting reporting can lead to suppliers being disinclined to share information about their chemical components.

Full Material Disclosures (FMDs) present a transformative approach by significantly diminishing the frequency of data requests to suppliers**.** FMDs offer the ability to **proactively screen against evolving lists such us PFAS** and monitor indicators of impending changes.

This guide outlines a strategic approach to data collection, due diligence, and reporting, ensuring not only compliance with regulatory obligations but also the adaptability of businesses to evolving global PFAS regulatory standards.

1. **Product Scope Identification:**

Initiate a process to identify products manufactured or imported for commercial use in the U.S. between January 1, 2011, and December 31, 2022.

2. **Current Database Check:**

Once you establish a scope of potential products, examine whether substance data is available for any of these items. Subsequently, assess whether any of the identified substances align with the TSCA PFAS definition. At this juncture, possessing Full Material Disclosure (FMD) for your products provides a solid foundation for further evaluation. Utilize tools like DXC's Compliance Data eXchange (CDX) to reinforce your assessment of products against rule requirements.

To integrate data into the CDX, you can either manually create the structure or opt for web service uploads from your EPR in-house system. This process establishes a definitive baseline for evaluating products with existing substance data, highlighting those containing TSCA-listed substances. This systematic approach ensures a comprehensive understanding of product composition and facilitates a thorough evaluation in compliance with TSCA PFAS regulations.

3. **Gap Analysis and Prioritization:**

Once you identify the products for which data is available, it is essential to pinpoint those with data gaps. Addressing these gaps becomes integral during the data collection process from your suppliers. Given the potentially extensive nature of this task, effective prioritization becomes crucial. Therefore, after discerning which components lack sufficient data within the products, prioritize them based on the potential risk of containing PFAS.

Concentrate your efforts on evaluating high-risk components as a starting point to streamline the assessment process. This focused approach ensures a targeted and efficient evaluation, allowing resources to be allocated where they are most needed. By adopting this strategy, you can systematically address data gaps in a manner that aligns with the risk profile, optimizing the overall effectiveness of the evaluation process.

Compliance Data Exchange (CDX) by DXC Technology offers a cloud-based Software-as-a-Service (SaaS) solution accessible through a web browser, eliminating the need for complex IT infrastructure. It facilitates **the creation, search, extraction, evaluation, exchange, and retention of information required for TSCA 8(a)(7) compliance.** DXC's CDX includes data validation rules and curated substance lists to enhance accuracy and streamline data collection.

Stay up to date with regulatory changes through DXC's CDX, ensuring compliance with global regulatory landscape.

Integrate DXC's CDX with existing systems using the Web Services Interface (WSI) to automate data exchange and enhance product development and reporting workflows.

4. **Preparation for Data Collection Campaign:**

It is crucial to brief your suppliers on the upcoming data collection campaign before initiating the requests. Organize a webinar featuring a Q&A session to elucidate the purpose of the requests, guide them on the process of providing data within specified timelines, and communicate your expectations clearly. Outline potential consequences if they encounter challenges and inquire about the support they may require from your end to ensure timely data submission. To consolidate this information, develop comprehensive guidance, factsheets, FAQs, and support teams, aiming to actively engage and assist your suppliers throughout the process.

5. **Utilize DXC's Compliance Data eXchange (CDX) for Early Reporting:**

Once you identify the gaps in your knowledge, take proactive steps to gather the missing data from y our supplier. It is advisable to focus on obtaining information at the Full Material Disclosure (FMD) level whenever feasible. This could be an opportune moment to revisit and enhance your supplier agreements and tender processes, incorporating specific requirements for the provision of FMD data.

The process of gathering data extends beyond mere request submissions, encompassing potential phone calls or email inquiries directed towards upstream suppliers, downstream users, employees, or other agents involved in various stages of the manufacturing process, including research and development, import, production, or marketing of the PFAS. This may involve a thorough examination of manufacturer-maintained files, such as marketing studies, sales reports, or customer surveys, as well as consulting standard references containing information on the use or concentrations of chemical substances in mixtures, such as Safety Data Sheets (SDS) or supplier notifications.

6. **Report data to EPA's Central Data Exchange**

Starting from **April 13, 2026**, you are able to report already collected data to the EPA CDX Portal. Complete this task once you have data to avoid reporting everything at once.

The EPA CDX portal will remain open for submissions until the reporting deadline on **October 13, 2026**. For small manufacturers functioning as article importers, the reporting deadline is extended to **April 13, 2027**.

Meeting these deadlines is essential for compliance and participation in regulatory requirements.

7. **Evaluate Corrective Actions:**

After completing the data collection phase, conduct a comprehensive assessment to evaluate the feasibility of replacing PFAS in products with alternative solutions. Examine the effects of changing regulatory trends and consider measures to align your products with new environmental standards to ensure long-term sustainability.

It is crucial to note that the submission timeline extends until the reporting deadline on **October 13, 2026**. For small manufacturers functioning as article importers, the reporting deadline is extended to **April 13, 2027**.

By following these steps, companies meet TSCA 8(a)(7) reporting requirements and demonstrate environmental responsibility in adapting to regulatory changes.

Key Definitions for Compliance

Definitions act as your guiding stars, ensuring that your reporting stays on course and aligns flawlessly with regulatory expectations. This precision isn't just about compliance; it's your secret sauce for data accuracy, elevating your reporting game to new heights of consistency and reliability.

Embrace the strategic advantage: these definitions are your risk-assessment allies, providing a structured framework to navigate potential pitfalls. By adhering to these regulatory signposts, you're not just ensuring compliance; you're safeguarding your brand from inadvertent missteps and setting the stage for a future of unblemished legal integrity.

A clear understanding of definitions is essential for compliance with the TSCA 8(a)(7) rule. Accurate identification of substances, alignment with regulatory requirements, and consistent interpretation among stakeholders are crucial. A thorough grasp of definitions is fundamental for navigating the complexities of the rule, facilitating accurate reporting, and contributing to overall regulatory compliance and effective risk management.

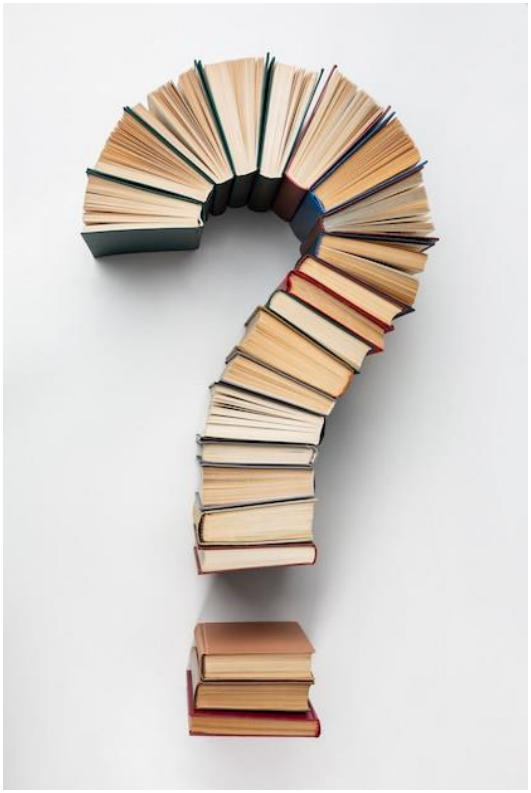
- **Article:** a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those 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. (40 CFR 704.3).
- **Byproduct:** a chemical substance produced without separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s). (40 CFR 704.3)).
- **EPA's Central Data Exchange (CDX):** EPA's centralized electronic document receiving system, or its successors, including associated instructions for registering to submit electronic documents.
- **Chemical substance:** any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. "Chemical substance" does not include:

  (1) Any mixture;

  (2) Any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide;

  (3) Tobacco or any tobacco product;

  (4) Any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.] and the regulations issued under such Act);



(5) Any article the sale of which is the subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [26 U.S.C. 4181] (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges); and

(6) Any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. (See TSCA 3(2))

- **Commercial use:** the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.
- **EPA:** the United States Environmental Protection Agency. (40 CFR 704.3)
- **Importer:** any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the United States and includes: the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his/her behalf..
- **Manufacture:** to manufacture, produce, or import, for commercial purposes.

  Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of substances. A chemical substance is co-manufactured by the person who physically performs the manufacturing and the person contracting for such production when that chemical substance, manufactured other than by import, is: (1) produced exclusively for another person who contracts for such production, and (2) that other person dictates the specific identity of the chemical substance and controls the total amount produced and the basic technology for the manufacturing process. [15 U.S.C. 2602(9)]
- **Manufacturer** means a person who manufactures a chemical substance.
- **Manufacture for commercial purposes:** to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes among other things, such “manufacture” of any amount of a chemical substance or mixture:
  - For commercial distribution, including for test marketing.
  - For use by the manufacturer, including use for product research and development, or as an intermediate.

  Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture.
- **Parent Company:** a company that owns or controls another company. (40 CFR 704.3)

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