



THE COMPLETE GUIDE TO PFAS Reporting Under **TSCA Section 8(a)(7)**

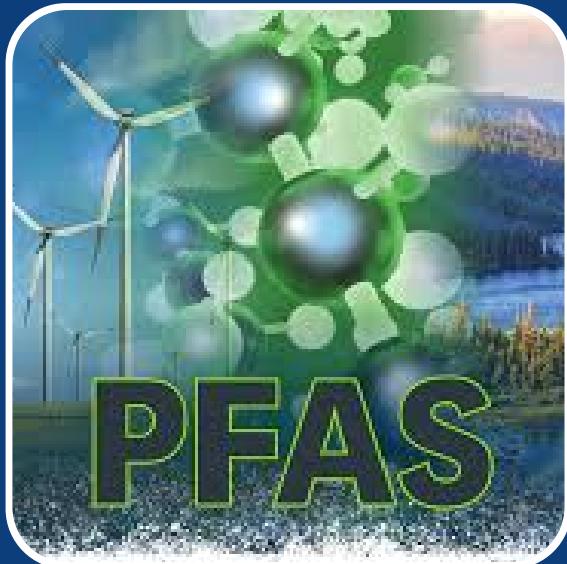
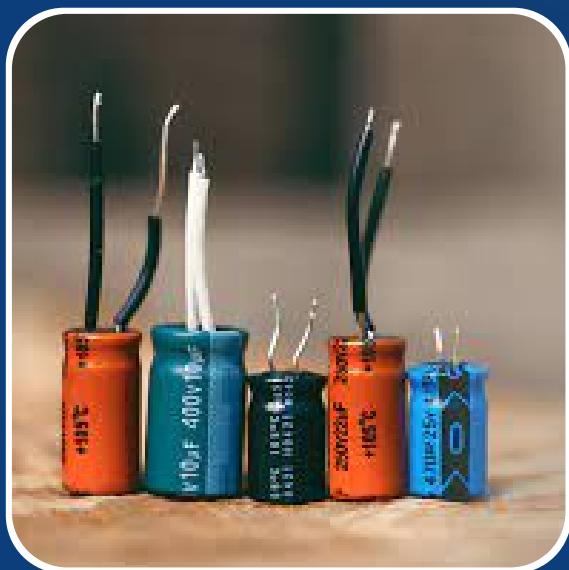


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Chapter 1: Background of US EPA PFAS Final Rule (TSCA Section 8(a)(7))

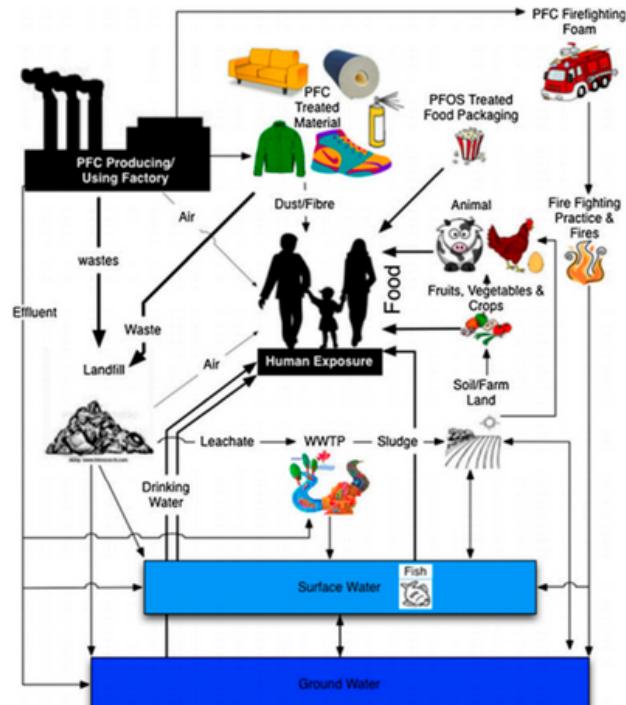
In the ever-evolving terrain of environmental governance, a seminal moment emerged with the introduction of the PFAS Final Rule under Section 8(a)(7) of the Toxic Substances Control Act (TSCA) in October 2023. This landmark regulation served as a pivotal milestone in addressing the complex challenges posed by Per- and Polyfluoroalkyl Substances (PFAS).



The Rise of PFAS and Growing Concerns: PFAS are a diverse group of synthetic chemicals with unique properties like water and oil repellence, making them widely used in various industries. However, their growing ubiquity has coincided with increasing scientific evidence suggesting potential health and environmental risks associated with their use and disposal. Studies show possible links between PFAS exposure and various health problems. Furthermore, the persistent nature of PFAS and their mobility in the environment raise concerns about water contamination and potential harm to wildlife.

Recognizing the growing concerns surrounding PFAS, the EPA established the PFAS Final Rule to:

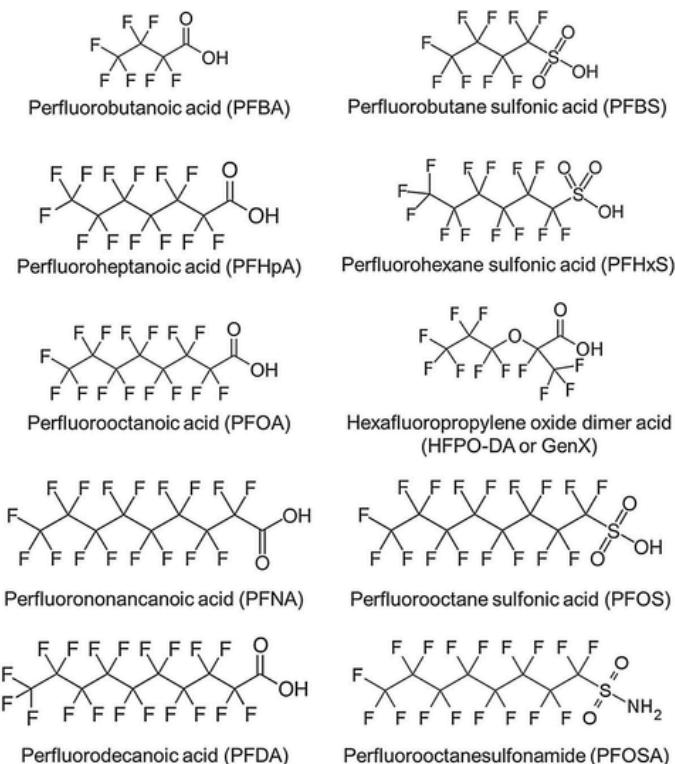
- Gain a comprehensive understanding of the scope and scale of PFAS manufacturing and use in the United States: This data will be crucial for informing future regulatory actions and risk assessments related to PFAS management.
- Empower stakeholders with valuable information: The collected data will be beneficial for researchers, policymakers, and the public, fostering a more informed discussion and easing the development of effective PFAS management strategies.
- Lay the groundwork for future regulatory actions: By establishing a baseline understanding of the current PFAS landscape, the EPA can better tailor future regulations and interventions aimed at mitigating potential risks associated with these chemicals.



The rule became effective in October 2023, and companies have designated deadlines to submit their initial reports to the EPA.

Chapter 2: The Rising Concern of PFAS: Drivers Behind Regulatory Actions

PFAS is a type of man-made chemical known for its strong and durable structure. What makes PFAS special is the powerful bond between carbon and fluorine atoms, called the carbon-fluorine (C-F) bond. This bond is incredibly robust, giving PFAS exceptional stability and resilience against breaking down. It's like having a super-strong glue holding everything together.



The backbone of PFAS is made up of a series of carbon atoms linked to fluorine atoms, creating what's known as a fluorocarbon structure. This unique arrangement gives PFAS a hydrophobic (water-repellent) nature, making them resistant to water, oil, and other liquids. Because of the sturdy carbon-fluorine bond, PFAS can withstand harsh environmental conditions without breaking apart easily, which is why they tend to stick around in the environment for a long time.

Diverse Group with Widespread Applications:

PFAS come in many different forms, each with its own set of properties that make them valuable to various industries. Here are some examples of where you might find PFAS being used:



- Non-stick Coatings:** Think of your favorite non-stick frying pan or baking sheet. PFAS are often used in these coatings to make them resistant to sticking.
- Water Repellents:** Your waterproof jacket or stain-resistant carpet may contain PFAS to repel water and stains.
- Firefighting Foams:** Airports and military bases use PFAS-based foams to extinguish fires quickly and effectively.
- Industrial Applications:** PFAS are used in metal plating, electronics manufacturing, and various paints and coatings for their protective properties.
- Medical Devices:** Certain medical devices like implantable devices and catheters utilize PFAS for their biocompatibility and durability.

Potential Health Concerns: Although PFAS offer a range of valuable functionalities, growing scientific evidence suggests potential health risks associated with their use and disposal. Several studies have found possible links between PFAS exposure and various health issues, including:

Health Concerns	Environmental Concerns
Cancers	Persistence
Developmental problems in children	Mobility
Thyroid issues	Bioaccumulation
Immune system dysfunction	

In essence, PFAS are a versatile group of chemicals with a wide range of uses, thanks to their unique structure and properties. However, their persistence in the environment and potential health concerns have sparked debates and regulatory actions aimed at better understanding and managing their impact.

Chapter 3: USA TSCA Section 8(a)(7) PFAS Reporting & Record-keeping Requirement

TSCA section 8(a)(7) requires EPA to promulgate a rulemaking requiring manufacturers (including importers) of a perfluoroalkyl or polyfluoroalkyl substance (PFAS) in any year since January 1, 2011, to submit a report to EPA holding information outlined in section 8(a)(2) for each year since January 1, 2011, through 2022.



Manufacturers: Any company that produces PFAS domestically.
(Not processors/ users/ disposers)



Importers: Any company that brings PFAS into the US from other countries.
(Chemicals/ Chemicals in containers/ PFAS in articles (products))

To comply with the PFAS data reporting rule, manufacturers (including importers (articles)) must utilize the section 8(a)(7) reporting tool on the EPA's CDX platform for submissions in accordance with the section 8(a)(7) rule ([40 CFR Part 705](#)). Online registration with CDX is mandatory, specifying the company's name on whose behalf the submission is made. Paper and electronic media submissions are not accepted by the EPA for section 8(a)(7) submissions (40 CFR 705).

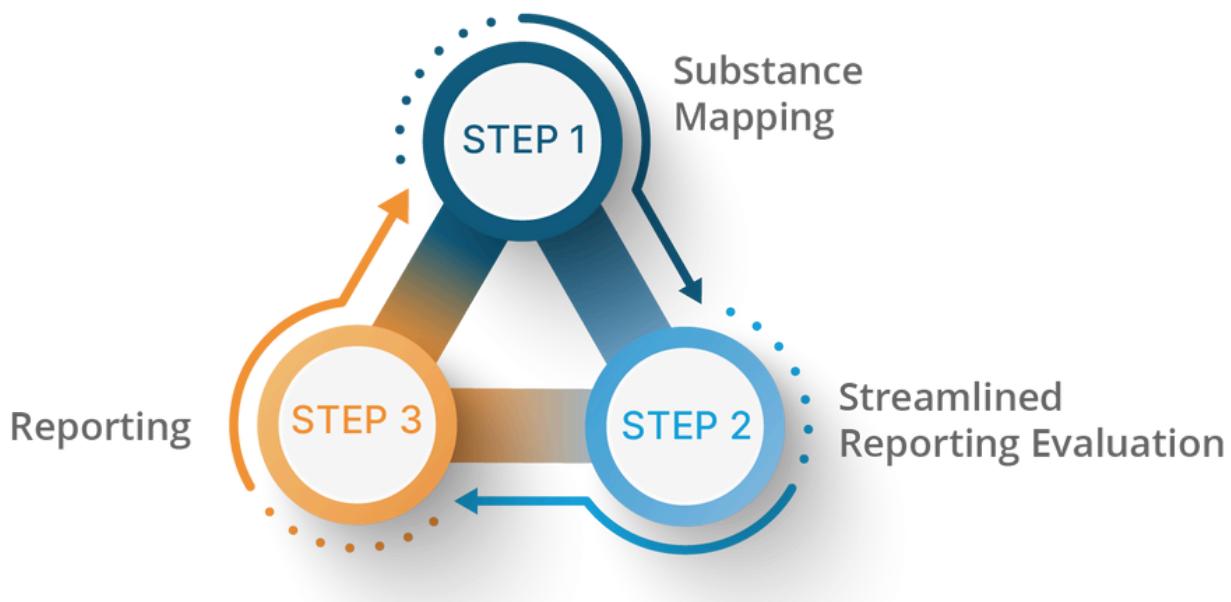
It is important to note that the terms "manufacture" and "manufacturer" also include "import" and "importer," respectively.
Importer of article* which has PFAS are subjected to comply with this rule.

*Article: means a manufactured item which:

- Is formed to a specific shape or design during manufacture.
- Has end-use function(s) depending in whole or in part upon its shape or design during end use.
- 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.

Chapter 4: Determining PFAS Reporting Obligation for Your Business Under TSCA Section 8(a)(7)

To determine reporting requirements for each PFAS chemical substance domestically manufactured (including imported) into the United States from 2011 to 2022, consider the following three steps:



Step I: Substance Mapping

The first step in determining your reporting obligations is Substance Mapping. This involves identifying the PFAS chemicals your business deals with and assessing their production or import timeline.

Begin by examining any chemicals your business manufactures (imports, or uses in products/articles) to determine if they contain any of the following three structural units:

- I. **R-(CF₂)-CF(R')R'',** where both CF₂ and CF are saturated carbons.
- II. **R-CF₂OCF₂-R',** where R and R' can be fluorine (F), oxygen (O), or saturated carbons.
- III. **CF₃C(CF₃)R'R'',** where R' and R'' can be fluorine (F) or saturated carbons.

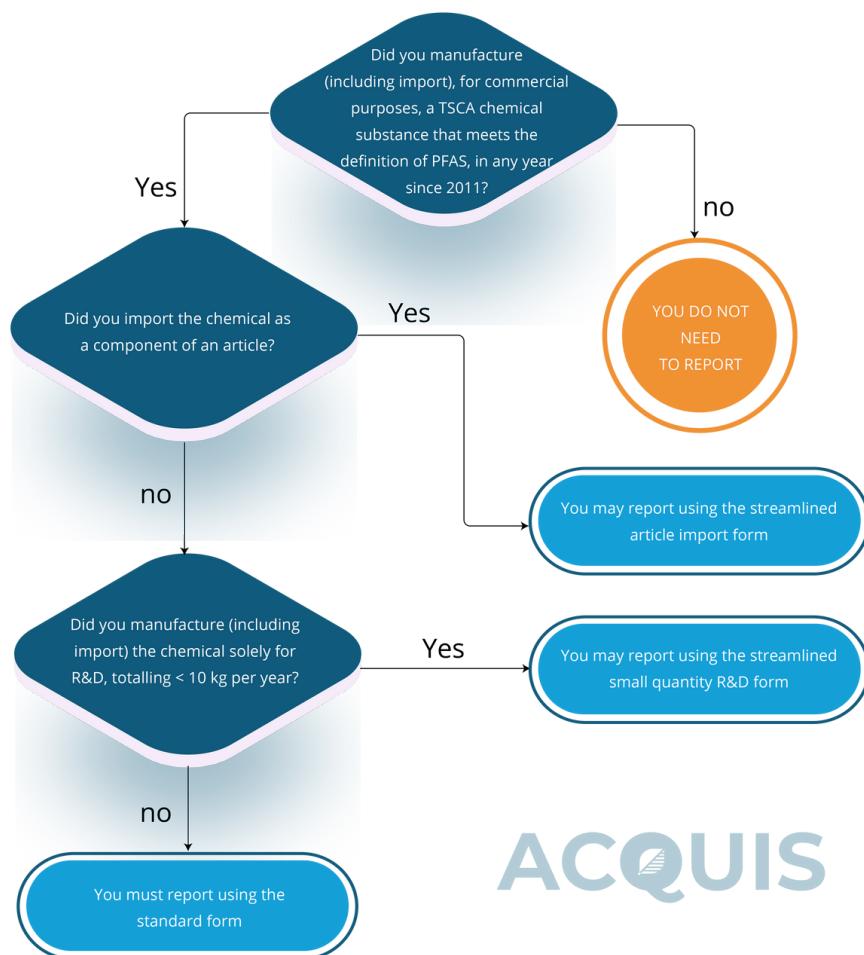
Then, cross-reference the manufacturing or import dates of these chemicals/articles with the established timeline to confirm if your business is subject to reporting requirements. If there are any questions regarding changes in ownership or legal entities, consult the [CDR Rule release of 2016](#) for clarification on a case-by-case basis.

Keep in mind that the definition of PFAS in this rule may vary from other definitions used by the EPA or other organizations. For more accurate mapping, refer to the [EPA's CompTox Dashboard](#).

It's crucial to note that manufacturing PFAS as a byproduct, impurity, or non-isolated intermediate does not exempt your business from reporting obligations, unlike certain other reporting regulations.

Step II: Streamlined Reporting Evaluation

This is the second step in finding the obligation. Refer to the below logic diagram to understand clearly which category applies to your business. This will help you in landing in exact obligations.



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Step III: Reporting

After completing Steps I and II and confirming that you fall under the reporting obligations as a manufacturer (including importer) of a PFAS subject to reporting, this section details the specific information you are required to submit.

If you are obligated to report and do not qualify for streamlined reporting, you must provide all the information outlined in 40 CFR 705. However, importers of PFAS-containing articles and manufacturers (including importers) dealing with small quantities for research and development (R&D) purposes may choose to use streamlined reporting forms.

The following fields are mandatory for businesses during the reporting process:

- Name of the PFAS
- CAS number
- Structural definition
- Categories of use
- Amount produced or used.
- PFAS byproducts
- Existing information on environmental and health effects
- Number of people exposed.
- Manner of disposal for each PFAS

It's important to note that while streamlined reporting offers a simplified process for some entities, comprehensive reporting is required for others, ensuring transparency and compliance with regulatory standards.

TSCA Section 8(a)(7) Exemptions

There are no generic exemptions provided for this rule unlike other CDR rules and the exemptions are extremely limited.

- Any businesses / persons manufactured (including import) only before January 1, 2011, are exempted from this rule. (However, change in organization/ ownership must be assessed)
- Persons who have only processed, distributed in commerce, used, and/or disposed of PFAS are exempted from reporting.
- No minimum volume or concentration exemption – any amount of PFAS known to be manufactured is reportable.
- Sites that import municipal solid waste streams for disposal or destruction are excluded from reporting those amounts of PFAS imported in MSW for disposal/destruction.
- No small manufacturer exemptions are in effect for this data call.

Chapter 5: Step-by-Step Process for PFAS Reporting in CDX Portal

Let's first understand how to create an account in EPA's CDX portal required for TSCA Section 8(a)(7) PFAS Reporting.

- Visit the [CDX portal](#) and login if you already have an account, or click on the "Register with CDX" button.
- Read and accept the terms and conditions presented.
- Select the appropriate program service, such as TSCA.
- Provide your user ID, password, and organization data as requested.
- Confirm the code received in your email to finalize the account creation process.
- Once your account is created, you can start reporting according to the rule requirements.
- For further guidance and ease of understanding, refer to the [guide document](#) provided.



The standard reporting format have certification statement & three parts. Each segment demands a different set of data fields for comprehensive reporting.

Part I

This part includes details such as Company information, Site details, Contact information. (Some of this information is automatically filled in from your CDX account data).

The certification statement is covered in this part. (To acknowledge submitted data legally/ officially)

After completing this section for a reporting site, the reporting tool will automatically use the provided information for any additional forms related to the same site.

The above information is to be filled out once for each reporting site

Part II

This part is quite bigger and requests to fill out the fields with chemical data, and this part is segmented into 8 sections namely (A, B, C, D, E, F, G, H)

Section A, B, C	For each PFAS you need to report. This includes identity, manufacture, and properties of the chemical substance.
Section D	For any byproducts produced during the manufacture of each PFAS.
Section E	For each PFAS, covering its environmental and health effects.
Section F	For each PFAS, focusing on information related to workers' exposure.
Section G	For each PFAS, providing details about how the substance is disposed of
Section H	Open & optional field to provide additional remarks/information.

These sections are subject to vary based on your obligations (Chemical manufacturer/ Article Importer/ R&D Manufacturer). Kindly ensure you're selecting the appropriate form before seeding your information.

Part III

This part is for each chemical substance at the site where confidentiality claims are made for certain data elements.

If substantiations of these confidentiality claims are necessary during data submission, provide the required information in this section.

Important Terminologies You Must Know Before Reporting:

Duplicate Data:

If your business has previously reported section 8(a)(7) data to EPA through another program (example CDR/ GHGRP), check whether EPA has labelled it as "duplicative" in the section 8(a)(7) rule. If so, you don't need to re-report duplicative information, but you must submit a report including all details required by this data call that haven't been reported to EPA before. For the years 2011 to 2022, report any missing information.

If previously reported data lacks the required detail or used exemptions not applicable to this data call, report the necessary information at the required level. If new, more accurate, or detailed information is available, report it under this data call.

Ascertainable Data:

Submitters are required to exercise certain levels of due diligence in gathering the information required by the section 8(a)(7) rule. You must report your information to the extent that the information is known to or reasonably ascertainable by you and your company.

This means known to or reasonably ascertainable by 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.

CBI:

CBI stands for Confidential Business Information. It refers to sensitive business-related information that, if disclosed, could harm a company's competitive position. Under



various regulations, including the Toxic Substances Control Act (TSCA), businesses can claim certain information as CBI to keep it confidential. However, these claims are approved only after performing various evaluation methods by EPA. If you're claiming any CBI, then substantiations are to be submitted and check box for CBI should be checked. Otherwise, the data will be publicly shared without any notification.

Reporting UVCB:

If a PFAS is produced through a chemical reaction, it qualifies as a UVCB substance under TSCA, treated as a single chemical. For imported mixtures, report individual PFAS components. Domestic manufacturers assess if PFAS results from manufacturing mixtures and report accordingly. If no chemical reaction occurs, no reportable substances are generated. Consider identifying domestically manufactured or imported chemical combinations as a single UVCB substance.

Chapter 6: PFAS Reporting Deadlines & Challenges

Act quickly and don't wait for the deadline. As you've understood the actual expectations from EPA, start collecting the actual data within/out of your organisations. This timeline is spread over 18 months from the date of enforcement of this rule.

The EPA Final Rule on PFAS Reporting (Record-keeping under Section 8(a)(7)) was enforced on 11th October 2023.

Key Dates	Description
11th October 2023	EPA Final Rule Enforced
11th November 2024	*1 year period for data collection on chemicals
12th November 2024	**The reporting portal opens (CDX)
8th May 2025	***Deadline for most manufacturers
10th November 2025	****Deadline for small manufacturers

*One year period is generic timeframe to collect the information on covered chemicals. However, manufacturers can override this date but ensuring the final reporting deadline should be met (8th May 2025)

**The reporting section of the portal will be accessible for the registered user only after this date.

***This is common deadline for all the manufacturers (including importers). No deviation will be allowed as per current amendments.

****This is extended deadline only applicable to small manufacturers (including importers) as described in [40 CFR 704.3](#).

Each company required to report must maintain records documenting any information reported to EPA. The records must be maintained for five years after that company's reporting deadline.

Sourcing PFAS data manually within the supply chain is a complex task that may not be feasible without the presence of proper expertise, such as experienced compliance professionals, consultants, or effective tools. Additionally, it's important to note that exemptions provided under this rule are extremely limited, and the majority of businesses involved in handling PFAS substances are required to report their data.

Challenges in reporting under TSCA Section 8(a)(7) rule:

Reporting under TSCA Section 8(a)(7) presents unique hurdles for both importers and manufacturers of articles. Below are the key challenges they confront:

- 1. Identifying PFAS in Articles:** Discerning PFAS presence in imported articles is intricate, especially for complex products or those lacking transparent supply chains.
- 2. Data Collection in the Supply Base:** Accurate reporting relies on data from foreign suppliers, often hindered by communication barriers and differing regulations.
- 3. Estimating PFAS Content:** Quantifying PFAS amounts within articles is complex, particularly for intricate mixtures or when specific data is elusive.
- 4. Understanding the Reporting Tool:** Unfamiliarity with the EPA's online reporting system may lead to errors or delays, posing challenges for companies unaccustomed to such platforms.
- 5. Meeting Deadlines:** Tight reporting deadlines add pressure, particularly for companies requiring additional time for comprehensive data gathering and analysis.
- 6. Confidentiality Concerns:** Balancing reporting requirements with trade secret protection for PFAS formulations demands meticulous consideration, especially when confidentiality is paramount. Even CBI functionality requires proper substantiation.
- 7. Limited Resources:** Smaller enterprises with constrained resources may struggle to allocate personnel and technical expertise for efficient data collection and reporting.
- 8. Staying Updated:** Keeping abreast of potential regulatory changes or clarifications demands time and vigilance, requiring companies to stay informed through regular EPA updates.



Overcoming these challenges demands a strategic and informed approach, enabling article importers and manufacturers to ensure precise and timely reporting while adeptly manoeuvring the complexities of TSCA Section 8(a)(7).

TSCA PBT EU Batteries WEEE EU Packaging EU MDR TSCA 8(a)(7) PFAS ...

* Compliant

No

* Substance of Concern

Pentadecafluorooctanoic acid (PFOA)

Concentration of PFAS

5000

Concentration Unit

ppm

Compliance Document

PFAS Declaration.pdf

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Acquis Compliance offers a free tool to kickstart your PFAS compliance journey. With the free subscription, you can import up to 3000 parts or up to 100 suppliers and reach out to them, requesting PFAS declarations, substances of concern, and their concentrations (if any) using a unique supplier portal provided to each supplier, listing the parts they supply to your company.

Designed especially for Complex Product/Article Manufacturers, Acquis Compliance Tool allows you to gather information from your sub-suppliers, enabling you to generate the necessary reports for TSCA Section 8(a)(7) reporting.

If needed, you can also utilize the help of experienced compliance resources at Acquis to manage your regulatory program, engage with a global supplier base, validate the sourced documents, and assist you in submitting the report to the EPA via the CDX system on time.



Chapter 7: Consequences of Non-Compliance with PFAS Reporting & Record-Keeping Requirements

Section 17 of the Toxic Substances Control Act (TSCA) is a crucial component when it comes to enforcement actions related to non-compliance with PFAS reporting and record-keeping requirements. This section empowers the EPA with a range of tools and authorities to ensure that companies and entities adhere to the regulations set forth under the TSCA framework.

1. Civil Administrative Penalties:

- a) The EPA Administrator may assess civil penalties of up to \$37,500 per day/ violation of Section 15 or 409 (prohibited acts).
- b) Each day of non-compliance constitutes a separate violation. The penalty amount considers the nature, severity, and duration of the violation, the violator's ability to pay and potential impact on business operations, any prior violations, and other relevant factors.
- c) The Administrator has the discretion to compromise, modify, or remit assessed penalties.

2. Criminal Penalties:

- a) Knowing or wilful violations of Section 15 or 409 can result in criminal prosecution, leading to Fines of up to \$50,000 per day of violation, or imprisonment for up to one year, or both.
- b) Knowing and wilful violations that create imminent danger of death or serious bodily injury carry harsher penalties for individual (up to \$250,000 or imprisonment for up to 15 years, or both) and for businesses (Fines of up to \$1 million per violation)

3. Injunctive Relief:

The EPA may seek court injunctions to the following actions listed below:

- a) Restrain violations of Section 15 or 409.
- b) Prohibit actions in violation of Sections 5, 6, or Title IV of the TSCA.
- c) Compel actions required by the TSCA.

Order manufacturers or processors of non-compliant products to:

- a) Notify distributors and potentially exposed individuals about associated risks.
- b) Issue public warnings regarding the risks.
- c) Recall or repurchase non-compliant products.

4. Seizure:

The EPA has the authority to seize the following:

- a) Substances/ mixtures/ products manufactured, processed/ distributed (if violated)
- b) Articles containing such non-compliant substances or mixtures.
- c) Seized items are subject to court-ordered condemnation.



**OTHER RESOURCES YOU
MAY BE INTERESTED**

- [Mastering PFAs Global Regulation For Manufacturers](#)
- [Regulatory Compliance: 2023 Year in Review By Acquis Compliance](#)
- [The Complete Guide to ROHS Compliance](#)
- [The Complete Guide to Conflict Minerals Reporting](#)
- [PFAS Blog](#)

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