



# TSCA Section 8(a) PFAS Reporting

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**Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 88 Fed. Reg. 70516 (Oct. 11, 2023); 40 C.F.R. Part 705.**

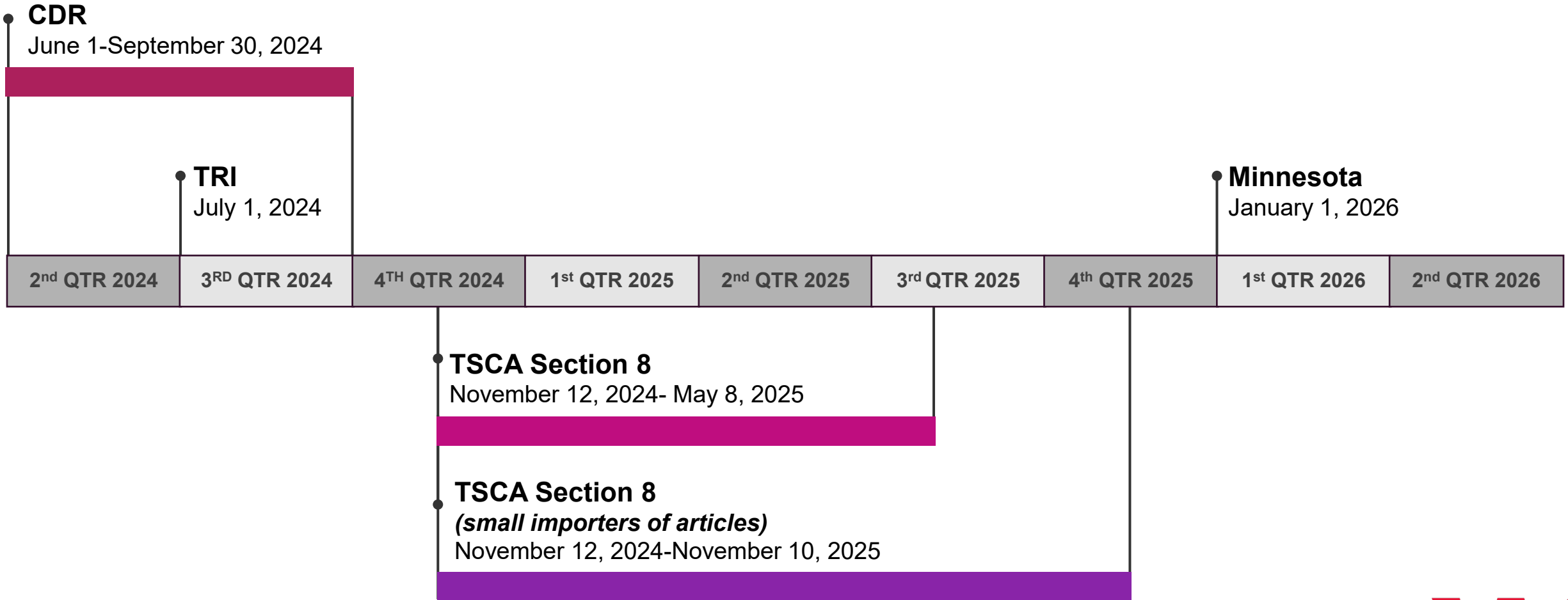


# Today

- Trends
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- Articles
- Systematic Approaches
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# PFAS Reporting is Trending



# TSCA Section 8(a) Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Reporting Rule

- **WHO:** The TSCA Section 8(a)(7) PFAS reporting requirement applies to **manufacturers (including importers)** both small and large that have manufactured PFAS in any year from **January 1, 2011, through the end of the last calendar year prior to November 13, 2023**. 40 C.F.R. § 705.10.
- **WHAT:** EPA will make a list of reportable PFAS with Chemical Abstracts Service Registry Numbers (CASRN) available on the [CompTox Chemicals Dashboard](#). However, reporting is also required for PFAS that do not have CASRNs if they meet the definition in the rule.
  - No exemptions for articles, impurities, or byproducts and no de minimis threshold for reporting.
- **WHEN:** Reporting begins on **November 12, 2024**. Forms are due by **May 8, 2025**, except for small importers of articles, whose reports are due **November 10, 2025**. 40 C.F.R. § 705.20.
- **HOW:** Aside from the **regular reporting form**, EPA provides the shorter, **streamlined reporting form** for article importers that do not know or cannot reasonably ascertain all of the information on the standard form, and for manufacturers of R&D substances in quantities below 10 kilograms annually. **Joint submissions** are available for PFAS manufacturers to work with suppliers who want to protect the identity of their ingredients. Companies should claim CBI consistent with the provisions under TSCA Section 14.



## PFAS Definition (for Section 8(a) Reporting)

- PFAS is defined as including at least one of these three structures:
  - $R-(CF_2)-CF(R')R''$ , where both the  $CF_2$  and  $CF$  moieties are saturated carbons;
  - $R-CF_2OCF_2-R'$ , where  $R$  and  $R'$  can either be  $F$ ,  $O$ , or saturated carbons; and
  - $CF_3C(CF_3)R'R''$ , where  $R'$  and  $R''$  can either be  $F$  or saturated carbons.
- The definition includes fluoropolymers regardless of molecular weight and gases but does not include substances that only have a single fluorinated carbon, or unsaturated fluorinated moieties (e.g., fluorinated aromatic rings and olefins).
- *Historical Note on proposed definition: Per- and polyfluoroalkyl substances or PFAS, for the purpose of this part, means any chemical substance or mixture that structurally contains the unit  $R-(CF_2)-C(F)(R')R''$ . Both the  $CF_2$  and  $CF$  moieties are saturated carbons. None of the  $R$  groups ( $R$ ,  $R'$  or  $R''$ ) can be hydrogen. This is the first structure above. EPA added the two additional structures to refine the risk-based approach of the definition.*

# Form Choice for Imported Articles: EPA Instructions

- Section 2.3, p. 2-8 – Article importers have the option to use the **streamlined article import form**. No conditions for selection – just use it.
- Selecting this form reduces the due diligence inquiry.
  - No obligation to seek out chemical identity. Still need information on processing and use.

**Example 2-3.** Example Company I begins importing an article containing Example PFAS I in 2017 and continues importing the article through 2022. Example PFAS I provides stain resistance in a finished textile product. Example Company I does not produce or import any other products containing Example PFAS I.

Because Example PFAS I is only imported in an article, Example Company I reports for this chemical using the streamlined article importer form.



# Choice of Forms – Streamlined Article Import Form

## \* remaining areas for due diligence inquiry

1. Company and plant site information of the submitter, authorized official, and technical contact.
2. NAICS code, D&B number, other site identifiers for each site.
3. To the extent known, trade name, specific chemical name and associated CASRN, Accession number, LVE number, generic name, and molecular structure as applicable. *If specific chemical identity information is not known, provide a generic name or description.*
4. Selected code designations for the categories of industrial processing and use, industrial sector(s), and function.
5. Up to ten commercial and consumer product category code designations, functional purpose, and whether the product is intended for children.
6. For each consumer and commercial product category, a range for the estimated typical maximum concentration, by weight, per year.
7. Whether the PFAS in the article is ever physically present at the reporting site.
8. Import volume of the article and the unit of measurement (e.g., quantity of the imported article, pounds, tons).
9. Any other information the article importer wishes to provide.



# Choice of Forms for Articles - Standard Form

\* overlap with streamlined article import form

1. Company and plant site information of the submitter, authorized official, and technical contact.
2. NAICS code, Dun & Bradstreet (D&B) number, other site identifiers for each site.
3. Trade name, specific chemical name and associated CASRN, Accession number, LVE number, generic name, and molecular structure, as applicable. *If specific chemical identity is not known, due diligence to identify a joint submitter is necessary.*
4. For joint submissions, contact information for the supplier, a trade name or other designation for the chemical substance, and a copy of the request to the supplier or other entity.
5. Selected code designations for the categories of industrial processing and use, industrial sector(s), and function.
6. Up to ten commercial and consumer product code designations, functional purpose, and whether the product is intended for children (14 years or less).
7. For each consumer and commercial product category, a range for the estimated typical maximum concentration, by weight, per year.
8. For each PFAS at each site, whether the imported PFAS is physically present at the site, site-limited, or recycled on-site.
9. The physical form(s) of the PFAS as it is sent off-site from each site. If the PFAS is site-limited, each physical form of the PFAS at the time it is reacted on-site to produce a different chemical is needed.
10. The total amount of PFAS manufactured (including imported) per year, amounts for each category of use, and separated reporting for the amount domestically manufactured or imported per site.
11. For each reported combination of industrial processing, use, sector, and function, the estimated percentage, rounded off to the closest 10 percent, of total production volume of each PFAS.
12. For each reported consumer and commercial product category, the estimated percentage, rounded off to the closest 10 percent, of the site's total production volume.
13. The volume directly exported of each PFAS domestically manufactured or imported at each site.
14. Each byproduct produced from the manufacture, processing, use, or disposal of a PFAS, if it is released to the environment and in what quantity.
15. All existing information concerning the environmental and health effects of each substance or mixture.
16. The number of workers exposed, type of activity, daily and annual exposure duration estimates for each activity, maximum exposure and duration.
17. Releases to air, water, and land, the manner or method of disposal of each substance or mixture, and any change in such manner or method.





# Streamlined article import form: no due diligence on chemical identity required.

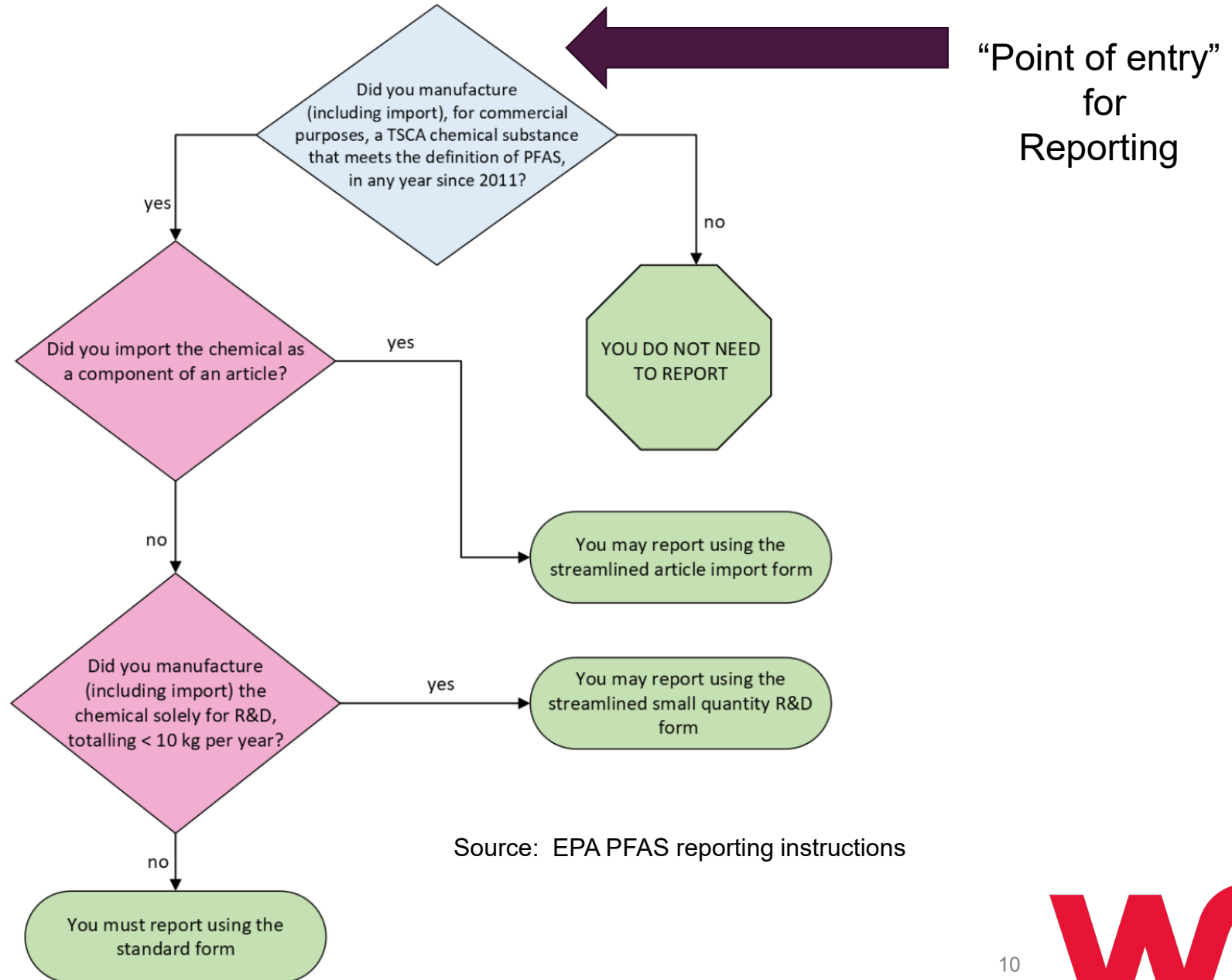
- EPA REPORTING INSTRUCTIONS, Section 4.13.1, p. 4-66:  
Note that not all submitters are required to initiate joint submissions.  
**Article importers using the article importer reporting form** will not be required or have the option to initiate joint submissions.
- EPA REPORTING INSTRUCTIONS, Section 4.5.6, p. 4-19:  
**Importers of articles using the streamlined article import form** are not required to assert or substantiate CBI claims for chemical identity. Therefore, joint submissions are not required or enabled for article importers.



# Decision Tree for Federal Reporting

## Reporting Standard: "Known to or Reasonably Ascertainable"

Submitters must conduct a reasonable inquiry (not just managerial employees). A reasonable inquiry internally and with suppliers is needed. Files maintained by the manufacturer such as marketing studies, sales reports, or customer surveys; information contained in standard references showing use information or concentrations of chemical substances in mixtures, including Safety Data Sheet or a supplier notification. No need to conduct new testing or new surveys for purposes of this rule.



# Point of Entry For Reporting - Manufacture of PFAS for Commercial Purposes

- Consistent with the TSCA definition of manufacture at 40 C.F.R. § 705.3:
  - Manufacture means to **import** into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202)), **produce**, or manufacture **for commercial purposes**. (emphasis added).
- Manufacture of reportable PFAS may be either intentional **OR** inadvertent.

# PFAS Reporting – Point of Entry Summary

U.S. chemical manufacturer:

- Reports domestically manufactured PFAS

Chemical importer of record:

- Reports imported PFAS

Article (components, parts, equipment) importer of record:

- Reports imported articles containing PFAS

Others in the value chain do not report.

- Processors are not required to report (**unless they are an importer**). Simply receiving and processing PFAS sourced from domestic suppliers is not, in itself, considered manufacturing PFAS for commercial purposes.
- Entities need to report on the PFAS they have manufactured (including imported), if any.
- No reporting of domestically manufactured articles unless inadvertent PFAS formation occurs.

# Definition Of “Manufacture For Commercial Purposes”

## 40 C.F.R. § 705.3 includes inadvertent formation:

(1) 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 containing a chemical substance:

(i) For commercial distribution, including for test marketing; and/or

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) Manufacture for commercial purposes **also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture** containing a chemical substance, including both byproducts that are separated from that other substance or mixture containing a chemical substance and impurities that remain in that substance or mixture containing a chemical substance. **Such byproducts and impurities may, or may not, in themselves have commercial value.** They are nonetheless produced for the purpose of obtaining a commercial advantage since they are **part of the manufacture of a chemical product for a commercial purpose.**

**NOTE:** Inadvertent, reportable PFAS manufacture may occur coincidental during manufacturing, processing, use, or disposal of another substance or mixture.



# Processors of Reportable PFAS Do Not Have to Submit Reports . . . as long as they did not import the PFAS.

- EPA can require processors to report under TSCA Section 8(a), but the agency did not use this authority for this rule. Processors do not have to report.
- Final Rule Unit II.B.1: Persons who have only processed, distributed in commerce, used, and/or disposed of PFAS are not required to report under this rule, unless they also have manufactured PFAS for a commercial purpose. If an entity (such as a wastewater treatment plant) **is simply processing PFAS they received domestically**, and not also manufacturing PFAS, including as a byproduct, **then the entity is not covered by this rule**. Although EPA received several public comments about extending the rule to cover processors (see Unit IV.), TSCA section 8(a)(7) only refers to manufacturers and expanding the rule to processors would be pursuant to EPA's separate rulemaking authority at TSCA section 8(a)(1), which the Agency is not pursuing at this time. 88 Fed. Reg. at 70519.
- Final Rule Unit II.B.2: As described in Unit III.B.1, simply receiving PFAS from domestic suppliers or other domestic sources is not, in itself, considered manufacturing PFAS for commercial purposes. Entities that process and/or use PFAS only need to report on PFAS they have manufactured (including imported), if any. 88 Fed. Reg. at 70520.



# Definition of Process

- Under TSCA, a “processor” is broadly defined as “any person who processes a chemical substance or mixture.” 15 U.S.C. § 2602(14).
- To “process” means to prepare a “chemical substance or mixture, after its manufacture, for distribution in commerce (A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture.” 15 U.S.C. § 2602(13).
- Examples when a company is acting as a processor rather than a manufacturer:
  - Example 1. A person reacts chemicals X and Y to produce a new chemical substance Z. This person is a processor of X and Y and a manufacturer of Z.
  - Example 2. A person who purchases or manufactures chemicals and then mixes or reacts them is a processor of each chemical if the mixtures or compounds are distributed in commerce. Processors that fall within this example include producers of paints, automotive products (e.g., antifreeze, oil additives, etc.) and specialty cleaners and floor wax preparations.” **NOTE THAT THE PERSON IN THIS EXAMPLE IS ALSO A MANUFACTURER OF CERTAIN CHEMICALS IN THIS EXAMPLE.**
- EPA, Chemical Processing Under TSCA: Background Information Document, (August 26, 1992), pp. 12-13, accessible at [nepis.epa.gov](http://nepis.epa.gov).



# Reporting Standard – “Known to or Reasonably Ascertainable”

## 40 C.F.R. § 705.3

“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.”

## Key Elements

1. Submitters must conduct a reasonable **internal** inquiry, which includes:
  - Relevant, not just managerial, employees.
  - Information in possession or control of that site, subsidiaries or general partnerships.
  - Files maintained such as marketing studies, sales reports, or customer surveys;
  - Standard references showing use information or concentrations of chemical substances in mixtures. What is standard may vary by company. EPA gives two examples - Safety Data Sheets and a Supplier Notification.
  - Company knowledge must be taken into account.
2. Also includes reasonable level of proactive inquiry **with customers/suppliers**.
  - Directly and/or through their websites.
  - No requirement to secure a response.
3. **No need to conduct new testing** or new surveys for purposes of this rule.





# Supply chain inquiry

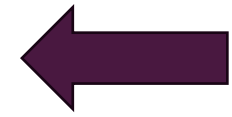
- Table 4.1  
Examples –  
EPA  
Reporting  
Instructions



**Scenario:** Example Company N imports an article with a water repellant “fluoropolymer” surface. However, Example Company N does not know the chemical identity or molecular structure of the fluoropolymer coating.

**Application of KRA Reporting Standard:**

If:	Then:
Example Company N contacts their supplier to determine the name, CASRN, and molecular structure of the fluoropolymer. The supplier provides this information or a joint submission is initiated.	Duties Likely Fulfilled
Example Company N did not contact their supplier to obtain information on the fluoropolymer coating	Duties Not Fulfilled



**Scenario:** Example Company O imports stain-resistant garments. Example Company O does not know specifically what chemical is used to impart stain resistance, but Example Company O does know that chemicals used to impart stain resistance are often fluorinated chemicals and could meet the definition of PFAS.

**Application of KRA Reporting Standard:**

If:	Then:
Example Company O contacts their supplier to determine the name, CASRN, and molecular structure of the stain-resistant chemical. The supplier provides this information or a joint submission is initiated.	Duties Likely Fulfilled
Example Company O did not contact their supplier to obtain information on the stain-resistant chemical.	Duties Not Fulfilled



# Table 4.1 Examples – What is a “reasonable” supplier inquiry process?

**Scenario:** Example Company M has never maintained information on how a particular PFAS (Example PFAS M) is processed or used by its customers. However, it is typical for comparable manufacturers to collect such information as part of their reasonable business practices. Example Company M has one major customer and ten minor customers.

**Application of KRA Reporting Standard:**

If:	Then:
Example Company M asks its major customer to supply information about how Example PFAS M is processed and used, but that customer is unwilling to supply this information. Example Company M reasonably expects that the only remaining way to substantially fill this data gap would be to send a survey to its ten minor customers. Example Company M reports that the information is “not known or reasonably ascertainable” to it.	Duties Likely Fulfilled
Example Company M did not endeavor to obtain processing and use information from its customers and	Duties Not Fulfilled
designated the information as “not known or reasonably ascertainable.”	



# Table 4.1 Examples – Loss of Information

Scenarios, Actions, and Outcomes	
<p><b>Scenario:</b> Example Company J discovers that it has no knowledge of how a particular PFAS (Example PFAS J) is processed or used by its customers. Example Company J usually maintains marketing data documenting customers' use of its chemicals, in line with the reasonable business practices typical of comparable manufacturers, but it irrevocably lost these data for Example PFAS J due to an inadvertent computer malfunction. Example Company J has many customers, but it expects that it could substantially reconstruct this missing information by briefly contacting its largest customer and asking that customer what Example PFAS J is generally used for.</p>	
<p><b>Application of KRA Reporting Standard:</b></p>	
<b>If:</b>	<b>Then:</b>
Example Company J contacts its largest customer and reports on the basis of the processing and use data that the customer was willing to provide.	Duties Likely Fulfilled
Example Company J did not endeavor to supplement the information it already knew.	Duties Not Fulfilled



# Table 4.1 Example –Knowledge Factor

**Scenario:** Example Company O imports stain-resistant garments. Example Company O does not know specifically what chemical is used to impart stain resistance, but Example Company O does know that chemicals used to impart stain resistance are often fluorinated chemicals and could meet the definition of PFAS.

**Application of KRA Reporting Standard:**

If:	Then:
Example Company O contacts their supplier to determine the name, CASRN, and molecular structure of the stain-resistant chemical. The supplier provides this information or a joint submission is initiated.	Duties Likely Fulfilled
Example Company O did not contact their supplier to obtain information on the stain-resistant chemical.	Duties Not Fulfilled

# A word on estimates

- Some areas of the forms require estimates to the level of two significant figures (e.g., production volume of imported article).
- Other areas require production volume rounded off to the closest 10 percent (e.g., use and sector estimates).
- Other areas require ranges.
  - **Streamlined article import form** requires, for each consumer and commercial product category, a range for the estimated typical maximum concentration, by weight, per year.

**Scenario:** Example Company L maintains seasonal marketing data on changes in use patterns for a particular PFAS (Example PFAS L). Comparable manufacturers typically only maintain such data on an annual basis, in line with reasonable business practices. Example Company L irrevocably loses its summer marketing data for Example PFAS L, due to an inadvertent computer malfunction. Example Company L expects that it could substantially reconstruct the missing summer marketing data by contacting its largest customer and asking the customer what it used or processed Example PFAS L for in the past summer.

#### Application of KRA Reporting Standard:

If:	Then:
Instead of attempting to reconstruct the summer data by contacting its largest customer, Example Company L reports on the basis of the processing and use data that it already knows (regarding the winter, spring, and fall of the year).	Duties Likely Fulfilled
Example Company L designated the information as "not known or reasonably ascertainable" simply because one of the seasonal marketing reports was missing	Duties Not Fulfilled



# Q&A # 57 on other estimates

- **The rule states: “In the event that actual data is not known to or reasonably ascertainable by the submitter, then reasonable estimates may be submitted.” How does a manufacturer determine whether an estimate is appropriate, or if they should report information is NKRA? Response:**

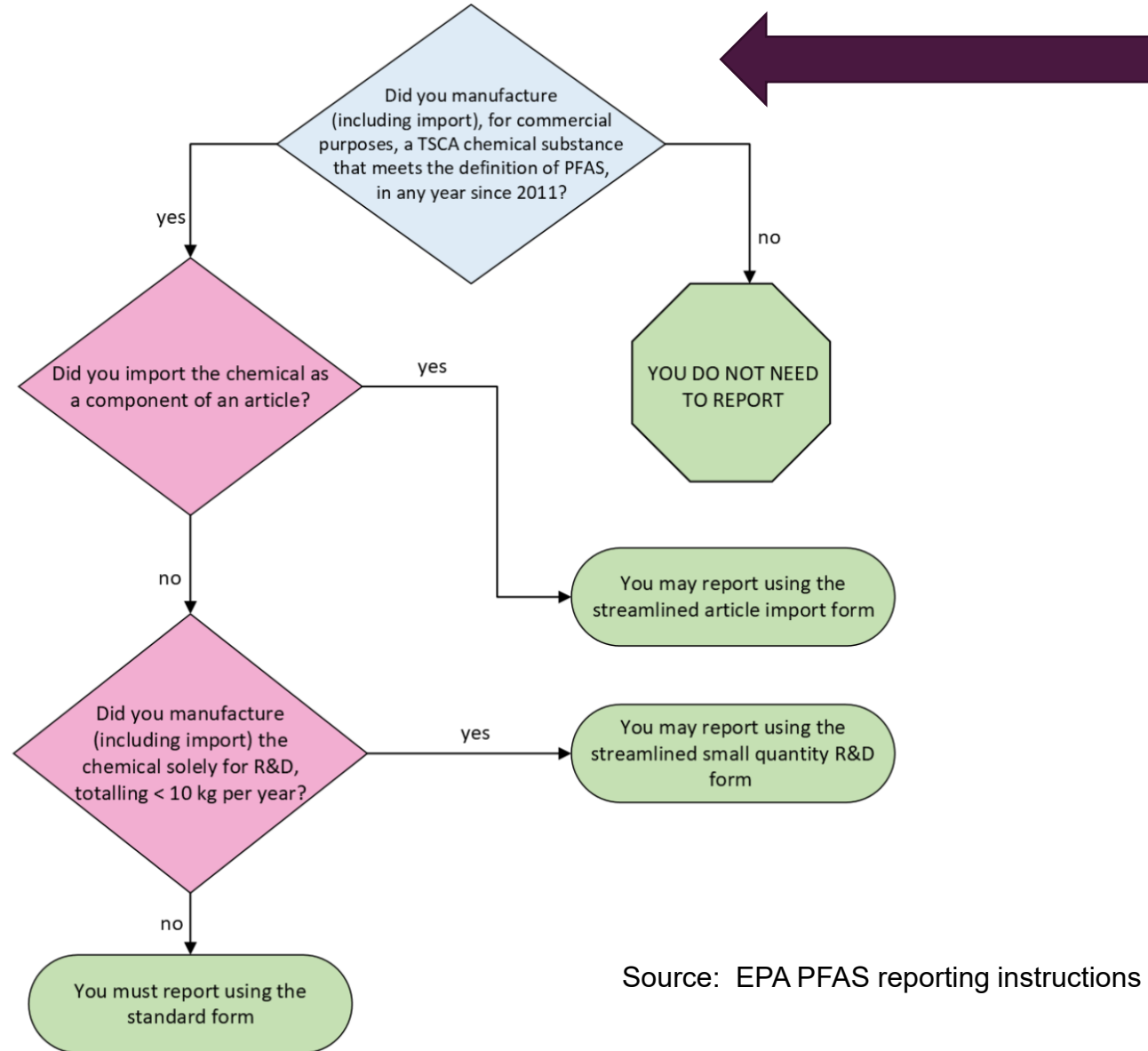
Whether an estimate is appropriate should be considered on a case-by-case basis, taking into account the data type requested, the level of confidence in the estimate, and how closely the estimate aligns to the requested data element. Reporting NKRA should only happen when data are truly not reasonably ascertainable or are unattainable. Facility recordkeeping must be able to support NKRA claims.

. . . . “Reasonable estimates” may rely, for example, on approaches such as mass balance calculations, emissions factors, or best engineering judgment.

- Estimates where not specifically requested are purely voluntary.



# Systematic Approaches



**“Point of entry” for Reporting**

Source: EPA PFAS reporting instructions



# Example Approaches for Article Identification – (other approaches possible as well)

- Screen out articles not subject to TSCA.
- EPA's Decision Tree.
  - Identify articles for which the company is the importer (or co-importer) of record and how that is defined.
  - Examples in recent Q&A from EPA
- Screen imported articles using “standard references”.
  - SDS's and Supplier Notifications;
  - Product codes in the rule to select imports; or
  - Publications (peer reviewed) exist on products that may contain PFAS;
- Screen based on characteristics (grease/water resistance, ability to function under temperature extremes/fire resistance).
- Make the choice on which form to use.
- Conduct due diligence to align with the information requested on the form.





# CBI

## **CBI statutory requirements (from 2016 Lautenberg Act and 2023 TSCA CBI procedural rule):**

- The submitter must substantiate claims of confidentiality at the time information is submitted to EPA, except for types of information listed as exempt in TSCA (e.g., production volume) (TSCA sections 14(c)(2) and (3))
- The submitter must also provide a statement supporting the claim and must certify that the statement is true and correct (TSCA sections 14(c)(1)(B) and (5))
- Information on uses that customarily would be shared with the general public or within an industry or industry sector cannot be claimed as confidential (TSCA section 14(b)(3)(B))
- Information in health and safety studies has limited CBI protection under TSCA:
  - Chemical identity is always considered part of health & safety study.
  - CBI protections for health & safety studies generally limited to personally identifying information and process-related information. Other data elements may, depending on circumstance, be protected from disclosure.



# PFAS Reporting Rule specific CBI claims and limits.

- Generally, all authorized CBI claims need to be substantiated.
- Special rules for the following data elements.
  - No CBI claims for the following data elements.
    - PFAS chemicals on the public inventory or submitted as LVEs where identity is not claimed as CBI.
    - General processing and use code information.
    - Public identifiers of CBI PFAS substances (LVE numbers, accession numbers etc.)
    - Submitted health and safety data (with exceptions)
  - CBI claims for the following data elements do not require substantiation:
    - Production volume information.
    - Certain information related to joint submitters.
  - Limited CBI claim substantiation requirements for importers of articles.



# Rule Specific CBI Requirements

From EPA PFAS webinar <https://www.epa.gov/system/files/documents/2024-02/tsca-8a7-jan-2024-webinar.pdf>

- Generic name requirements
  - Generic names/descriptions for PFAS chemical identities need to contain “fluor”
- Article importers are not required to assert or substantiate CBI claims for chemical identity
  - EPA will not make CBI claim determination for chemical identity based on article importer reports
- Joint submission requirements
  - Manufacturers (other than article importers) who do not know the specific PFAS identity (i.e., CAS name, CASRN, Accession number or LVE number) must initiate a joint submission with their supplier or other entity who is able to identify the specific PFAS and assert and substantiate a CBI claim as appropriate
  - If any entity (other than article importer) reporting the specific PFAS identity fails to assert and substantiate a chemical identity as CBI, EPA intends to start the process of moving that chemical identity to the public portion of the TSCA Inventory, following public notification via EPA’s website of the Accession numbers of PFAS that EPA intends to move to the public Inventory



# Strategies for addressing CBI claims

- CBI is broadly defined as confidential proprietary information, the release of which would cause substantial business injury to the owner.
- Companies generally request CBI for confidential proprietary information believed to give other companies an advantage in the marketplace, such as details of their manufacturing processes and formulas.
- Submitters need to be concerned about how the release of the assembled data in a data collection will injure their competitive position. Central to CBI protection is thwarting efforts to connect the dots of publicly available data elements to uncover CBI.
- With the limits placed on CBI claims in the rule, entities will want to focus on ensuring CBI status for company name and related identifiers to limit competitor access to information on specific activities of submitter.
- Key to the protection of CBI in this rule is the development of robust substantiations.



# Review Questions

- Can a company can be both a manufacturer of reportable PFAS for commercial purposes and a processor?
- Do you need to report if you inadvertently manufacture reportable PFAS during manufacture, processing, use, or disposal of another substance or mixture?
- When you buy a reportable PFAS domestically and add it to a mixture, but the mixture is not distributed in commerce, you are not a processor. What are you?
- If you import an article, do you ever have to use the longer reporting form?



# Questions?

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