



Due diligence approach to
EPA TSCA “Reporting and Recordkeeping
Requirements for Certain Per- and Polyfluoroalkyl
Substances” - 40 CFR Part 705

Best Practices

Process Flow

Q&A

Executive Summary

The Association of Equipment Manufacturers (AEM) is the North American-based international trade group representing nonroad equipment manufacturers and suppliers with more than 1,000 member companies and over 200 different machine forms across five diverse industry sectors. Our members design products to satisfy various safety, regulatory, durability, quality, and customer requirements to effectively operate in various extreme and demanding environments with lifespans measured in decades. Original Equipment Manufacturers (“OEMs”) utilize a mixture of old and new technologies to meet their company goals, with Per- and Polyfluoroalkyl Substances (PFAS) performing a variety of essential use functions to help achieve success.

AEM recognizes the importance of identifying, addressing, and educating manufacturers, suppliers, and other industry stakeholders on important compliance issues. Chemical regulations, in particular, have far reaching effects on the entire nonroad equipment supply chain, requiring an industry wide investment of resources, time, knowledge, and expertise to effectively comply with these types of rules. To mitigate our collective compliance risks, AEM developed this best practice guidance document to help educate companies on the requirements found in the Environmental Protection Agency’s (EPA) new rule, *Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*¹.

Due to the complex nature of the nonroad equipment industry’s supply chains and products, the unique requirements found in the EPA’s rule, and the relatively short timelines companies have to report, AEM drafted this document to help industry stakeholders understand and comply with this new regulation. The document contains several sections:

1. Best Practices
2. Process Flow
3. Q&A
4. Definitions

As the EPA releases new information, or provides additional guidance, AEM will update this document to accurately represent the most up-to-date information available. For this reason, this document should be viewed as a non-exhaustive living document, representing the industry’s best understanding at that particular moment.

Disclaimer

The contents of this document are intended to offer support to AEM members by providing information on industry best practices in their efforts to comply with EPA PFAS reporting rule. This does not constitute legal advice and should not be relied upon as such. It is the sole responsibility of each individual company to determine their own compliance requirements.

¹ <https://www.federalregister.gov/documents/2023/10/11/2023-22094/toxic-substances-control-act-reporting-and-recordkeeping-requirements-for-perfluoroalkyl-and>

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Introduction to the EPA PFAS Reporting Rule

The Environmental Protection Agency (EPA) has promulgated reporting and recordkeeping requirements for Per- and Polyfluoroalkyl Substances (PFAS)² under the Toxic Substances Control Act (TSCA) section 8(a)(7)³. In accordance with obligations under TSCA, as amended by the National Defense Authorization Act for Fiscal Year 2020, EPA is requiring any person that manufactures (including import) or has manufactured (including imported) PFAS or PFAS-containing articles in any year since January 1, 2011, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards.⁴

Any entities, other than small entities, that have manufactured (including imported) PFAS in any calendar year since 2011 will have 18 months following the effective date of this rule to report PFAS data to EPA. The rule went into effect on November 13, 2023. The electronic reporting portal is set to open on November 12, 2024, and close on May 8, 2025.⁵

EPA has published reporting instructions for this rule, available online.⁶

Reporting entities must maintain records documenting information reported under this rule, including records that demonstrate performed due diligence, and provide EPA access to this documentation when requested. EPA may request or subpoena records under this rule when it deems necessary. Noncompliance with the reporting and recordkeeping requirements will incur civil penalties and may lead to criminal prosecution.⁷

² [40 CFR Part 705](#).

³ [15 U.S.C. §2607\(a\)\(7\)](#).

⁴ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping>.

⁵ [40 CFR 705.20](#).

⁶ [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023.

⁷ [40 CFR 705.1\(b\) and \(c\)](#).

Best Practices

AEM has been tracking the regulatory developments concerning PFAS and submitting comments to rulemakings in different jurisdictions. Based on these and other similar industry efforts, AEM suggests the following best practices in support of its members' efforts to comply with the EPA PFAS Reporting Rule:

1. Conduct a supplier risk assessment based on product composition and product performance requirements.
 - a. Consider commodity groups and known PFAS uses⁸
2. Supplier Outreach: Send a PFAS information request by part number to applicable suppliers and include references to PFAS educational materials, where appropriate⁹

Recommended: follow up on the initial outreach on a case-by-case basis (and/or based on the supplier risk assessment)
3. Document and maintain all outgoing due diligence and outreach efforts as well as incoming supplier responses.
4. Register with CDX portal ahead of time to resolve any technical issues.

⁸ For reference, see AEM PFAS Position Paper at <https://www.aem.org/safety-product-leadership/epa-pfas-reporting-and-recordkeeping-compliance-requirements>

⁹ <https://youtu.be/Gr0j6yHCsU>

Information Gathering and Reporting Process Flow (Steps)

Timeframe	OEMs	AEM	Suppliers outside of the US
Feb-Mar 2024	<p>Review any internally available information from any previous data collection efforts.</p> <p>Conduct supplier risk assessment.</p> <p>Draft supplier information request</p>	<p>Review and prepare PFAS information resources for members and their supply chain.</p> <p>Suggest Due Diligence Best Practices</p>	
April 2024	<p>Decide on the use of a PFAS Reference List</p> <p>Define Suppliers to be Queried. (Direct & Indirect, including suppliers of manufacturing machines and fluids)</p> <p>Prepare to track the supplier communications and clarifications</p>	<p>Conduct AEM PFAS Webinar</p> <p>Publish PFAS educational materials on the AEM website</p>	
May-June 2024	<p>Start Supplier Outreach:</p> <p>Send supplier information request by part number, include PFAS background information, reference to AEM educational materials, and PFAS reference list</p>	<p>Maintain PFAS awareness raising and educational content</p>	<p>Receive PFAS information request.</p> <p>Use educational materials to obtain more information.</p> <p>Investigate the OEM request.</p> <p>Review data on PFAS in products purchased or manufactured.</p>

Timeframe	OEMs	AEM	Suppliers outside of the US
			<p>Communicate to their suppliers to verify PFAS information.</p> <p>Communicate any CBI issues to OEMs</p>
June-July 2024	<p>Continue and finalize Supplier Outreach</p> <p>Follow-up case-by-case where applicable and/or based on risk</p>		Supplier provides results of their investigation/review to OEMs
August-September 2024	Review and organize received data	Continue to support members and adjust best practice suggestions based on insight from supply chain	
Sept-November 2024	<p>Review Part Numbers with PFAS against importing record</p> <p>Per PFAS substance: Determine the total volume of imported articles containing that PFAS, per calendar year</p> <p>Learn how to use the reporting tool when it becomes available</p>	Actions as needed	
December 2024	<p>Start submitting data (imports 1.1.2011-12.31.2022) to EPA via reporting tool.</p> <p>Streamlined reporting for imported PFAS in products or parts and standard</p>	Actions as needed	

Timeframe	OEMs	AEM	Suppliers outside of the US
	reporting for PFAS in bulk liquids.		
January 2025- May 8, 2025	Continue submitting data	Actions as needed	
May 8 2025	Reporting Tool closes for Importers (small manufacturers may report until November 10, 2025)		

Q&A

The answers in this section are compiled from the EPA PFAS reporting rule, as contained in the Code of Federal Regulations, and are based on the Instructions for Reporting PFAS Under TSCA Section 8(a)(7),¹⁰ the TSCA Chemical Data Reporting Fact Sheet: Imported Articles,¹¹ and the EPA TSCA Chemical Data Reporting Fact Sheet: Reporting After Changes to Company Ownership or Legal Identity,¹² as well as the webinar¹³ EPA presented on January 25, 2024.

About the EPA PFAS Reporting Rule

1. What is the purpose of this document?

AEM aims to provide information and clarification for Original Equipment Manufacturers (OEMs) and their suppliers. This document reflects AEM's suggested best practices in performing due diligence to comply with the EPA PFAS Reporting Rule.¹⁴ As most OEMs do not manufacture PFAS in the U.S. and only import products or parts likely to contain PFAS, this document is focused on the article importer streamlined reporting option.

2. What rule is this document about?

The focus of this document is the EPA PFAS Reporting Rule, full title - "Reporting and Recordkeeping Requirements for Certain Per- And Polyfluoroalkyl Substances", contained in 40 CFR Part 705.¹⁵ This rule sets out the reporting and recordkeeping requirements for manufacturers and importers based on section 8(a)(7) of the Toxic Substances Control Act (TSCA).

To summarize, this rule requires EPA to collect data on all PFAS manufactured or imported into the US for commercial purposes in the period between January 1, 2011, and December 31, 2022. Manufacturers including importers (other than "small manufacturers") introducing PFAS into the United States are required to report the PFAS information by May 8, 2025. Manufacturers including importers are required to conduct a reasonable inquiry into their own organization as well as their supply chain to meet the reporting standard. For accurate reference and definitions, please refer to the official text of the rule.

3. What law is this rule based on?

This rule is based on Section 8(a)(7) of the Toxic Substances Control Act (TSCA), recorded as 15 U.S. Code § 2607(a)(7).¹⁶

¹⁰ <https://www.epa.gov/system/files/documents/2023-11/tsca-8a7-reporting-instructions-10-11-23.pdf>.

¹¹ https://www.epa.gov/sites/default/files/2020-05/documents/fact_sheet_imported_articles_04.28.2020.pdf.

¹² https://www.epa.gov/sites/default/files/2015-05/documents/cdr_fact_sheet_company_changes.pdf.

¹³ EPA TSCA Section 8(a)(7) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar.

¹⁴ [Reporting and Recordkeeping Requirements for Certain Per- And Polyfluoroalkyl Substances, 40 CFR Part 705.](#)

¹⁵ [40 CFR Part 705.](#)

¹⁶ [15 U.S.C. §2607\(a\)\(7\).](#)

4. Who must report?

Companies who manufactured and/or imported a substance identified as PFAS contained in an article or a mixture in any period between January 1, 2011, and December 31, 2022.¹⁷

5. Who is considered an importer?

EPA defines “Importer” in [40 CFR 704.3](#) as:

“(1) 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:

(i) The person primarily liable for the payment of any duties on the merchandise,
or

(ii) An authorized agent acting on his behalf.

(2) Importer also includes, as appropriate:

(i) The consignee.

(ii) The importer of record.

(iii) The actual owner if an actual owner's declaration and superseding bond have been filed in accordance with [19 CFR 141.20](#).

(iv) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of [19 CFR part 144](#).

(3) For the purposes of this definition, the customs territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia.”¹⁸

According to EPA’s instructions, for “importers, the site where you import a chemical substance is considered the site of the operating unit within your organization that is directly responsible for importing the chemical substance and that controls the import transaction. For section 8(a)(7), all importers must provide a U.S. address for the controlling site; this site may be your company’s headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on the importer’s behalf who is authorized to accept service of process for the importer ([40 CFR 711.3](#)). In the event that more than one person may meet the definition of “importer” ([40 CFR 704.3](#)), only one person should report. See [40 CFR 711.22\(b\)](#).”

¹⁷ See [40 CFR Parts 705.10, 705.5, 705.3](#).

¹⁸ [40 CFR 704.3](#) “Importer”.

6. What if a company merged, was acquired, or created a spin-off?

Please refer to the EPA TSCA Chemical Data Reporting Fact Sheet: Reporting After Changes to Company Ownership or Legal Identity, published in January 2016.¹⁹ This document, in general terms, describes different scenarios of company changes.

7. Who does not need to report?

Entities that only process, use, and/or dispose of PFAS do not need to report. This includes the entities who purchase goods that contain PFAS from domestic U.S. suppliers.²⁰ Please refer to the definitions at the end of this document.

Companies that import municipal solid waste streams for the purpose of disposal or destruction of the waste are not required to report under this rule.²¹

8. When to report?

The 6-month reporting window for article importers opens on November 12, 2024, and closes on May 8, 2025. There is an extended reporting window for article importers who qualify as a small manufacturer.²²

9. What happens if a company fails to report?

Noncompliance with the reporting and recordkeeping requirements will incur civil penalties and may lead to criminal prosecution.²³

10. What is the recordkeeping obligation, and how long does it last?

Reporting entities must retain records that document any information reported to EPA. EPA also recommends to keep records of all due diligence efforts even if no PFAS is found and/or reported.²⁴ Records must be kept for a period of five (5) years starting on May 8, 2025.²⁵ Failing to retain records and produce them to EPA upon request will incur civil penalty or may lead to criminal prosecution.²⁶

11. What is the difference between reporting an imported product or part (streamlined reporting) and imported liquid in bulk (standard reporting)?

Standard reporting²⁷ is more extensive and detailed than the streamlined reporting. The streamlined reporting option²⁸ is only available for article importers and manufacturers of

¹⁹ [EPA TSCA Chemical Data Reporting Fact Sheet: Reporting After Changes to Company Ownership or Legal Identity](#).

²⁰ [EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 23.

²¹ [40 CFR 705.12](#).

²² [40 CFR Part 705.20](#).

²³ [40 CFR 705.1\(b\) and \(c\)](#).

²⁴ [EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 15.

²⁵ [40 CFR 705.25](#).

²⁶ [40 CFR 705.1\(b\)](#).

²⁷ [40 CFR 705.15](#).

²⁸ [40 CFR 705.18](#).

a PFAS R&D substance that was manufactured in volumes no greater than 10 kilograms per year.

12. What items must be reported under standard reporting even if they were imported?

Items that contain PFAS and are not articles. For example: liquids or gasses purchased in bulk from overseas suppliers must be reported under the standard reporting form. While they are imported, they are not considered articles, because they are intended to be removed from or released from the article (e.g., 50-gallon drum), and have intended end use or commercial purpose separate from the article (drum).

“EPA guides that “some things imported for the purpose of making articles are not themselves articles (e.g., liquid varnish imported for the purpose of manufacturing furniture).”²⁹

13. What items may be reported under streamlined reporting?

Imported items that contain reportable PFAS and are considered articles or parts of articles. For example: a car is an article. EPA guides that some “things imported for the purpose of making articles are themselves articles (e.g., car doors imported for the purpose of manufacturing cars).”³⁰

14. Is packaging included in this reporting obligation?

Yes. Based on the definition of “article”³¹ and the EPA’s instructions,³² packaging is considered an article in itself and thus included in the PFAS reporting obligation for imported articles. For example:

- Imported product or part (imported article) enclosed in packaging: e.g., a steel crate or plastic wrapping:
 - o the packaging is imported with a specific shape or design which supports the end use/commercial purpose: to fit and protect the product/part during shipping and storing. The packaging has no change of chemical composition during its use.
- A wholesale import of packaging supplies (e.g., a bulk purchase of pre-cut cardboard boxes shipped flat):
 - o The cardboard boxes have a specific shape and design supporting their end use/commercial purpose: to fit and protect the product/part during shipping and storing, but in this case, these boxes are not yet fulfilling their end use. The packaging will not change its chemical composition during its use.
- Packaging used to transport liquids purchased in bulk (e.g., brake fluid purchased in bulk in 50-gallon drums):

²⁹ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 1&2.

³⁰ [Id.](#) at 1&2.

³¹ [40 CFR 705.3 “Article”](#).

³² [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023.

- The drum has a specific shape and design supporting its end use/commercial purpose as a container for transporting, storing, and dispensing the brake fluid. The drum does not change its chemical composition during its use.³³

PFAS Definitions and Lists

15. What is PFAS according to the EPA?

“Any chemical substance or mixture containing a chemical substance that structurally contains at least one of the following three sub-structures:

(1) R-(CF₂)-CF(R')R”, where both the CF₂ and CF moieties are saturated carbons.

(2) R-CF₂OCF₂-R', where R and R' can either be F, O, or saturated carbons.

(3) CF₃C(CF₃)R'R”, where R' and R” can either be F or saturated carbons.”³⁴

Please remember that this definition is specific to this rule and differs from other PFAS definitions in state and federal rules.³⁵

16. Are polymers included in EPA's PFAS definition?

Yes. According to EPA's PFAS reporting instructions, a “polymer should be reported as a single PFAS. Provide any known information about the structure and variability of the structure in the chemical description and molecular structure data fields.”³⁶

17. What if PFAS presence is unintentional?

It is still in scope of this reporting rule. EPA PFAS Reporting rule applies to intentionally added PFAS as well as PFAS present as an impurity, byproduct, or a non-isolated intermediate.³⁷

In contrast, “Intentionally added PFAS” is the language used in the state regulations on PFAS, e.g., currently in force in Maine and Minnesota.

³³ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 7.

³⁴ [40 CFR 705.3 “Per- and polyfluoroalkyl substances or PFAS”](#).

³⁵ [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 2-3.

³⁶ [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 4-14.

³⁷ [40 CFR 705.3 “Manufacture for commercial purposes” \(2\); Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 2-2.

18. What is the minimum (de minimis) threshold that triggers the reporting obligation?

EPA PFAS reporting rule has no de minimis threshold. This means that any amount of manufactured or imported PFAS, even if unintentionally present, like an impurity or a by-product, is covered by this rule.³⁸

19. Is there a comprehensive list of PFAS substances that I can reference while gathering information?

There is no comprehensive or exhaustive list. The EPA definition of PFAS is based on the three chemical structures identified under question 15. While EPA published several PFAS lists in an effort to assist companies with identifying reportable PFAS, the agency cautions that these are not exhaustive and will be updated as new chemicals are registered.

To boost efficacy of supplier outreach, you may refer to the PFAS section of the Heavy Equipment Declarable Substance List (HEDSL),³⁹ published by AEM. HEDSL contains chemical substances identified for use in the heavy and off-road equipment industry and lists a subset of substances that meet the EPA PFAS structural definition.

Please remember that both the industry specific HEDSL and the EPA PFAS lists are non-exhaustive and will be regularly updated. They are for reference only, while the structural definition is the only legal definition for this rule.

Remember to perform your due diligence efforts according to the EPA PFAS definition contained in 40 CFR 705.3 “Per- and polyfluoroalkyl substances or PFAS.”⁴⁰

20. Is there a PFAS list for the off-road/heavy equipment industry?

The AEM Heavy Equipment Declarable Substance List (HEDSL),⁴¹ contains chemical substances identified in the commodities purchased in the heavy and off-road equipment industry. HEDSL contains a section identifying a subset of substances that meet the EPA PFAS structural definition. Please remember that HEDSL is non-exhaustive and will be regularly updated. It is for reference only, while the structural definition is the only legal definition for this rule.

³⁸ [40 CFR 705.22\(g\); EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 11; [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 1-2.

³⁹ <https://www.aem.org/getmedia/64763ff2-1e70-4f90-80ae-3ace9e960b27/AEM-PFAS-Reference-List.xlsx>

⁴⁰ [40 CFR 705.3 “Per- and polyfluoroalkyl substances or PFAS”](#).

⁴¹ AEM.org

Products, Parts, and Bulk Liquids: EPA Definitions and Examples of Article, Substance as Part of an Article, and Mixture

21. What is the definition of an article?

EPA definition:

“Article means a manufactured item which:

- (1) Is formed to a specific shape or design during manufacture;
- (2) Has end use function(s) depending in whole or in part upon its shape or design during end use; and
- (3) Has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.”⁴²

22. Wasn’t “article” exempt from reporting?

No. EPA PFAS reporting rule includes articles, in contrast to the CDX reporting rule, where articles are exempted. EPA refers to the CDX article exemption fact sheet for definitions and examples, stressing that articles are not exempt under the PFAS reporting rule.⁴³

23. What are examples of an article?

*EPA examples:*⁴⁴ “The following are considered articles or parts of articles:

- a) Transformers (including the contained transformer fluid); cigarette lighters (including the contained lighter fluid), automobiles (including the contained crankcase oil), desiccant packets (including the contained silica gel beads).
 - The chemical substances contained in these articles are not intended to be removed from or released by these articles, and have no intended end use or commercial purpose separate from the articles.
 - While the substances contained in the articles would not themselves be articles if they were separately imported in bulk (e.g., in a 50-gallon drum), they are considered parts of the overall imported articles in these instances.
- b) Metal or plastic sheets, wire, coated fabric, rolled carpet, and sheets of plywood.
 - These items are articles if they are imported in a specific shape or design for a particular end use application, and this shape or design is maintained as an essential feature in the finished product.

⁴² [40 CFR 705.3 “Article”](#).

⁴³ [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 2-4 and 2-6; [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#).

⁴⁴ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 3&4.

- These items are imported as articles, even if they are later rolled or drawn thinner, cut or trimmed, printed on, laminated, drilled, welded together, polished, buffed, or thermoformed, as long as their original shape or design is to be an essential feature of the finished product.
- c) Thermoformed plastics.
- If a plastic sheet is thermoformed (molded) into a plastic box, the characteristic shape of the plastic sheet is essentially maintained by virtue of the flat, rectangular sides and bottom of the box, even if the thickness of the sheet is somewhat changed. The imported sheet can in this case still be considered an article.
- d) Molded plastic parts, machined metal parts, finished pipes, and other shaped and finished construction materials.
- These items are imported with specific shapes or designs for particular end uses.
- e) Batteries, instant photographic film.
- These items undergo changes of composition which have no commercial purpose separate from that of the article.
- f) Finished fabric.
- With respect to dyes, water repellent coatings, and flame retardant coatings: even though the dye or coating may be removed or released from the fabric during handling or washing, the removal or release serves no end use function and is not intended to occur. Therefore, the dyes and coatings are considered a part of the imported fabric articles.
 - Note: This concept applies for other similar products that are treated or coated. EPA recognizes that the coating may be removed or released gradually or intermittently during the life of the product (e.g. washing, handling). The coating substance is still imported as part of an article, because its release in these situations is not intended to occur and serves no end use function.”

24. What is not considered an article?

According to EPA’s guidance: “Items that exist solely in fluid (including liquid and gas) or particulate form are expressly excluded from the definition of “article.” Furthermore, an item consisting solely of fluid(s) and/or particles does not have a definite shape and, therefore, cannot meet the other elements of the definition of an article in 40 CFR 704.3 (referenced in 40 CFR 711.3).”⁴⁵

25. What are examples of items not considered articles or parts of articles?

EPA states that “[t]he following are not considered articles or parts of articles:

⁴⁵ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 3.

- a) Ink in pens, caulk in canisters, fire extinguisher fluid, substances or mixtures in aerosol cans, windshield washer fluid in cars, lighter fluid in refill cans.
- While these substances are contained within an article at the point of import, they are intended to be removed from or released by that article and have an end use or commercial purpose separate from the containing article.
- b) Metal ingots, billets, blooms, or other bulk metal raw material imported in a shape suited for shipping convenience.
- Because these items are imported in a shape suited for shipping convenience, their shape does not serve a function with respect to the end use of the items. Following importation, they are expected to be processed in a way that results in a significant change from the shape at the time of import.
- c) Blocks of plastic or other bulk plastic shapes that are imported and converted into finished plastic articles.
- These items are imported in a shape suited for shipping convenience. Following importation, they are converted into finished plastic articles through extrusion, injection molding, or other converting processes.
- d) Articles that have been previously disposed of and are now being imported for reclamation of specific chemical substances or for conversion into a new form, shape or design, such as scrap metal (including scrapped electronics or metal fixtures).
- These items do not have end use functions dependent in whole or in part upon their shape or design during end use.
- e) Chemical substances comprising paints, inks, powder coatings, and adhesives, and other chemical substances or mixtures that are imported “in bulk” in fluid or particulate form.
- Items which consist solely of fluids and/or particles are not articles. Also, if fluid(s) or particles imported in a container are intended to be eventually released from that container, then they are not part of an article because they have an end use that is separate from the shape or design of the article.”⁴⁶

26. Can you provide a simple example of “article” and “not-article”, using car and car parts analogy?

EPA provided such an example situation:⁴⁷

“An agent accepts import of imported cars containing brake fluid as well as 50-gallon drums containing brake fluid. Would the brake fluid in the imported cars qualify as being imported as part of an article? Would the brake fluid in the imported drums qualify as being imported as part of an article?”

⁴⁶ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 4&5.

⁴⁷ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 7.

When imported as a component of the imported car, the brake fluid is part of the article. The brake fluid is not intended to be released during the use of the car, and the brake fluid does not serve any commercial purpose separate from being a component of the car. [...]

When imported in a drum, the brake fluid is not part of the article because the brake fluid in the drum is intended to be removed from the drum and has an end use separate from the drum (i.e., to be used in a car). The drum was imported as a container for transporting, storing, and dispensing brake fluid. Therefore, when imported in a drum, the brake fluid would [not be considered an article, but would be considered a mixture].”

27. How does the rule consider products (used or new) which contain residual or trace amounts of PFAS chemicals?

These products are in scope of this rule. Products may contain residual or trace amounts of PFAS chemicals, either from use or the manufacturing process. According to EPA guidance, if the chemical substances contained in these products (articles) are not intended to be removed from or released by these articles, and have no intended end use or commercial purpose separate from the articles, they are considered articles or parts of articles. For example: transformers (including the contained transformer fluid); cigarette lighters (including the contained lighter fluid), automobiles (including the contained crankcase oil), desiccant packets (including the contained silica gel beads).⁴⁸

Moreover, EPA PFAS reporting rule has no de minimis threshold. This means that any amount of manufactured or imported PFAS, even if unintentionally present, like an impurity or a by-product, is in scope of this rule.⁴⁹

Both used and new products may be considered an article for the purpose of this rule, unless the articles “that have been previously disposed of and are now being imported for reclamation of specific chemical substances or for conversion into a new form, shape or design, such as scrap metal (including scrapped electronics or metal fixtures). These items do not have end use functions dependent in whole or in part upon their shape or design during end use.”⁵⁰ Therefore, used products imported for scrap purposes are not considered an article.

28. What is considered a chemical substance imported “as part of an article”?

EPA guides that: “A chemical substance is considered to be imported “as part of an article” if the substance is not intended to be removed from that article and has no end use or commercial purpose separate from the article of which it is a part.”⁵¹

⁴⁸ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 3&4.

⁴⁹ [40 CFR 705.22\(g\); EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 11; [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 1-2.

⁵⁰ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 4&5.

⁵¹ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 1.

29. What is not considered a chemical substance imported “as part of an article”?

According to the EPA: “A chemical substance is not considered to be “imported as part of an article” when:

- The article is a container used to transport, contain or dispense the substance, or
- The substance is intended to be removed (or released) during the use of the article, or
- The substance has an end use or commercial purpose separate from the article.

If you import a chemical substance in a drum, barrel, or other container for intentional release, that substance [...] is intended to be removed from the article and has an end use separate from the article.

If you import a chemical substance that you intend to later incorporate into an article for commercial purposes, this intent does not establish whether the substance [is considered part of an article]. What matters is whether the substance is imported as part of an article. Some things imported for the purpose of making articles are not themselves articles (e.g., liquid varnish imported for the purpose of manufacturing furniture). Other things imported for the purpose of making articles are themselves articles (e.g., car doors imported for the purpose of manufacturing cars).⁵²

30. Are both a machine and a spare part considered articles?

A machine is considered an article⁵³ because it is manufactured to have a specific shape or design; its end use functions depend upon its shape or design during end use, and it will not change its chemical composition during its end use, and any wear has no commercial purpose separate from the machine.

As for spare parts, EPA guides that some “things imported for the purpose of making articles are themselves articles (e.g., car doors imported for the purpose of manufacturing cars).”⁵⁴

31. What is a mixture?

EPA’s definition is: “The term “mixture” means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; [...]”⁵⁵

32. What is an example of a mixture?

Hydraulic oil, Teflon grease, mold release agents, cutting fluid are considered mixtures. EPA guides that mixtures that are imported “in bulk” in fluid or particulate form are not

⁵² [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 1&2.

⁵³ [40 CFR 705.3 “Article”](#).

⁵⁴ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 1&2.

⁵⁵ [TSCA Sec. 3 \(10\), 15 U.S. Code § 2602 \(10\)](#).

considered article or part of an article.⁵⁶ Therefore, you will have to use the standard reporting option to report each PFAS substance imported as a fluid in bulk.

33. What about coatings or surface treatments?

The distinction is whether the coating has already been applied onto a product, or whether it is being imported in bulk.

“EPA recognizes that the coating may be removed or released gradually or intermittently during the life of the product (e.g. washing, handling). The coating substance is still imported as part of an article, because its release in these situations is not intended to occur and serves no end use function.”⁵⁷

However, coatings or treatments that are imported in bulk in fluid or particulate form, are not articles. If fluids or particles imported in a container are intended to be eventually released from that container, then they are not part of an article because they have an end use that is separate from the shape or design of the article.

“Known to or Reasonably Ascertainable by” Reporting Standard/Due Diligence Level

34. When can a reporting entity use a streamlined reporting form based on its due diligence level?

The rule states that article importers have the option to use a streamlined reporting form if they do not know nor can reasonably ascertain information requested under standard reporting⁵⁸ beyond what is listed in the requirements for the streamlined reporting.⁵⁹

35. How is the reporting standard “Known to or Reasonably Ascertainable by” (“KRA”) defined for the streamlined reporting option?

“Any importer of an article which contains a chemical substance that is a PFAS and who meets the reporting requirements [...] has the option to submit information to EPA using a streamlined reporting form for that PFAS in the imported article, for each year since January 1, 2011, in which the PFAS was imported in an article. Information must be submitted to the extent the submitter knows or can reasonably ascertain. In the event that actual data is not known to or reasonably ascertainable by the submitter, then reasonable estimates may be submitted.”⁶⁰

⁵⁶ [TSCA Chemical Data Reporting Fact Sheet: Imported Articles](#) at 5.

⁵⁷ *Id.* at 4-5.

⁵⁸ [40 CFR 705.15](#).

⁵⁹ [40 CFR 705.18](#).

⁶⁰ [40 CFR 705.18\(a\)](#).

For the categories and description of information requested on the streamlined reporting form for article importers, please consult [Title 40 Section 705.18\(a\)](#) in the Code of Federal Regulations.

36. What does “Known to or reasonably ascertainable by” (“KRA”) mean?

“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.

Possession or control means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner.) Information is included within this definition if it is:

(1) In files maintained by submitter's employees who are:

- (i) Associated with research, development, test marketing, or commercial marketing of the chemical substance in question; and/or
- (ii) Reasonably likely to have such data.

(2) Maintained in the files of other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question in the course of their employment as such agents.

37. What is EPA's guidance on the “KRA” standard?

EPA instructs that relevant information also includes knowledge gained through discussions, symposia, and technical publications. For purposes of this PFAS reporting rule, the known to or reasonably ascertainable by standard applies to all the information required by the rule.

38. What are examples of the types of information that are considered to be known or reasonably ascertainable?

Examples of types of information that are considered to be in a person's possession or control, or that a reasonable person similarly situated might be expected to possess, control, or know include:

- Files maintained by the manufacturer, such as marketing studies, sales reports, or customer surveys,

- Information contained in standard references, such as a safety data sheet (SDS) or a supplier notification, and
- Information from the Chemical Abstracts Service (CAS) and from Dun & Bradstreet D-U-N-S®.⁶¹

EPA further guides that “KRA” due diligence may require outreach to other entities (suppliers, customers).⁶²

39. What are the hypothetical “KRA” examples offered by EPA?

EPA stresses that because the standard applies on a case-by case basis, these examples cannot substitute for a complete analysis of a submitter’s particular circumstances.

Scenario:⁶³ 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.

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

For more hypothetical scenarios, please refer to the TSCA PFAS Reporting Instructions, Chapter 4.

40. Does “KRA” due diligence standard require testing?

EPA states that “this reporting standard does not confer a testing requirement on manufacturers. But, if manufacturers have previously tested their products for the presence of PFAS, then that information may be considered known to or reasonably ascertainable to them and should be submitted to EPA as appropriate.”⁶⁴

⁶¹ [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 4-2 and 4-3.

⁶² [EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 15.

⁶³ [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 4-4.

⁶⁴ *Id.* at 4-3.

41. What if I don't know whether my company imported a PFAS and the overseas suppliers cannot be reached or are non-responsive?

EPA stated it does not expect the scope of KRA information to look the same for all entities. Factors influencing this scope include (but are not limited to) the importer's size and resources, the number of suppliers, the importer's current relationship with suppliers, the supplier's responsiveness.⁶⁵

EPA guides that any manufacturer (particularly article importers) who does not know nor can reasonably ascertain that they manufactured a PFAS, does not need to report. EPA recommends documenting the due diligence efforts undertaken (e.g., attempts to reach suppliers and other entities to obtain information), although this is not required.⁶⁶

42. What if I know we have manufactured a covered PFAS, but I am not sure which one specifically or am unsure of the trade name?

You need to report. As EPA instructs, in that case, you will report a generic name/description with as much structural information as possible.⁶⁷

43. What if there are no commercially available analytic methods to determine which PFAS I imported?

"Commercially available analytic methods" is the language used in state PFAS legislations and rules, e.g., Maine and Minnesota. For EPA reporting, the standard is "known or reasonably ascertainable" information. EPA guides that if a manufacturer does not know nor can reasonably ascertain whether they have manufactured or imported a covered PFAS, they need not report.⁶⁸

Submitting the streamlined reporting form on EPA website

44. What information should an OEM reporting as "article importer" collect to report to EPA?

For an overview of the data elements required for submission, see Part 705.18(a) as published in the Code of Federal Regulations.⁶⁹ See also the "Data Elements included in the TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, Final Rule" spreadsheet published by the EPA on October 10, 2023.⁷⁰

⁶⁵ [EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 24.

⁶⁶ *Id.* at 15.

⁶⁷ [EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 24.

⁶⁸ *Id.*

⁶⁹ [Article importer substance reporting options, 40 CFR 705.18\(a\).](#)

⁷⁰ <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0187>.

45. How many streamlined reporting forms should an article importer submit?

Each reportable PFAS substance requires its own reporting form. If an article or mixture is comprised of two or more reportable PFAS, the manufacturer must report on each PFAS.⁷¹ A polymer should be reported as a single PFAS.⁷²

To illustrate: if there are ten different PFAS in one product, this means filling out ten reports, one per PFAS for each applicable year. Conversely, if ten products contain one and the same PFAS, this means one report for this one PFAS for each applicable year.

Unlike the state reporting frameworks which are product-based, this rule requires reporting on a chemical level.

46. Is there a guidance on how to use EPA CDX database to report in the PFAS reporting module?

EPA stated that the reporting format/module is not yet completed. EPA will issue a guidance on how to use the reporting tool in the future. EPA recommends logging on and create an account in Central Data Exchange “CDX” portal, to resolve any technical issues with pop-up blockers and such. EPA guidance on how to register for CDX is available online.⁷³

47. Do I report PFAS for commercial use as well as for consumer use?

For each relevant calendar year, the report for each PFAS imported in an article must include categories of use.⁷⁴ The categories of use are: industrial processing and use information, including sector specific categories and functions; and consumer and commercial use information, including product specific functions and use designation.⁷⁵

Commercial use is defined as “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.”⁷⁶

Consumer use is defined as “the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) when sold to or made available to consumers for their use.”⁷⁷

Industrial use is: “use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed.”⁷⁸ And industrial function is defined as “the intended physical or chemical characteristic for which a chemical substance or

⁷¹ [EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 8.

⁷² [Instructions for Reporting PFAS Under TSCA Section 8\(a\)\(7\)](#), October 2023 at 4-14.

⁷³ <https://cdx.epa.gov/About/UserGuide>.

⁷⁴ [40 CFR 705.18\(a\)\(3\)](#).

⁷⁵ The subsection describing the reporting for consumer products intended for children is not discussed here, [40 CFR 705.18\(a\)\(3\)\(vii\)](#).

⁷⁶ [40 CFR 705.3 “Commercial use”](#).

⁷⁷ [40 CFR 705.3 “Consumer use”](#).

⁷⁸ [40 CFR 705.3 “Industrial use”](#).

mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product or article; repackaged; or used.”⁷⁹

48. Do I calculate the imported PFAS per product or per part that is incorporated into a product?

An imported assembled product is considered an article, and separately imported unassembled parts are considered articles as well. Please see the answer to question 13 that uses the car and car door example.

EPA guides that for “article importers reporting on the Article Importer form, you should report the volume of the article imported, rather than attempting to calculate the volume of the PFAS contained within the articles. You may choose to report the total weight of the PFAS-containing articles (e.g., in tons or pounds) or the quantity of the article imported (e.g., the number of vehicles). You must specify the unit of measurement for the reported production volume.”⁸⁰

Furthermore, for imported articles used in consumer and commercial products, the report must include the estimated typical maximum concentration percentage of PFAS calculated by weight of the article.⁸¹

49. How do I assert Confidential Business Information “CBI” as an “article importer”?

EPA states that 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.⁸²

50. Will I be in a better position if I use a third-party consultant to gather and process PFAS information for my company?

EPA stated that use of consultants is optional. “EPA does not expect the scope of KRA information to look the same for all entities. Factors influencing this scope include (but are not limited to) the importer’s size and resources, the number of suppliers, the importer’s current relationship with suppliers, the supplier’s responsiveness.”⁸³

Depending on the factors mentioned above, you may decide whether it would be more efficient and/or effective to hire a consultant.

⁷⁹ [40 CFR 705.3 “Industrial function”](#).

⁸⁰ [Instructions for Completing Section 8\(a\)\(7\) Reporting](#), Section 4.7.2.2. at 4-35; [40 CFR 705.18\(a\)\(4\)](#).

⁸¹ [40 CFR 705.18\(a\)\(3\)\(viii\)](#).

⁸² [EPA TSCA Section 8\(a\)\(7\) Rule: Reporting and Recordkeeping Requirements for PFAS Webinar](#) 01/25/2024 at 13.

⁸³ *Id.* at 24.

Definitions

Please consult the text of the rule in the Code of Federal Regulations to see the full list of definitions.⁸⁴

Who must report ⁸⁵	Persons who have manufactured for commercial purposes chemical substances and mixtures containing a chemical substance (including articles) that are a PFAS, consistent with the definition of PFAS (see above), at any period from January 1, 2011, through December 31, 2022.
Substances to report ⁸⁶	All chemical substances and mixtures containing a chemical substance (including articles) that are a PFAS, consistent with the definition of PFAS at § 705.3 .
Article ⁸⁷	<p>means a manufactured item which:</p> <p>(1) Is formed to a specific shape or design during manufacture.</p> <p>(2) Has end use function(s) depending in whole or in part upon its shape or design during end use; and</p> <p>(3) Has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.</p>
Mixture ⁸⁸	The term “mixture” means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.
Per- and polyfluoroalkyl substances or PFAS ⁸⁹	means, for the purpose of this part, any chemical substance or mixture containing a chemical substance that structurally contains at least one of the following three sub-structures:

⁸⁴ [40 CFR 705.3](#).

⁸⁵ [40 CFR 705.10](#).

⁸⁶ [40 CFR 705.5](#).

⁸⁷ [40 CFR 705.3 “Article”](#).

⁸⁸ [TSCA Sec. 3 \(10\), 15 U.S. Code § 2602 \(10\)](#).

⁸⁹ [40 CFR 705.3 “Per- and polyfluoroalkyl substances or PFAS”](#).

	<p>(1) R-(CF₂)-CF(R')R", where both the CF₂ and CF moieties are saturated carbons.</p> <p>(2) R-CF₂OCF₂-R', where R and R' can either be F, O, or saturated carbons.</p> <p>(3) CF₃C(CF₃)R'R", where R' and R" can either be F or saturated carbons.</p>
Commercial Use ⁹⁰	means 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.
Consumer Use ⁹¹	means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) when sold to or made available to consumers for their use.
Industrial function ⁹²	means the intended physical or chemical characteristic for which a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product or article; repackaged; or used.
Industrial use ⁹³	means use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed.
Manufacture ⁹⁴	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.
Manufacture for commercial purposes ⁹⁵	<p>means:</p> <p>(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:</p>

⁹⁰ [40 CFR 705.3 "Commercial use"](#).

⁹¹ [40 CFR 705.3 "Consumer use"](#).

⁹² [40 CFR 705.3 "Industrial function"](#).

⁹³ [40 CFR 705.3 "Industrial use"](#).

⁹⁴ [40 CFR 705.3 "Manufacture"](#).

⁹⁵ [40 CFR 705.3 "Manufacture for commercial purposes"](#).

	<p>(i) For commercial distribution, including for test marketing; and/or</p> <p>(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.</p> <p>(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.</p>
<p>Importer⁹⁶</p>	<p>means</p> <p>“(1) 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:</p> <p style="padding-left: 40px;">(i) The person primarily liable for the payment of any duties on the merchandise, or</p> <p style="padding-left: 40px;">(ii) An authorized agent acting on his behalf.</p> <p>(2) Importer also includes, as appropriate:</p> <p style="padding-left: 40px;">(i) The consignee.</p> <p style="padding-left: 40px;">(ii) The importer of record.</p> <p style="padding-left: 40px;">(iii) The actual owner if an actual owner's declaration and superseding bond have been filed in accordance with 19 CFR 141.20.</p> <p style="padding-left: 40px;">(iv) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR part 144.</p> <p>(3) For the purposes of this definition, the customs territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia.”</p>

⁹⁶ [40 CFR 704.3 “Importer”](#).

<p>Known to or reasonably ascertainable by, "KRA"⁹⁷</p>	<p>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.</p>
<p>Possession or control⁹⁸</p>	<p>means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner.) Information is included within this definition if it is:</p> <p>(1) In files maintained by submitter's employees who are:</p> <p>(i) Associated with research, development, test marketing, or commercial marketing of the chemical substance in question; and/or</p> <p>(ii) Reasonably likely to have such data.</p> <p>(2) Maintained in the files of other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question in the course of their employment as such agents.</p>

⁹⁷ [40 CFR 705.3 "Known to or reasonably ascertainable by"](#).

⁹⁸ [40 CFR 705.3 "Possession or control"](#).