SMALL ENTITY COMPLIANCE GUIDANCE FOR THE TSCA PFAS DATA CALL

TSCA SECTION 8(a)(7) REPORTING AND RECORDKEEPING

REQUIREMENTS FOR PERFLUOROALKYL AND POLYFLUOROALKYL SUBSTANCES

October 2023

EPA-705-G-2023-3730

This guide was prepared pursuant to section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104-121 as amended by Pub. L. Number 110-28. THIS DOCUMENT IS NOT INTENDED, NOR CAN IT BE RELIED UPON, TO CREATE ANY RIGHTS ENFORCEABLE BY ANY PARTY IN LITIGATION WITH THE UNITED STATES. The statements in this document are intended solely as guidance to aid you in complying with the TSCA Section 8(a)(7) reporting and recordkeeping requirements for perfluoroalkyl and polyfluoroalkyl substances (PFAS). EPA may decide to revise this guide without public notice to reflect changes in EPA's approach to implementing TSCA Section 8(a)(7) or to clarify and update text.

To determine whether EPA has revised this guide and/or to obtain copies, contact EPA's Small Business Ombudsman Hotline at (800) 368-5888 or (202) 566-1970 in DC, or consult the EPA's TSCA Section 8(a)(7) website at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping. The full texts of TSCA Section 8(a)(7) and the implementing regulations are also available at this website.

The contents of the guidance document do not have the force and effect of law and that the Agency does not bind the public in any way and intends only to provide clarity to the public regarding existing requirements under the law or Agency policies, except as authorized by law or as incorporated into a contract.

Introduction

This document is published by EPA as the official compliance guide for small entities, as required by the Small Business Regulatory Enforcement Fairness Act of 1996. Before you begin using the guide you should know that the information in this guide was compiled based on the regulation entitled "TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances," published on October 11, 2023 (88 FR 70516). EPA is continually improving and upgrading its rules, policies, compliance programs, and outreach efforts. You can determine whether EPA has revised or supplemented the information in this guide by consulting EPA's TSCA Section 8(a)(7) website at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ tsca-section-8a7-reporting-and-recordkeeping.

Contents

This guide is organized as follows:

Acronym List

CASRN	Chemical Abstracts Service Registry Number
CDX	Central Data Exchange
CFR	Code of Federal Regulations
EPA	U.S. Environmental Protection Agency
NAICS	North American Industrial Classification System
NDAA	FY 2020 National Defense Authorization Act
PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances
R&D	Research and Development
TSCA	Toxic Substances Control Act
U.S.C.	U.S. Code

Terminology

Throughout this guide the term "article" means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other

chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design. (40 CFR 705.3)

The term ‘‘chemical substance’’ means any organic or inorganic substance of a particular molecular identity, including—

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and

(ii) any element or uncombined radical. [15 U.S.C. 2602(2)(A)]

Note that this term does not include –

(i) any mixture,

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

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. [15 U.S.C. 2602(2)(B)]

The term ‘‘food’’ as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act). [21 U.S.C. 1033]

Even though the definition of chemical substance excludes mixtures, PFAS as a chemical substance may be present in a mixture. Therefore, this rule requires reporting on each chemical substance that is a PFAS, including as a component of a mixture. This rule does not require reporting on components of a mixture that do not fall under the structural definition of PFAS.

The term “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), produce, or manufacture for commercial purposes. [15 U.S.C. 2602(9)]

Finally, throughout this guide the term “PFAS” refers to Perfluoroalkyl and Polyfluoroalkyl Substances. PFAS are a group of synthetic chemicals that have been in use since the 1940s and can be found in a wide array of industrial and consumer products (Ref. #1). PFAS are synthesized for many different uses, ranging from firefighting foams to coatings for clothes and furniture, to food contact substances, to the manufacture of other chemicals and products. PFAS can be released to the environment throughout the lifecycle of manufacturing, processing, distribution, use, and disposal (Ref. #2). There is evidence that

exposure to some PFAS in the environment may be linked to harmful health effects in humans and animals, and that continued exposure above specific levels to certain PFAS may lead to adverse health effects (Ref. #1; Ref. #2).

For the purposes of the PFAS 8(a)(7) Reporting Rule, PFAS means any chemical substance that includes at least one of these three structures:

1) R-(CF_2)-CF(R')R'', where both the CF_2 and CF moieties are saturated carbons
2) R-CF_2OCF_2-R', where R and R' can either be F, O, or saturated carbons
3) $CF_3C(CF_3)$R'R'', where R' and R" can either be F or saturated carbons

Note that this definition may not be identical to other definitions of PFAS used within EPA and/or other organizations. Appendix B of the Instructions for Reporting PFAS Under TSCA Section 8(a)(7) presents examples of PFAS covered by this rule.

Other key terminology is defined in the Appendix: Glossary of Terms.

Who Should Use this Guide?

You should use this guide if you are a small business and currently manufacture or have previously manufactured (including imported) a chemical substance that is a PFAS between January 1, 2011, and December 31, 2022. The following are examples of businesses that are likely to be covered under the regulation:

- Construction (NAICS 23)
- Manufacturing (NAICS 31 – 33)
- Wholesale Trade (NAICS 42)
- Retail Trade (NAICS 44 – 45)
- Waste Management and Remediation Services (NAICS 562)

How Do I Obtain a Copy of the Rule?

A complete copy of the final rule is in the Federal Register (Vol. 88, p. 70516) and in docket EPA-HQ-OPPT-2020-0549 at https://www.regulations.gov/, which also includes supporting documents. See the section below entitled For More Information for additional resources.

Regulation Summary and Compliance Timetable

Regulation Summary

The FY 2020 National Defense Authorization Act (NDAA) amended the Toxic Substances Control Act (TSCA) to add section 8(a)(7), which mandates a one-time reporting event on Per- and Polyfluoroalkyl Substances (PFAS). On October 11, 2023, EPA published a final rule under section 8(a)(7) of TSCA requiring persons who have manufactured (including imported) PFAS for commercial purposes in any year since January 1, 2011, through December 31, 2022, to electronically report certain information to EPA. This TSCA section 8(a)(7) rule does not exempt small manufacturers or article importers from reporting and recordkeeping requirements. Note that there are no testing requirements or labeling requirements imposed by this rule.

Compliance Timetable

EPA's regulation is effective on November 13, 2023. Most entities, including small entities, have 18 months from the effective date of this rule to submit the requested information. The submission period will be a six-month period beginning twelve months after the effective date of the final rule: reporting due by May 8, 2025. EPA is granting small manufacturers (as defined at 40 CFR 704.3) who would report exclusively as article importers an additional six months to report data. Therefore, those small article importers would have 24 months from the effective date of this rule to submit the requested information on their imported articles: reporting due by November 10, 2025. The following table summarizes the regulatory requirements and compliance dates. The compliance date is the date after which compliance obligations apply.

The How to Comply section of this guide provides more detail on what you must do to comply with the reporting and recordkeeping requirements if you are a manufacturer or importer of PFAS.

Requirement	Compliance Date
Reporting	
Manufacturers (including importers) must report information on PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects for any year since January 1, 2011.	**May 8, 2025** (18 months from the effective date of this rule)
Small manufacturers (as defined at 40 CFR 704.3) who would report exclusively as article importers must report information on PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects for any year since January 1, 2011. They may fill out the streamlined Article Importer form.	**November 10, 2025** (24 months from the effective date of this rule)
Recordkeeping	
All manufacturers (including article importers) must retain records that document any information submitted to EPA for five years.	For five years following date of reporting deadline

Who Must Comply

How Can I Tell If I Am Subject to This Rule?

You are subject to this rule if you have manufactured (defined by statute at 15 U.S.C. 2602(9) to include import) a PFAS for a commercial purpose at any time since January 1, 2011. The potentially regulated community consists of entities that produce PFAS domestically or import PFAS into the United States. The small entities directly regulated by this rule include any entities manufacturing or importing PFAS; these entities may have been exempt from past TSCA Section 8(a) rulemakings based on their size but are not exempt under this rule. Importers of PFAS in articles are considered PFAS manufacturers and therefore subject to this rule. Waste management sites who import PFAS-containing waste (including in municipal solid waste) for the purpose of recycling or reuse for PFAS-containing products, as well as waste management sites who import PFAS in wastes that are not municipal solid waste streams are subject to this rule.

What Does Manufacture for Commercial Purposes Mean?

Manufacture for commercial purposes includes the import, production, or manufacturing of a chemical substance or mixture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer. This includes, but is not limited to, the manufacture of chemical substances or mixtures for commercial distribution, including test marketing, or for use by the manufacturer itself as an intermediate or for product research and development. Manufacture for commercial purposes also includes the coincidental manufacture of byproducts and impurities that are produced during the manufacture, processing, use, or disposal of another chemical substance or mixture. (40 CFR 705.3)

What is Not Reportable under this Rule?

Manufacturing activities associated with non-commercial scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research organizations (e.g., universities, colleges, teaching hospitals, and research institutes), are beyond the scope of manufacturing for commercial purposes and this rule. Additionally, because entities that import municipal solid wastes (MSW) for the purpose of disposal or destruction are not likely to know or reasonably ascertain that they imported PFAS in the MSW streams, these waste management activities are not within the scope of this rule's reporting requirements, consistent with TSCA section 8(a)(5)(C). However, note that other waste importers (including all importers of wastes that are not MSW streams and sites importing MSW for purposes other than disposal or destruction) are not exempt.

Is Processing Covered by this Rule?

No, persons who have only processed, distributed in commerce, used, and/or disposed of PFAS are not required to report under this rule, unless they have also manufactured (including imported) PFAS, including any PFAS coincidentally manufactured as byproducts or impurities.

Are Importers of PFAS-Containing Articles Subject to this Rule?

Yes, importers of articles containing PFAS must comply with the reporting requirements of this rule. However, EPA is providing a reporting option that allows article importers to provide their data on a streamlined form. The streamlined form allows article importers to report production volume as the total weight of the imported articles or as the quantity of articles imported, rather than weight of the PFAS. It also greatly reduces the amount of information that must be reported.

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. See 42 FR 64583 (1977). 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 are unsure whether you are importing an article, refer to the CDR "Imported Articles" factsheet at https://www.epa.gov/chemical-data-reporting/tsca-chemical-data-reporting-fact-sheet-imported-articles-2020.

Is Manufacture for Research and Development Subject to this Rule?

"Manufacture for commercial purposes" encompasses any importing, production, or other manufacturing activities with the purpose of obtaining an immediate or eventual commercial advantage and includes chemicals "for use by the manufacturer, including use for product research and development." R&D substances that meet the scope of "manufactured for commercial purposes" must be reported under this rule, even if the PFAS itself was not later commercialized. R&D substances that do not meet the scope of "manufactured for commercial purposes" are not reportable under this rule.

If you manufacture (including import) PFAS in quantities below 10 kg per year exclusively for research or analysis for commercial purposes, you may use the streamlined small quantity R&D form. The streamlined small quantity R&D form requires reporting only of the chemical substance identification information, domestic manufacture and imported volumes, indication of whether the substance was imported but never on site, and an optional "additional information" field.

Are There Any Exemptions to this Rule?

There are no reporting exemptions or production volume thresholds. Articles containing PFAS, including imported articles containing PFAS (such as articles containing PFAS as part of surface coatings), byproducts, impurities, polymers, and non-isolated intermediates are included under this data call, although those cases are exempt from reporting under Chemical Data Reporting (CDR).

How to Comply

What Must I Do to Comply?

This section provides guidance on how to comply with the TSCA PFAS Data Call reporting and recordkeeping requirements. The requirements for small entities are the same as for other entities.

What Information Must I Report?

You must report the following information to the extent such information is known to or reasonably ascertainable by you:

- The covered common or trade name, chemical identity and molecular structure of each chemical substance
- Categories of use for each substance or mixture
- Total amount of each substance or mixture manufactured, the amounts manufactured for each category of use
- Import production volume of the imported article and the unit of measurement for that production volume (e.g., quantity of the imported article, pounds, tons).
- Descriptions of byproducts resulting from the manufacture, processing, use, or disposal of each substance or mixture
- All existing information concerning the environmental and health effects of each substance or mixture
- The number of individuals exposed, and reasonable estimates on the number of individuals who will be exposed, to each substance or mixture in their places of work and the duration of their exposure
- The manner or method of disposal of each substance or mixture, and any change in such manner or method.

What Timeframe Should my Report(s) Cover?

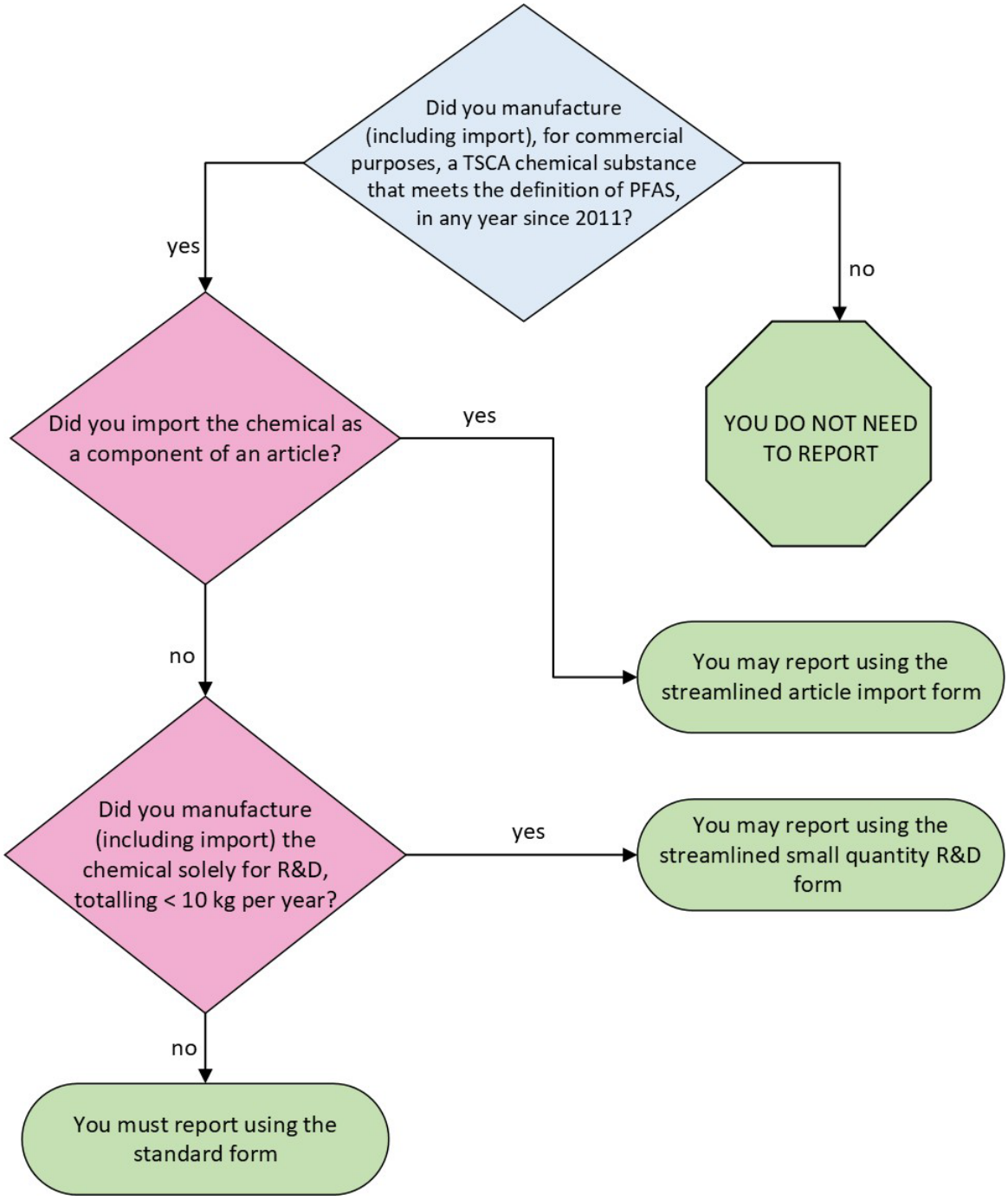
You must report on your activities from January 1, 2011, through December 31, 2022. All data elements applicable to you must be reported for all years in which you manufactured a PFAS. If you did not manufacture the PFAS in every year, the reporting software will provide you with the option to report on a subset of years.

What Form Should I Use to Report?

There are three online forms that reporters may use depending on their circumstances:

- Standard Form
- Streamlined Article Import Form
- Streamlined Small Quantity R&D Form

Use the following flow chart to determine the correct form to use.



How do I meet the Due Diligence Requirements?

Submitters are required to exercise certain levels of due diligence in gathering the information required by the PFAS 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.

The term "known to or reasonably ascertainable by" is defined in 40 CFR 705.3, meaning 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. This includes, but is not limited to, information that may be possessed by employees or other agents of the company reporting under the PFAS 8(a)(7) rule, including persons involved in the research, development, manufacturing, or marketing of a chemical substance and includes knowledge gained through discussions, symposia, and technical publications. For purposes of PFAS 8(a)(7) reporting, the known to or reasonably ascertainable by standard applies to all of the information required by the rule. 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®.

This table provides examples of how to interpret the known to or reasonably ascertainable by standard:

Scenario: Example Company A has never maintained information on how a particular PFAS (PFAS #A) 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 A has one major customer and 10 minor customers, who it believes processes and uses the particular PFAS in a similar manner and it expects that it could substantially fill this data gap by reviewing the public website of its largest customer.

Application of KRA Reporting Standard:

If:	Then:
Example Company A reviews its largest customer's website, and reports on the basis of the information contained on the website.	Duties Likely Fulfilled
Example Company A did not endeavor to supplement the information it already knew.	Duties Not Fulfilled

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

Application of KRA Reporting Standard:

If:	Then:
Example Company B contacts their supplier to determine the name, CASRN, and molecular structure of the fluoropolymer. The supplier provides this information for Example Company B's report. If Example Company B did not import this as an article, then they could initiate a joint submission with their supplier.	Duties Likely Fulfilled
Example Company B did not contact their supplier to obtain information on the fluoropolymer coating.	Duties Not Fulfilled

Scenario: Example Company C imports stain-resistant garments. Example Company C does not know specifically what chemical is used to impart stain resistance, but Example Company C 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 C contacts their supplier to determine the name, CASRN, and molecular structure of the stain-resistant chemical. The supplier provides this information for Example Company C's report or a joint submission is initiated.	Duties Likely Fulfilled
Example Company C did not contact their supplier to obtain information on the stain-resistant chemical.	Duties Not Fulfilled

See the Instructions for Reporting PFAS Under TSCA Section 8(a)(7) for additional examples of how to interpret the known or reasonably ascertainable by standard.

Can I Claim Any Information as Confidential?

Information submitted under this data call may be claimed as confidential; however, such claims must be made at the time of submission and substantiated in accordance with TSCA section 14 and the PFAS 8(a)(7) reporting rule. Submitters must provide upfront substantiation of all confidentiality claims except for claims made for domestic manufacture and, import volume information, and certain joint submission information. Certain processing and use data elements, a blank response, or a response that is designated as "not known or reasonably ascertainable" may not be claimed as confidential (40 CFR 711.30).

How do I Avoid Duplicative Reporting?

If you have already reported certain PFAS 8(a)(7) data to EPA, you are not required to re-report this information. Duplicative reporting is limited to the following: submissions to the CDR rule, the Toxics Release Inventory (TRI), the Greenhouse Gas Reporting Program (GHGRP), TSCA sections 4 (including voluntary submissions of information concerning environmental and health effects), 8(d) and 8(e), and PFAS manufactured as byproducts that are being separately reported under TSCA section 8(a)(7). **Information must have been reported *as required by the section 8(a)(7) rule***; for example, other programs may have exemptions, such as for articles or impurities, that could mean information reported to those programs was not reported as required by this data call. Due to differences in reporting requirements, exemptions, and other programmatic requirements, reporting to TRI and GHGRP may not meet the requirements of TSCA section 8(a)(7).

Information potentially duplicative of CDR:

- Physical state of the PFAS pursuant to § 711.15(b)(3)(C)(ix);

- Industrial processing and use type, sector(s), functional category(ies), and percent of production volume for each use, pursuant to § 711.15(b)(4)(i)(A) through (D);
- Consumer and/or commercial indicator, product category(ies), functional category(ies), percent of production volume for each use, indicator for use in products intended for children, and maximum concentration in the product, pursuant to § 711.15(b)(4)(ii)(A) through (F);
- Number of workers reasonably likely to be exposed for each combination of industrial processing or use operation, sector, and function, pursuant to § 711.15(b)(4)(i)(F), and the number of commercial workers reasonably likely to be exposed when the substance is used in a commercial product, pursuant to § 711.15(b)(4)(ii)(G).

Information potentially duplicative of TRI:

- Total volume recycled on-site
- Description of disposal process(es)
- Total volume released to land
- Total volume released to water
- Total volume released to air
- Total volume incinerated on site

Information potentially duplicative of GHGRP:

- Production volume (imported)
- Volume directly exported
- Total volume incinerated on site

Information potentially duplicative of previous submissions of environmental and health effects of PFAS:

- Information in substantial risk notifications pursuant to TSCA section 8(e)
- Other unpublished health and safety studies under TSCA section 8(d)
- Information submitted pursuant to a TSCA section 4 action, or other health and environmental effects information submitted voluntarily
- Other relevant information concerning environmental or health effects for PFAS

The manufacturers must indicate the rule or program to which they submitted that prior information concerning the environmental or health effects of that PFAS and the year in which it was submitted to EPA.

PFAS byproducts reporting as potentially duplicative: When a byproduct is also a reportable PFAS, information on that PFAS's environmental releases would be requested twice, both as a byproduct of the originally manufactured PFAS and as a commercially manufactured PFAS itself. To mitigate potentially duplicative reporting concerns in such situations, manufacturers of byproducts that are also reportable PFAS under this rule need not re-report the environmental release information of that byproduct on the original PFAS's form.

If you have previously submitted any of the above information to EPA, you must still submit a section 8(a)(7) PFAS report that includes all other required information and indicate what information was previously reported and where that information can be found. That means you must report information for missing years if you had reported for some but not all years from 2011 to 2022. Additionally, if you previously reported information, but not to the level of detail required by this data call, or used exemptions not applicable to this data call, you must report that information under this data call to the level of detail required, if known to or reasonably ascertainable by you. Similarly, if new, more accurate, or more detailed information has become known to or reasonably ascertainable by you, that information must be reported under this data call.

How do I Submit my Form?

All reporting entities must report PFAS data electronically, using the PFAS 8(a)(7) web-based reporting tool within EPA's Central Data Exchange (CDX) system. Registration with CDX is required prior to accessing the online PFAS 8(a)(7) tool to submit your PFAS data call information. You may find the following two guides helpful:

- CDX Registration Guide, which covers the specifics of CDX registration (https://cdx.epa.gov/About/UserGuide)
- PFAS 8(a)(7) Reporting Instructions, which provides information for getting started with the reporting tool and includes representative screenshots. (available in the docket and on EPA's webpage for the PFAS 8(a)(7) rule)

What Happens if the Agency Discovers a Violation?

To maximize compliance, EPA implements a balanced program of compliance assistance, compliance incentives, and traditional law enforcement. EPA knows that small businesses that must comply with complicated new statutes or rules want to do the right thing, but may lack the requisite knowledge, resources, or skills. Compliance assistance information and technical advice helps small businesses to understand and meet their environmental obligations. Compliance incentives, such as EPA's Small Business Policy, apply to businesses with 100 or fewer employees and encourage persons to voluntarily discover, disclose, and correct violations before they are identified by the government (more information about EPA's Small Business Policy is available at https://www.epa.gov/enforcement/small-businesses-and-enforcement). EPA's enforcement program is aimed at protecting the public by ensuring compliance with the TSCA section 8(a)(7) Rule.

In accordance with section 15 of TSCA, it is unlawful to fail or refuse to comply with any requirement under TSCA, or with any rule promulgated under TSCA. Therefore, any failure to comply with the final rule would be a violation of section 15 of TSCA. In addition, under section 15 of TSCA, it is unlawful for any person to: (1) Fail or refuse to establish or maintain records as required by the final rule or other regulations promulgated under this chapter; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA. Violators of the TSCA section 8(a)(7) Rule may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty for each violation. Each day in violation of the final rule could constitute a separate violation. Knowing or willful violations could lead to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies are available to EPA under TSCA.

EPA encourages small businesses to work with the Agency to discover, disclose, and correct violations. The Agency has developed self-disclosure, small business, and small community policies to mitigate penalties for small and large entities that cooperate with EPA to address compliance problems. For more information on compliance assistance and other EPA programs for small businesses, please contact EPA's Small Business Ombudsman at (202) 566-2075.

For More Information

Detailed reporting guidance is available in the Instructions for Reporting PFAS Under TSCA Section 8(a)(7). Additional information, including a copy of the final rule, is available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping. The regulations can be found in the Federal Register (88 FR 70516) or at docket EPA-HQ-OPPT-2020-0549 at https://www.regulations.gov/.

Where Can I go if I Have Questions or Need Further Assistance?

Please contact EPA's TSCA Hotline with questions by telephone at (800) 471-7127, or by email at tsca-hotline@epa.gov.

Appendix

Glossary of Terms

Article means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design. (40 CFR 705.3)

Byproduct means a chemical substance produced without separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s). (40 CFR 704.3)

Central Data Exchange (CDX) means EPA's centralized electronic document receiving system, or its successors, including associated instructions for registering to submit electronic documents.

CF moiety means a segment of a molecule containing one carbon atom bonded to one fluorine atom.

CF_2 moiety means a segment of a molecule containing one carbon atom bonded to two fluorine atoms.

Commerce means trade, traffic, transportation, or other commerce: (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, transportation, or commerce described in clause (A) (TSCA 3(3)).

Commercial use 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. (40 CFR 705.3)

Environmental or health effects information means any information of any effect of a chemical substance or mixture containing a chemical substance on health or the environment or on both. This includes all health and safety studies.
(1) Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture containing a chemical substance on health or the environment is also included. Any information that bears on the effects of a chemical substance on health or the environment would be included.
(2) Examples are:
(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; and acute, subchronic, and chronic effects.
(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: Acute toxicity tests, chronic toxicity tests, critical life-stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture containing a chemical substance on the environment, including surveys, tests, and studies of: Biological, photochemical, and chemical degradation; structure/activity relationships; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility.
(iv) Monitoring data, including but not limited to when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture containing a chemical substance. (40 CFR 705.3)

Health and safety studies means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture containing a chemical substance, and any test performed under TSCA. [15 U.S.C. 2602(8)]

Impurity means a chemical substance which is unintentionally present with another chemical substance. (40 CFR 704.3)

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. (40 CFR 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), produce, or manufacture for commercial purposes. [15 U.S.C. 2602(9)]

Manufacture for commercial purposes means

(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:
(i) For commercial distribution, including for test marketing.
(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, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. 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. (40 CFR 705.3)

Non-isolated intermediate means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance

passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. (40 CFR 704.3)

Person means any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof, or any municipality; any interstate body; and any department, agency, or instrumentality of the Federal government. (40 CFR 704.3)

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.
(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. (40 CFR 705.3)

Small manufacturer means a manufacturer (including importer) that meets either of the following standards:

(1) *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $120 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lbs), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $12 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer). (40 CFR 704.3)

List of References

Reference #1 – Research on Per- and Polyfluoroalkyl Substances (PFAS), https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas

Reference #2 - PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf