

PRE-PUBLICATION NOTICE

On September 28, 2023, Michal Freedhoff, the EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, signed the following document:

Action: **Final Rule**
Title: **Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances**
FRL #: **7902-02-OCSP**
Docket ID #: **EPA-HQ-OPPT-2020-0549**

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Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <http://www.regulations.gov>.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 705

[EPA-HQ-OPPT-2020-0549; FRL-7902-02-OCSPP]

RIN 2070-AK67

**Toxic Substances Control Act Reporting and Recordkeeping Requirements for
Perfluoroalkyl and Polyfluoroalkyl Substances**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing reporting and recordkeeping requirements for per- and polyfluoroalkyl substances (PFAS) under the Toxic Substances Control Act (TSCA). In accordance with obligations under TSCA, as amended by the National Defense Authorization Act for Fiscal Year 2020, EPA is requiring persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, to submit information to EPA regarding PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects. In addition to fulfilling statutory obligations under TSCA, this rule will enable EPA to better characterize the sources and quantities of manufactured PFAS in the United States.

DATES: This final rule is effective on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*]**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0549, is available online at <https://www.regulations.gov>. Additional instructions for visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Alie

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action may apply to you if you have manufactured (defined by statute at 15 U.S.C. 2602(9) to include import) PFAS for a commercial purpose at any time since January 1, 2011. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Construction (NAICS code 23);
- Manufacturing (NAICS code 31 through 33);
- Wholesale trade (NAICS code 42);
- Retail trade (NAICS code 44 through 45); and
- Waste management and remediation services (NAICS code 562).

This list details the types of entities that EPA is aware could potentially be regulated by this action. Other types of entities not listed could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in 40 CFR 705.10 and 40 CFR 705.12. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What is the Agency's authority for taking this action?

EPA is promulgating this rule pursuant to its authority in TSCA section 8(a)(7) (15 U.S.C. 2607(a)(7)). The National Defense Authorization Act for Fiscal Year 2020 (FY 2020 NDAA) (Pub. L. No. 116-92 section 7351) amended TSCA section 8(a) in December 2019, adding section 8(a)(7), titled “*PFAS Data*.” TSCA section 8(a)(7) requires EPA to promulgate a rule “requiring each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011” to report information described in TSCA section 8(a)(2)(A) through (G). This includes a broad range of information, such as information related to chemical identity and structure, production, use, byproducts, exposure, disposal, and health and environmental effects.

TSCA section 14 imposes requirements for the assertion, substantiation, and review of information that is claimed as confidential business information (CBI).

C. What action is the Agency taking?

In this action, EPA is promulgating reporting and recordkeeping requirements for entities who have manufactured (including imported) a PFAS for commercial purposes at any point since January 1, 2011. This rule takes into consideration comments received on the proposed rule (86 FR 33926, June 28, 2021 (FRL-10017-78)) input from the Small Business Advocacy Review (SBAR) Panel that was convened following publication of the proposed rule, and comments received on the SBAR Panel Report and Initial Regulatory Flexibility Analysis (IRFA), which EPA published with a Notice of Data Availability (NODA) (Ref. 1). Details on the final rule requirements, including modifications from the proposal, are explained in Unit III.

EPA is finalizing this rule both to fulfill its obligations under TSCA section 8(a)(7), as amended by the FY 2020 NDAA, and to create a more comprehensive database of previously manufactured PFAS to improve the Agency's understanding of PFAS in commerce and to support actions to address PFAS exposure and contamination.

D. Why is the Agency taking this action?

TSCA section 8(a)(7) requires EPA to promulgate a rule requiring each person who has manufactured a PFAS in any year since January 1, 2011, to report certain information for each year since January 1, 2011.

E. What are the incremental economic impacts?

EPA has evaluated the costs and benefits of this rulemaking and provided an Economic Analysis of the potential impacts associated with this rule (Ref. 2). The primary benefit of this rule is providing EPA with data on PFAS which have been manufactured, including imported, for commercial purposes since 2011; the Agency is not currently aware of any similar source of information for these substances of interest. Subsequently, EPA will use these data to support activities addressing PFAS under TSCA, as well as activities and programs under other environmental statutes. The additional data on the production, use, exposure, and environmental and health effects of PFAS in the United States may allow EPA to more effectively determine whether additional risk assessment and management measures are needed. This information may lead to reduced costs of risk-based decision making and improved decisions concerning PFAS.

EPA has evaluated the potential costs of this reporting and recordkeeping requirement for manufacturers and article importers. Since the Notice of Proposed Rulemaking for this action published on June 28, 2021, (86 FR 33926 (FRL-10017-78)), EPA found additional data and received feedback via public comments to update its economic analysis, including estimating the number of PFAS article importers. EPA revised cost estimates from \$10.8 million in industry costs detailed in the draft Economic Analysis for the proposed rule to \$876 million detailed in the IRFA and NODA (Ref. 1), to \$843 million using a 3 percent discount rate and \$800 million using a 7 percent discount rate at the final rule stage. The final Economic Analysis (Ref. 2), which is available in the docket, is briefly summarized here. The regulated community is expected to incur one-time burdens and costs associated with rule familiarization, compliance

determination, form completion, CBI claim substantiation, recordkeeping, and electronic reporting activities. Industry is estimated to incur a burden of approximately 11.6 million hours, with a cost of approximately \$843 million and \$800 million under a 3 percent and 7 percent discount rate, respectively. The Agency is expected to incur a cost of \$1.6 million. The total social cost is therefore estimated to be approximately \$844.8 million and \$801.7 million under a 3 percent and 7 percent discount rate, respectively.

II. Background

A. What are PFAS?

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 (Refs. 2 and 3). 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. They are used in a wide variety of products, including textiles, electronics, wires and cables, pipes, cooking and bakeware, sport articles, automotive products, toys, transportation equipment, and musical instruments, which may be imported into the United States as finished articles (Ref. 2). PFAS can be released to the environment throughout the lifecycle of manufacturing, processing, distribution, use, and disposal (Refs. 3 and 4). 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 (Refs. 2; 3, and 4).

B. What is TSCA section 8(a)(7)?

On December 20, 2019, the National Defense Authorization Act for Fiscal Year 2020 (NDAA) was signed into law (PL 116-92). Among other provisions, section 7321 of NDAA added TSCA section 8(a)(7) which states that the Administrator shall promulgate a rule in accordance with this subsection requiring each person who has manufactured a chemical

substance that is a perfluoroalkyl or polyfluoroalkyl substance (PFAS) in any year since January 1, 2011, to submit to the Administrator a report that includes, for each year since January 1, 2011, the information described in subparagraphs (A) through (G) of paragraph (2). The categories of information described in Sections 8(a)(2)(A) through (G) are:

- The common or trade name, chemical identity and molecular structure of each chemical substance or mixture for which a report is required;
- Categories or proposed categories of use for each substance or mixture;
- Total amount of each substance or mixture manufactured or processed, the amounts manufactured or processed for each category of use, and reasonable estimates of the respective proposed amounts;
- 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; and
- The manner or method of disposal of each substance or mixture, and any change in such manner or method.

Finally, in carrying out TSCA section 8, section 8(a)(5) requires EPA, to the extent feasible, to (A) not require unnecessary or duplicative reporting, (B) minimize compliance costs on small manufacturers and processors, and (C) apply any reporting obligations to those persons likely to have information relevant to effective implementation of TSCA.

C. What did EPA propose?

In the proposed rule, EPA published for the reporting and recordkeeping requirements for

PFAS manufacturers under TSCA section 8(a)(7). EPA proposed to require any entity who had commercially manufactured a PFAS that is a TSCA chemical substance at any time since January 1, 2011, to electronically report certain information to EPA regarding PFAS identity, production volumes, industrial uses, commercial and consumer uses, byproducts, worker exposure, disposal, and any existing information related to environmental and health effects. Such information would be reported for each year since 2011 in which a covered PFAS was manufactured, to the extent such information were known to or reasonably ascertainable by the reporter. EPA also proposed a five-year recordkeeping period following the submission date.

EPA also proposed the following structural definition of PFAS: per- and polyfluorinated substances that structurally contain the unit $R-(CF_2)-C(F)(R')R''$. Both the CF_2 and CF moieties are saturated carbons and none of the R groups (R , R' , or R'') can be hydrogen. Under the proposal, reporting would have been required for any TSCA chemical substance (including any mixture with a chemical substance) which met the proposed structural definition and had been manufactured for a commercial purpose at any time since January 1, 2011.

EPA did not propose any reporting exemptions or production volume thresholds. The scope of covered chemical substances under the proposed rule included any amounts of PFAS which were known to or reasonably ascertainable by the manufacturer, including PFAS-containing articles, byproducts, and impurities. EPA also did not propose any exemptions or flexibilities for small manufacturers.

EPA proposed a six-month information collection period following the effective date of the final rule, after which the reporting tool would open for a six-month reporting period. Thus, the proposed rule stipulated a reporting deadline one year from the effective date of the final rule.

III. Final PFAS Reporting and Recordkeeping Requirements

In this unit, EPA discusses in detail the final reporting and recordkeeping requirements,

including changes from the proposed rule in response to public input.

A. What substances are covered by this rule?

1. The scope of PFAS for the purpose of this rule.

Under TSCA section 8(a)(7), EPA must collect information on chemical substances manufactured (including imported) for commercial purposes, including chemical substances present in a mixture, that are “perfluoroalkyl or polyfluoroalkyl substances,” or PFAS. TSCA section 8(a)(7) does not define or characterize “PFAS.” EPA has determined that any TSCA chemical substance (as that term is defined by TSCA section 3(2); see Unit IV.A.2.) that falls within the structural definition at 40 CFR 705.3 is subject to reporting under TSCA section 8(a)(7), if it has been manufactured for commercial purposes in any year since January 1, 2011. The proposed definition defined PFAS as a substance that includes the following structure: $R-(CF_2)-C(F)(R')R''$, in which both the CF_2 and CF moieties are saturated carbons and none of the R groups (R , R' or R'') can be hydrogen. EPA found that at least 1,364 substances from both the TSCA Inventory (Inventory) and Low-Volume Exemption (LVE) claims would meet the proposed structural definition. Separately, a count of chemicals meeting the proposed definition on EPA’s CompTox Chemicals Dashboard (Ref. 6) found approximately 9,400 structures, though many of those structures are not known TSCA chemical substances and would be out of scope of reporting for this rule, as explained in section III.A.2 of this rule.

EPA determined that a structural definition was more appropriate for this rule than a discrete list of specifically identified substances. Other TSCA requirements have relied on a structural definition when appropriate (e.g., the LCPFAC SNUR defines covered substances using a structural definition (40 CFR 721.10536) (Ref. 7), and the polymer exemption rule for new chemical pre-manufacture notices (PMNs) defines covered PFAS polymers using structural definitions (40 CFR 723.250)). Additionally, other scientific and regulatory bodies, such as the Organization of Economic Cooperation and Development (OECD) (Refs. 8 and 9), have defined

PFAS using various structural definitions. Thus, there is clear precedent for using a structural definition both for TSCA rules and for actions addressing PFAS, and a structural definition is consistent with the text of TSCA section 8(a)(7). EPA also determined that limiting the scope of reporting to a discrete list of chemicals would eliminate reporting on substances of interest to the Agency. Given various reporting exemptions for both existing chemicals (e.g., certain byproducts and research and development (R&D) substances are exempt from reporting in the Chemical Data Reporting (CDR) rule) and new chemicals (e.g., byproducts and impurities that are not listed on the Inventory), and with minimum reporting thresholds under other rules, EPA may be unaware of some TSCA chemical substances which meet this structural definition of PFAS. Providing a discrete list based on substances currently on the Inventory and in LVEs likely limits EPA's ability to capture all substances that meet the structural definition, and which may present properties similar to perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), and hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (popularly known as "GenX"). Therefore, EPA is defining PFAS for this TSCA section 8(a)(7) rule using a structural definition to avoid inadvertently limiting the scope of reporting to substances on a discrete list.

After reviewing public comments, EPA determined that the proposed definition may not include all substances for which EPA believes reporting of information is necessary (see additional discussion of relevant public comment in Unit IV.A). Therefore, EPA is modifying the definition of PFAS from the proposal. For the purpose of this TSCA section 8(a)(7) reporting rule, EPA is defining "PFAS" using a structural definition. PFAS is defined as including at least one of these three structures:

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

Manufacturers of substances that do not meet this structural definition are not required to report under this rule. EPA is providing a list of substances that meet this definition, gathered from the Inventory, LVEs, and the CompTox Chemicals Dashboard; this list will be available in the CompTox Chemicals Dashboard at <https://comptox.epa.gov/dashboard>. A substance that is not on this list but still falls under the definition of a “chemical substance” under TSCA (see Unit III.A.2) is subject to this rule if the substance has been manufactured for a commercial purpose since 2011.

EPA is modifying the proposed definition first to remove the R group requirements, resulting in the first sub-structure of this rule’s definition of PFAS (i.e., $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons). The removal of the R group requirements from the proposed definition will expand the universe of PFAS to include additional substances of potential concern because they are likely to be persistent. While the proposed definition was developed to focus on substances most likely to be persistent in the environment while excluding those substances that are “lightly” fluorinated (i.e., the molecule only contains unconnected CF_2 or CF_3 moieties), EPA acknowledges that substances that are not fully fluorinated may still be persistent in the environment. This is because the persistence of organofluoro compounds is more related to the density of C-F bonds within the molecule than simply the existence of fully fluorinated carbons (Ref. 10). The final definition, which does not include the proposed definition’s R group requirements focuses the definition on those substances most likely to persist in the environment. The final definition does not include substances that only have a single fluorinated carbon, or unsaturated fluorinated moieties (e.g., fluorinated aromatic rings and olefins). The latter set of substances are more susceptible to chemical transformation than their saturated counterparts, and therefore, are less likely to persist in the environment (Ref. 10). EPA has determined that, for the purpose of this rule, it is unnecessary to extend reporting requirements to substances that only have a single fluorinated

carbon or unsaturated fluorinated moieties and are therefore less likely to persist in the environment, unlike substances like PFOA, PFOS and GenX.

In addition to modifying the proposed definition by removing the R group requirements, EPA determined that the definition should be further expanded by adding two sub-structures that will include certain substances of interest to the Agency and to public commenters. Furthermore, the additional two sub-structures will encompass other chemical substances that are persistent in the environment but were not covered by the proposed definition. The second sub-structure ($\text{R-CF}_2\text{OCF}_2\text{-R}'$, where R and R' can either be F, O, or saturated carbons) aims to capture certain fluorinated ethers. EPA believes that these ethers are likely to be found in water; for example, PFMOAA (CASRN 674-13-5) and other chemicals with structures similar to GenX found in the Cape Fear River. However, they may not have been reported to the Inventory or as an LVE, and therefore would not have been considered when developing the proposed definition, which focused on substances in the known TSCA universe (i.e., the Inventory and LVEs). Additionally, it is possible that such substances are not on the Inventory due to TSCA reporting exemptions (e.g., byproducts, or certain R&D substances). Based on these ethers' properties and the lack of prior TSCA reporting, EPA believes that data related to the manufacturing of these PFAS is necessary to carry out TSCA section 8(a)(7) and would not be duplicative of other reporting. Thus, EPA is interested in known or reasonably ascertainable information on substances meeting this sub-structure definition, as it meets EPA's threshold of focusing on chemicals more likely to exhibit properties similar to GenX (along with PFOA and PFOS), including their likely presence in the environment.

Finally, the third sub-structure ($\text{CF}_3\text{C}(\text{CF}_3)\text{R}'\text{R}''$, where R' and R'' can either be F or saturated carbons) aims to capture a different type of branching for highly fluorinated substances that would not meet the proposed definition due to their non-adjacent fluorinated carbons. These substances are likely to be persistent, and EPA believes that reporting for these more branched

substances is necessary to collect the information described in TSCA section 8(a)(2)(A)-(G) for substances with similar persistence properties as PFOA, PFOS, or GenX. For instance, 4,4,4-Trifluoro-2,2,3,3-tetraakis(trifluoromethyl)butanoic acid (CASRN 1882109-62-7) would not have met the proposed definition due to its non-adjacent fluorinated carbons, but it has the same number of carbon, fluorine, and oxygen atoms as PFOA, and has been identified as an isomer of PFOA under the Stockholm Convention (Ref. 11). Further, this substance, like other substances meeting this sub-structure, has many highly fluorinated moieties such that EPA believes it is likely to be persistent in the environment. EPA is interested in known or reasonably ascertainable information on substances meeting this sub-structure definition, as these chemicals are likely to persist in environments to which they are released.

Under this rule's definition of PFAS, EPA identified additional substances that may be subject to the rule from the Inventory and LVEs, i.e., "known TSCA chemical substances." Specifically, EPA identified an additional 22 chemical substances on the Inventory and 19 LVEs, all of which are now covered under the first sub-structure of this rule's definition. To date, EPA has not identified any additional substances on the Inventory or as an LVE under the second and third sub-structures. This relatively modest increase of 41 known TSCA chemical substances would bring the known universe of TSCA chemical substances meeting this rule's definition of PFAS to 1,462, from 1,364 known TSCA PFAS identified by the proposed definition. However, as discussed previously, a substance's absence on the Inventory or LVEs may be due, at least in part, to several exemptions for Inventory and new chemicals reporting (e.g., byproducts, impurities, certain R&D substances). In the absence of those exemptions, a PFAS meeting the definition under TSCA section 3(2) may be subject to reporting under this rule.

EPA is also affirming that fluoropolymers which meet this rule's definition of PFAS are reportable under this rule; this includes higher molecular weight fluoropolymers. EPA does not believe the requested data on fluoropolymers would be considered duplicative or unnecessary:

this information is not reported to EPA otherwise, and any manufacturers' existing information on such fluoropolymers will inform EPA's understanding of such types of PFAS within U.S. commerce, including their downstream uses and their disposal methods.

EPA notes that this definition may not be identical to other definitions of PFAS used within EPA and/or by other organizations. The term "PFAS" has been used broadly by many organizations for their individual research and/or regulatory needs. Various programs or organizations have distinct needs or purposes apart from this TSCA section 8(a)(7) reporting rule, and therefore, different definitions of the term "PFAS" may be appropriate for other purposes. The Agency notes that this perspective, that different users may have very different needs and no single PFAS characterization or definition meets all needs, is shared by many other organizations, including OECD (see page 29, Ref. 8). EPA has determined the final definition of "PFAS" is the most appropriate definition for this TSCA section 8(a)(7) rule and acknowledges that there may be other rules or programs who apply different definitions to meet their own needs.

2. Definition of "chemical substance" under TSCA and PFAS in mixtures.

This rule is limited to manufacturers (including importers) of PFAS that are considered a "chemical substance." Under TSCA section 3(2), "chemical substance" means any organic or inorganic substance of a particular molecular identity, including: (1) Any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (2) Any element or uncombined radical. This rule does not require reporting on activities that are excluded from the definition of "chemical substance" in TSCA section 3(2)(B).

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, as

explained in Unit III.A.1.

B. Which entities are covered by this rule?

1. Scope of covered entities.

Anyone who has manufactured (including imported) a PFAS for a commercial purpose in any year since January 1, 2011, is covered by this rule. As noted in Unit III.B.2, “manufacture for a commercial purpose” includes the coincidental manufacture of PFAS as byproducts or impurities. EPA believes at least portions of the NAICS codes listed in Unit I.A. may be covered by this rule. This rule extends to manufacturers (including importers) only. Importers of PFAS in articles are considered PFAS manufacturers.

Persons who have only processed, distributed in commerce, used, and/or disposed of PFAS are not required to report under this rule, unless they also have manufactured PFAS for a commercial purpose. If an entity (such as a wastewater treatment plant) is simply processing PFAS they received domestically, and not also manufacturing PFAS, including as a byproduct, then the entity is not covered by this rule. Although EPA received several public comments about extending the rule to cover processors (see Unit IV.), TSCA section 8(a)(7) only refers to manufacturers and expanding the rule to processors would be pursuant to EPA’s separate rulemaking authority at TSCA section 8(a)(1), which the Agency is not pursuing at this time.

2. Scope of “manufacture for commercial purposes.”

Pursuant to TSCA section 8(f), the scope of “manufacturing” for the purposes of this rule is limited to entities manufacturing for a commercial purpose. EPA is defining “manufacture for commercial purposes” to align with definitions used in other rules. Specifically, “manufacture for commercial purposes” includes the import, production, or manufacturing of a chemical substance or mixture containing a chemical substance 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. As described in Unit III.B.1, simply *receiving* PFAS from domestic suppliers or other domestic sources is not, in itself, considered manufacturing PFAS for commercial purposes. Entities that process and/or use PFAS only need to report on PFAS they have manufactured (including imported), if any.

However, certain activities are not considered “manufacture for commercial purposes” under TSCA section 8(f) (e.g., non-commercial R&D activities such as scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research organizations, unless the activity is for eventual commercial purposes) and are not subject to the reporting requirements in this rule. For example, reporting would not be required for a federal agency which manufactures or imports PFAS when it is not for any immediate or eventual commercial advantage.

3. Non-reportable activities.

As discussed in Unit III.B.2, entities who have manufactured PFAS for a commercial purpose include those who have imported PFAS (including in wastes), or those who have coincidentally produced PFAS during the manufacture, processing, use, or disposal of another chemical substance or mixture. EPA noted in the proposed rule that this may include certain waste management companies, if they have imported PFAS in a waste or produced PFAS at their site during the disposal of another chemical substance or mixture. Through public comments and input during the SBAR Panel, EPA understands that entities engaged in certain waste management activities are in the unique position of not having knowledge of PFAS they may have manufactured for commercial purposes. Entities that import municipal solid wastes (MSW) for the purpose of disposal or destruction cannot know or reasonably ascertain that they imported

PFAS in the MSW streams. MSW streams are heterogeneous and generally difficult to characterize, in the absence of notification or labeling requirements related to the content of the waste. There were no federal labeling or notification requirements for PFAS in wastes concurrent with this reporting period, nor are there general labeling practices for PFAS in MSW streams that are sent for disposal or destruction. Additionally, standard analytical methods for PFAS in MSW streams were not available during this reporting period. Because no PFAS was listed as a hazardous waste and subject to notification requirements under the Resource Conservation and Recovery Act (RCRA) or other federal laws during this rule's lookback period (i.e., since January 1, 2011), and due to general industry practices, EPA understands that importers of MSW streams for disposal or destruction would not have any records or data that they had imported PFAS or any other information relevant to TSCA section 8(a)(7). Therefore, EPA has determined that waste management activities involving importing municipal solid waste streams for the purpose of disposal or destruction are not within scope of this rule's reporting requirements, per EPA's obligations under TSCA section 8(a)(5)(C).

However, EPA is not broadly exempting all waste management facilities from this rule. Facilities that have imported waste containing PFAS, other than in MSW streams for destruction or disposal, are likely to have information relevant to this rule. Other waste management sites may have relevant information regarding PFAS contents in waste they have imported outside of MSW, or for the purpose of recycle or reuse; thus, EPA is required to apply reporting requirements to such entities who may have relevant information, pursuant to TSCA section 8(a)(5)(C). This would include waste management sites who import PFAS-containing waste (including in MSW) 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. In the former activity, entities who import wastes that may contain PFAS, such as some carpets and rugs, for the purpose of recycling or reusing the PFAS-containing material, may be

aware of the general nature of those materials and the downstream processing and use information that is responsive to this rule (see Table 14, Ref. 12). In the latter activity, importers of PFAS-containing wastes that are not MSW (such as industrial wastes) may also have knowledge of the contents of the waste they have imported due to labeling or notification practices, including under international agreements affecting transboundary movement of wastes (Ref. 13). Because certain importers of waste (besides MSW that is imported for the purpose of disposal or destruction) are anticipated to know or reasonably ascertain that they have manufactured PFAS, EPA is extending reporting requirements to manufacturers (including importers) of PFAS in wastes, unless they have imported PFAS in municipal solid waste streams for the purpose of disposal or destruction.

C. What is the reporting standard of this rule?

For the purpose of this rule, the reporting standard is information known to or reasonably ascertainable by the manufacturer, which is the standard used in other TSCA section 8 rules, including CDR since 2011 (see TSCA section 8(a)(2)). “Known to or reasonably ascertainable by” is defined to include “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 704.3). This reporting standard requires reporting entities to evaluate their current level of knowledge of their manufactured products (including imports), as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. This standard carries with it an exercise of due diligence, and the information-gathering activities that may be necessary for manufacturers to achieve this reporting standard may vary from case-to-case.

This standard would require that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). This standard may also entail inquiries outside the organization to fill gaps in the

submitter's knowledge. Such activities may, though not necessarily, include phone calls or email inquiries to upstream suppliers or downstream users or employees or other agents of the manufacturer, including persons involved in the research and development, import or production, or marketing of the PFAS. Examples of types of information that are considered to be in a manufacturer'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 showing use information or concentrations of chemical substances in mixtures, such as a Safety Data Sheet or a supplier notification; and information from the CAS or from Dun & Bradstreet (D-U-N-S). However, if particular information cannot be derived or reasonably estimated without conducting further customer surveys (i.e., without sending a comprehensive set of identical questions to multiple customers), it would not be "reasonably ascertainable" to the submitter. Thus, there is not a need to conduct new surveys for purposes of this rule. As described previously, however, existing survey data may nevertheless be "known to" the organization. This information may also include documented knowledge gained through discussions, conferences, and technical publications. In addition, this is the same reporting standard employed in the TSCA section 8(a) CDR rule (40 CFR 711.15). In response to public comments and input received through the SBAR Panel, EPA has also created additional compliance guidance related to this reporting standard, including for small entities and for article importers (Ref. 14). Therefore, EPA anticipates many reporters under this rule are familiar with this reporting standard, and resources are available to support those reporters who may not be familiar with the standard.

In the event that a manufacturer (including importer) does not have actual data (e.g., measurements or monitoring data) to report to EPA, the manufacturer (including importer) should consider whether "reasonable estimates" of such information are ascertainable.

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“Reasonable estimates” may rely, for example, on approaches such as mass balance calculations, emissions factors, or best engineering judgment. EPA notes that many of the data elements requested under this rule, including production volumes or environmental release volumes, incorporate a level of estimation by requiring only two significant figures. Other data elements, including worker exposure, are reported as ranges, as with CDR. For instance, a manufacturer may be able to estimate the range of number of workers reasonably likely to be exposed for each commercial use based on the manufacturer’s knowledge of the commercial sites’ sizes, without specific workplace monitoring data; the manufacturer, would report the estimated range, rather than reporting that the information is not known. In general, EPA believes that industry possesses a greater knowledge than EPA about its own supply chain and operations related to the chemical substances it manufactures and the downstream uses, even if they do not control their customers’ sites. However, if manufacturers do not know nor can reasonably make estimates for certain data elements, except for production volumes, they may indicate such information is “Not Known or Reasonably Ascertainable” (NKRA) to them in lieu of the requested estimate or range. For instance, if a manufacturer does not know and cannot reasonably ascertain (including, having no basis for a reasonable estimate or assumption based on past experiences for the same or similar substances) how a PFAS is disposed of as a waste in a given year, the manufacturer may submit “NKRA” for that information. Reporters are also advised that “NKRA” designations cannot be claimed as CBI under TSCA section 14. Reporting NKRA should only happen when data are truly not reasonably ascertainable or are unattainable (e.g., when the appropriate recordkeeping period has lapsed and a past record is no longer available).

EPA has published reporting instructions and a Small Entity Compliance Guide, which include information related to this reporting standard and the activities that small entities, including article importers, may take to meet the due diligence requirement (Ref. 14).

If, after conducting due diligence and reviewing known or reasonably ascertainable

existing information, a manufacturer, particularly an importer of articles containing PFAS, may not have knowledge that they have manufactured or imported PFAS and thus need not report under this rule. EPA encourages such an entity to document its activities to provide evidence of due diligence. Additionally, consistent with their own business practices, companies may elect to retain documentation of their conclusion that they were not subject to reporting requirements.

D. What information must be reported under this rule?

1. General reporting form.

EPA is requiring that PFAS manufacturers submit the following information for each PFAS, for each year in which that substance was manufactured since January 1, 2011, to the extent the information is known or reasonably ascertainable. For the purposes of this rule, EPA is requiring this information to be submitted for each chemical substance that is a PFAS. For mixtures that contain at least one chemical substance that is a PFAS, manufacturers must submit information for each chemical substance in the mixture that is a PFAS. For example, a mixture comprised of PFAS A and PFAS B would result in the submission of two forms containing the information described later in this unit for each PFAS. For chemical substances of unknown or variable compositions, complex reaction products, and biological materials (UVCBs), including polymers, a single form may be submitted for that UVCB. EPA encourages submitters of mixtures and UVCBs that contain PFAS to provide additional information in the optional free text box related to the composition of that mixture or UVCB at the time of manufacture, if known.

EPA is largely finalizing the proposed reporting requirements, with a few modifications based on public comments. Changes to the proposed requirements include: removing the requirements for reporting maximum production volume in the first 12 months and maximum yearly production volume in any 3 years; removing the requirement for reporting the maximum quantity on-site at any time (including storage); modifying the requirement to submit the

molecular structure for each substance by making the submission optional for any Class 1 chemical substance on the Inventory (but required for all others); requiring submitters to provide a generic name or description (which indicates, at least, that the substance is fluorinated) in lieu of the specific chemical identity or trade name when neither are known; reporting analytical methods, if any; adding optional comment boxes to provide any additional information or clarification to EPA.

A spreadsheet containing the reporting requirements is also available in the docket (Ref. 15).

2. Streamlined reporting form option for article importers.

Article importers are not exempt from this rule. Given the reporting exemptions in other TSCA reporting rules, exempting imported articles from the scope of this TSCA section 8(a)(7) reporting rule would perpetuate data gaps in EPA's level of knowledge related to PFAS manufactured for a commercial purpose since 2011. EPA cannot know what requested information is "reasonably ascertainable" to all article importers without knowing the full range of potentially available information to be reported. Thus, EPA does not otherwise have the information outlined in TSCA section 8(a)(7) on PFAS within imported articles, and the Agency cannot justify a broad exemption of imported articles under TSCA section 8(a)(5)(A), which requires EPA, to the extent feasible, to not require unnecessary or duplicative reporting. However, after considering public input on the information that may be known to or reasonably ascertainable by some PFAS article importers, EPA is finalizing a reporting option for article importers to provide data to EPA on a streamlined form, if they do not know or cannot reasonably ascertain information requested on the longer standard form described in Unit III.D.1.

If an article importer determines they have imported a covered substance in an article, they would have the option to provide information to EPA through the streamlined form. The information requested through this streamlined form would still include chemical identity,

processing and use information, and production volume, as well as the option to provide any additional information to EPA that the entity may have (e.g., SDS, disposal information).

The production volume requested is the *volume of the imported article*, rather than the PFAS. EPA believes it is more likely that an article importer is able to determine the total imported production volume of articles rather than the volume related to just the PFAS contained within the article. For instance, an article importer may submit as the production volume the total weight of the PFAS-containing imported articles (e.g., in tons or pounds). Alternatively, the article importer could report the production volume in terms of quantity of the article imported (e.g., number of vehicles). The reporter would also be required to specify the unit of measurement reflected in the imported production volume. Based on information provided from article importers during the public comment period and the SBAR Panel, EPA believes that many article importers would have more difficulty providing precise production volumes of just the PFAS within an article. Industry input indicated that the historical documentation provided to article importers would not always or reliably include the weight or concentration of a PFAS contained in the article, making it more difficult for article importers to precisely calculate the production volume of just the PFAS contained within the article. Based on public input on the historical reporting practices and knowledge of PFAS in imported articles, and the fact that this rule is not a product testing requirement, EPA believes that article importers are more easily able to determine the imported production volume of the article itself. EPA acknowledges that it would be preferable to have the production volume of the chemical itself, though having the production volume of the imported article would still confer meaningful information to EPA for the purpose of chemical assessments under TSCA and other programs. Because EPA would rather have data on the production volume of the imported article, rather than many “NKRA” responses related to the production volume of the PFAS itself, EPA is requiring article importers to submit the production volume information on the whole article rather than the PFAS contained

within the article.

The streamlined article importer form would require the following information to the extent it is known or reasonably ascertainable:

1. Chemical identity:

a. Specific chemical name, or

b. Generic name(s) or description(s) if the specific chemical name(s) is claimed as CBI and/or when a manufacturer knows they have a PFAS but is unaware of its specific chemical identity. A generic name must meet the naming requirements for this rule and indicate the substance is a fluorinated substance (i.e., contain “fluor”).

2. Chemical identification number:

a. CASRN, or

b. Accession or LVE case number, if applicable, and if the specific CASRN is unknown.

EPA notes that this rule does not require manufacturers to obtain a CASRN or other identifier for a substance without such a number for the purpose of complying with this rule.

3. Trade name or common name, if applicable.

4. Representative molecular structure, for any PFAS that is not a Class 1 substance on the Inventory. And optional free text for further clarification on the chemical identity or molecular structure (such as for Class 2 substances, or where the molecular structure is of unknown or variable composition).

5. 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).

6. Industrial processing and use:

a. Type of process or use;

b. Sector(s);

c. Functional use category(ies); and

d. Percent of production volume for each use.

7. Consumer and commercial use:

a. indicator for whether this is a consumer and/or commercial product;

b. Product category;

c. Functional use category(ies);

d. Percent production volume for each use;

e. Maximum concentration in any product;

f. Indicator for use in products intended for children;

g. Indicator for imported but never physically at site; and

h. Any optional information the article importer wishes to provide.

Under TSCA section 8(a)(5)(C), EPA must, to the extent feasible, “apply any reporting obligations to those persons likely to have information relevant to the effective implementation of [TSCA].” EPA believes that this streamlined reporting form option for any article importer would still provide necessary information to EPA under TSCA section 8(a)(7), while reducing the reporting burden for the data elements that EPA understands may not be known to or reasonably ascertainable by article importers. However, to the extent any additional information requested on the longer forms is known to or reasonably ascertainable by the article importer (e.g., information on disposal of that PFAS, or an SDS or other existing information regarding environmental or health effects), the reporter would have the option and ability to submit that information to EPA through the “optional” field. EPA also notes that it is possible that a manufacturer both imports a PFAS within an article, and otherwise manufactures (including imports) the same PFAS beyond an article. In such scenarios, the reporter would still have to provide information on the longer standard form for the non-imported article and would have the option to report on the PFAS within the imported article either on the streamlined form or within the longer standard form. The reporting tool for this rule will enable multiple form options for

the same PFAS if appropriate.

3. Streamlined reporting form option for R&D substances manufactured below 10 kilograms.

EPA is also including R&D substances that were manufactured, including imported, for a commercial purpose within the scope of this rule. EPA notes that the scope of “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” (40 CFR 704.3). R&D substances which meet the scope of “manufacture for commercial purposes” must be reported under this rule, even if the PFAS itself was not later commercialized. However, R&D substances which have not been manufactured for commercial purposes (such as for scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research institutions, unless the activity is for eventual commercial purposes) would not be within scope of this rule (40 CFR 720.30(i)).

EPA believes that the submission of information related to the commercial manufacture of PFAS as R&D substances is necessary to understand the scope of PFAS manufactured in the United States. With existing R&D reporting exemptions under other TSCA rules (including CDR and PMN submissions), EPA does not have a dataset of PFAS manufactured as R&D substances. Therefore, reporting on such substances is necessary to the effective implementation of TSCA. Further, EPA understands that manufacturers of R&D substances that have been exempt under other reporting rules should have certain documentation available to support those exemption claims, in accordance with their recordkeeping requirements.

However, EPA understands through input from public commenters and the SBAR Panel that much of the information requested for this rule is unknown and not reasonably ascertainable to manufacturers of R&D substances, particularly small entities who may manufacture R&D

substances in small quantities. EPA believes that manufacturers of R&D substances in such low quantities are likely to have manufactured those substances purely for laboratory analytical purposes, which may be at their own site or their customers' sites. As such, these manufacturers are aware of the R&D chemical identity and production volume but are unlikely to have any other information requested. However, EPA believes that manufacturers of R&D chemicals manufactured in larger quantities (i.e., greater than 10 kilograms per year) are more likely to have the other information requested, including worker exposure information, disposal information, and health or environmental effects information (such as monitoring or toxicity data). Given EPA's understanding of typical recordkeeping practices of R&D activities, it is likely that a manufacturer with greater quantities of R&D substances would know the requested information on those substances beyond their identities and production volumes. Under TSCA section 8(a)(5)(C), EPA shall, to the extent feasible, apply reporting requirements to those persons likely to have relevant information. Therefore, EPA is providing another streamlined reporting option to manufacturers of R&D substances that were manufactured in volumes under 10 kilograms per year, if they do not know or cannot reasonably ascertain information requested on the longer standard form described in Unit III.D.1.

Information requested on this form, for each R&D PFAS manufactured below 10 kilograms per year, will include the following to the extent it is known or reasonably ascertainable:

1. Chemical identity:

a. Specific chemical name, or

b. Generic name(s) or description(s) if the chemical name(s) is claimed as CBI and/or

when a manufacturer knows they have a PFAS but is unaware of its specific chemical identity. A generic name must meet the naming requirements for this rule and indicate the substance is a fluorinated substance (i.e., contain "fluor").

2. Chemical identification number:

a. CASRN, or

b. TSCA Accession Number or LVE case number, if applicable, and if the specific CASRN is unknown. EPA notes that this rule does not require manufacturers to obtain a CASRN or other identifier for a substance without such a number for the purpose of complying with this rule.

3. Trade name or common name, if applicable.

4. Representative molecular structure, for any PFAS that is not a Class 1 substance on the Inventory. With optional free text for further clarification on the chemical identity or molecular structure (such as for Class 2 substances, or where the molecular structure is of unknown or variable composition).

5. Production volume:

a. Domestically manufactured.

b. Imported.

6. Indicator for imported but never physically at site.

7. Any optional information the manufacturer wishes to provide.

EPA believes that this streamlined reporting form option for any manufacturer of R&D substances in low volumes (i.e., below 10 kilograms per year) would still provide necessary information to EPA under TSCA section 8(a)(7), while minimizing the cost of compliance for certain small manufacturers, consistent with TSCA section 8(a)(5), for the data elements that EPA understands may not be known to or reasonably ascertainable by such manufacturers. However, to the extent any additional information requested on the longer forms is known to or reasonably ascertainable by the manufacturer (e.g., information on disposal of that PFAS, or existing information regarding environmental or health effects), the manufacturer would be required to submit that information to EPA through the “optional” field on the streamlined

reporting form.

E. What must be submitted as “all existing information concerning the environmental and health effects” of a chemical substance?

Pursuant to TSCA section 8(a)(2)(E), EPA is requiring the submission of “all existing information concerning the environmental and health effects” of the chemical substances covered by this rule. “All existing information concerning environmental and health effects” is defined as “any information of any effect of a chemical substance or mixture on health or the environment or both” (to be codified at 40 CFR 705.3) and is intended to be interpreted broadly. The scope of “all existing information concerning environmental and health effects” includes all health and safety studies but is not limited to formal studies. Chemical identity is always part of a health and safety study, and TSCA section 14(b) limits the extent to which health and safety studies and information from studies may be withheld from the public as confidential business information (CBI). Any information that bears on the effects of a PFAS on human health or the environment would be included, including information on the chemical substance developed or generated prior to the year 2011. The codified definition of “all existing information concerning environmental and health effects” at 40 CFR 705.3 provides non-exhaustive examples, such as:

- Toxicity information (e.g., long- and short-term tests of mutagenicity, carcinogenicity, teratogenicity; pharmacological effects; acute, subchronic, and chronic effects);
- Ecological or other environmental effects on fish, invertebrates, or other animals and plants, such as bioconcentration or bioaccumulation tests;
- Human and environmental exposure assessments, including workplace exposure, and the impacts of a chemical substance or mixture on the environment; and
- Other data relevant to environmental and health effects including monitoring data to measure the exposure of humans or the environment or a chemical substance, range-finding studies, preliminary studies, adverse effects reports, and any information, including medical

screening or surveillance, such as under the American Conference of Government Industrial Hygienists (ACGIH).

Following public comments, EPA is also clarifying that the scope of “all existing information concerning environmental and health effects” is information in the submitter’s possession or control. For the purpose of requiring existing information related to health or environmental effects, EPA is adopting the same definition of “possession or control” as in the TSCA Pre-Manufacture Notice (PMN) regulations (40 CFR 720.3(y)). Thus, a PFAS manufacturer would not necessarily be searching all information in the public realm but would be submitting information in their possession or control, or other information for which they are responsible. This includes any data or other information in files maintained by the submitter’s employees, or the employees of a submitter’s subsidiary or partnership which is associated with research and development, test marketing or commercial marketing of the PFAS, regardless of the publication status. EPA is not requiring manufacturers to search open scientific literature to find relevant information on a PFAS that was previously not in their possession or control for the purpose of this rule. EPA believes that implementing such a requirement may result in duplicative information, if multiple PFAS manufacturers are submitting the same studies or other information that are available publicly (including in EPA’s scientific literature databases).

EPA considered ways to avoid requiring the submission of potentially duplicative information concerning health and environmental effects (see TSCA section 8(a)(5)(A)), while still fulfilling EPA’s obligation under TSCA section 8(a)(7) to require reporting of such information. Such information concerning environmental or health effects may have been submitted to EPA previously under either TSCA section 8(d) rules (as unpublished health and safety information) or TSCA section 8(e) (as a substantial risk notice). If a reporter has already submitted information concerning environmental or health effects to EPA under specific TSCA submissions, they need not re-submit that information if they provide the details of to which

program (or under which rule) that information was submitted and in which year (e.g., TSCA section 8(e), in 2010). In the event of a reporter having previously submitted relevant environmental and health effects information, the reporter must ensure that the previous submission included all existing underlying information, including test data. Note that a previous submission of information concerning environmental or health effects does not relieve a manufacturer of providing *all* existing information concerning environmental or health effects that has not previously been submitted to EPA. See Unit III.F for more discussion on how EPA is mitigating potentially duplicative reporting for this rule.

For environmental and health effects information that was previously submitted to EPA as CBI, the reporter would need to resubmit if that information predated the 2016 Lautenberg Act amending TSCA and its CBI submission requirements and reassert the CBI claim (see section 705.22(f) and 705.30). If a reporter has submitted environmental and health effects information as CBI since the 2016 Lautenberg Amendments to TSCA were implemented, then the manufacturer must provide EPA with details regarding when, how, and under which title and/or statutory authority the CBI claim was submitted, and the TSCA section 14 certification. In order for a reporter to earn an exemption from resubmitting that environmental and health effects information and re-asserting a CBI claim, the reporter must be able to point to a previous claim that adequately covers the current claim. In any event of a reporter having previously submitted environmental or health effects information as CBI, whether pre- or post-Lautenberg Amendments, they must adequately substantiate their CBI claim. EPA encourages all reporters who have previously submitted environmental or health effects information as CBI to carefully review their previous submissions and determine whether the previous claims satisfy current CBI substantiation requirements, and to assert a new claim and substantiate if appropriate. More discussion on submitting CBI under this rule is in Unit III.G.

Additionally, EPA is finalizing the requirement to submit all existing information

concerning health and environmental effects in the format of OECD-harmonized templates, where such templates exist for the type of data (to be codified at 40 CFR 705.15(f)). OECD templates are accessible to the public online at <https://oecd.org/ehs/templates/harmonised-templates.htm> (Ref. 16). This can be accomplished by using the freely available IUCLID6 software by exporting the dossier in the OECD Harmonized Template working context. At the time of this rule publication, EPA can accept any dossiers generated using any version of IUCLID6. Users should refer to EPA webpages (to be identified) for updates on which version of IUCLID files will be accepted.

A standardized format such as the OECD templates will improve the efficiency of review and organization of the submitted data. EPA believes that some of the data will already be available as an OECD template if the company had already submitted the studies under the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation (Ref. 16). In addition to the required template format, those subject to this rulemaking must submit any associated full study reports or underlying data as support documents. The full study reports and support documents are necessary for EPA to understand the full context and evaluate the quality of the data, which is necessary for the Agency to review to determine whether such data may be used for any future Agency actions.

If an OECD-harmonized template is not available for a particular endpoint for which the manufacturer has relevant information, then the manufacturer must still submit the data. Such information may include, but is not limited to, raw monitoring data (regardless of having been aggregated or analyzed) of human or environmental exposure assessments and toxicity tests for either human health effects or ecological other environmental effects.

F. What steps is the Agency taking to reduce potentially “duplicative” reporting? Does information need to be reported on the basis that it has already been reported to the Agency?

TSCA section 8(a)(5)(A) requires EPA, to the extent feasible when carrying out TSCA

section 8, to avoid requiring unnecessary or duplicative reporting. The Agency seeks to avoid collecting data on PFAS that would duplicate information already reported to the Agency, while ensuring EPA obtains all data required to be collected under TSCA section 8(a)(7) and that such data are submitted in a format that is conducive to the collection and review of a manufactured PFAS dataset. While developing this rule, EPA reviewed the data elements submitted under the CDR Rule to evaluate whether there may be some overlap with the information requested under this rule. Through internal review, and from input received during the public comment periods and the SBAR Panel, the Agency has identified the following data elements that may have some overlap with CDR requirements:

- Physical state of the chemical or mixture;
- Production volume (domestically manufactured);
- Production volume (imported);
- Volume directly exported;
- Indicator for imported but never physically at site;
- Industrial processing and use type, sector(s), functional category(ies), and percent of production volume for each use;
- 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; and
- Number of workers reasonably likely to be exposed for each combination of industrial processing or use operation, sector, and function, and the number of commercial workers reasonably likely to be exposed if the PFAS is contained in a commercial product.

However, EPA notes that even though there are some potentially overlapping data elements between this rule and CDR, any duplication of reporting requirements is likely to be narrower in scope. For instance, CDR is limited to chemical substances on the Inventory. In

contrast, the reporting requirements in this rule extend beyond chemicals on the Inventory and may cover chemicals subject to LVEs, byproducts, and other chemicals that may not have been reported on or added to the Inventory. In addition, CDR has a reporting threshold of 25,000 pounds (or 2,500 pounds for chemicals subject to certain TSCA actions), along with several reporting exemptions, including for imported articles, certain byproducts, non-isolated intermediates, and small quantities of R&D substances, while this reporting rule does not incorporate any such thresholds or exemptions. Finally, while this rule requests the same data to be submitted for each year in which a PFAS has been manufactured since 2011, CDR requires different information to be submitted in different years: for instance, reporters submit the total annual domestically manufactured production volume and the total annual imported volume separately only for the principal reporting year (e.g., 2019 for the 2020 reporting cycle), but only the combined total annual production volume is required reporting for the intervening years. Additionally, the CDR rule has been amended over the course of this reporting period, meaning certain data elements were not requested or submitted for all CDR cycles overlapping this rule's lookback period. Specifically, the CDR industrial processing and use codes and consumer/commercial processing and use codes did not align with the OECD-harmonized use codes until the 2020 reporting cycle. While CDR submitters may have provided certain processing and use information related to PFAS they manufactured during previous CDR cycles, any CDR responses that do not sufficiently respond to this data call by providing the required OECD codes would not be duplicative of the information being reported under this rule. Therefore, while some data elements of this rule may be considered duplicative of CDR requirements, differences between CDR and this rule's requirements (including reporting thresholds and reporting exemptions) may limit the scope of what is duplicative and duplicative information does not need to be re-reported for this rule. If the previous submission for the same data element under a different reporting rule was not accurate for purposes of this rule (e.g., by

not reporting volumes related to an activity exemption that does not apply to this rule, or by reporting industrial processing and use information that does not align with the OECD-harmonized use codes required under this rule), then the submitter must report the accurate information and cannot rely on their prior submission to satisfy this rule's requirements.

Beyond the CDR rule, some commenters and participants in the SBAR Panel suggested that other information requested under this rule may have been reported to EPA through a TSCA section 8(d) rule. Under TSCA section 8(d), EPA has the authority to request unpublished health and safety data studies, or lists of such studies, known to or reasonably ascertainable by manufacturers, processors, and distributors of certain chemical substances or mixtures. Commenters suggested that some "existing environmental and health effects information" on PFAS may have already been submitted to EPA through a TSCA section 8(d) rule and would be duplicative of information requested under this rule.

While EPA agrees that any previous submissions of unpublished studies under TSCA section 8(d) need not be resubmitted under this TSCA section 8(a)(7) rule, EPA does not anticipate that there will be much overlap between information requested under this rule and information that may have already been submitted through the reporting requirements related to the TSCA section 8(d) rule codified in 40 CFR Part 716. First, only a few substances already listed in a section 8(d) rule would meet this rule's definition of PFAS; out of the many examples of PFAS, only oxirane, 2-(2,2,3,3,4,4,5,5,6,6,7,7,7-tridecafluoroheptyl)- (CASRN 38565-52-5), hexane, 1,1,1,2,2,3,3,4,4,5,5,6,6,6-tetradecafluoro- (CASRN 355-42-0), and 1-butanamine, 1,1,2,2,3,3,4,4,4-nonafluoro-N,N-bis(1,1,2,2,3,3,4,4,4-nonafluorobutyl)- (CASRN 311-89-7) are listed as PFAS, which can be found in 40 CFR 716. Secondly, the substances which are listed in 40 CFR Part 716 have sunset dates, or reporting deadlines. The PFAS that have previously been listed in a section 8(d) rule have sunset dates between 1988 and 1995; therefore, potentially duplicative section 8(d) reporting stops decades short of the scope of reporting for this rule (40

CFR 716) (53 FR 38645, September 30, 1988 (FRL-3439-9)). Finally, the scope of “unpublished health and safety studies” requested under a TSCA section 8(d) rule may not be as inclusive as the scope of “all existing information concerning the environmental and health effects” requested for the substances under this TSCA section 8(a)(7) rule. This rule’s scope of all existing information concerning environmental and health effects is intended to be broadly interpreted and is inclusive of any health and safety study, regardless of the date the information was collected or generated; see the discussion in Unit III.E.

Similarly, “all existing information concerning the environmental and health effects” of a PFAS may include previous submissions to EPA pursuant to TSCA section 8(e). TSCA section 8(e) requires manufacturers, processors, and distributors of chemicals to notify EPA immediately of information that reasonably supports the conclusion that their substances or mixtures present a substantial risk of injury to health or the environment. To the extent that a substantial risk notification under TSCA section 8(e) may be duplicative with this rule’s requirements, the reporter need not resubmit such information, but will be required to indicate when they had previously provided that notification under TSCA section 8(e) so that EPA is able to locate that previous submission and satisfy the requirements of TSCA section 8(a)(7). Manufacturers who have previously submitted information to EPA under TSCA section 8(d) or TSCA section 8(e) that may be considered “existing information concerning the environmental and health effects” of a PFAS for which they are reporting under this TSCA section 8(a)(7) rule need not resubmit the duplicative information. However, the manufacturer must indicate in the reporting form the year in which they had previously provided that information and under which rule (e.g., TSCA section 8(d), section 8(e)). If EPA has previously collected information relevant to the implementation of TSCA section 8(a)(7) and is able to locate that information based on the reporter’s submission, then EPA would be able to meet the information collection obligations under TSCA section 8(a)(7) without requiring potentially duplicative reporting.

EPA also considered other, non-TSCA reporting rules' potential overlap with this rule. These include the Toxics Release Inventory (TRI) and the Greenhouse Gas Reporting Program (GHGRP). Under the TRI, certain industrial and federal facilities are required to report their annual releases and other waste management quantities and activities for TRI-listed toxic chemicals that are manufactured, processed, or otherwise used above the respective threshold. Information reported to TRI that is also requested under this rule includes:

- 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; and
- Total volume incinerated on-site.

However, in the same vein as the limitations on potentially duplicative reporting with CDR and TSCA section 8(d) rules, EPA does not anticipate much, if any, overlap in reporting between this rule and TRI. First, PFAS were not on the TRI chemical list until the FY 2020 NDAA automatically added 172 PFAS effective calendar year 2020, with additional PFAS added annually since 2020 (Ref. 17). Therefore, the only potentially overlapping reporting of PFAS releases and other waste management quantities would be since 2020, instead of the entire lookback period of this rule. Additional limitations in the potential overlap between this rule and TRI include the PFAS reporting threshold for TRI of 100 pounds manufactured, processed, or otherwise used and certain TRI reporting exemptions for quantities below de minimis concentrations and in articles. Without a reporting threshold or similar reporting exemptions applicable for this rule, there may be more PFAS releases and other waste management activities reportable for this rule than for TRI.

EPA also considered potential overlaps with GHGRP. The GHGRP requires annual

reporting of greenhouse gas (GHG) data and other information from large GHG emissions sources (i.e., those that emit at least 25,000 tons of CO₂-equivalent, any electricity generation site, aluminum, ammonia or cement production facility, and some municipal solid waste landfills), fuel and industrial gas suppliers, and carbon dioxide injection sites (Ref. 18) (40 CFR part 98). 111 compounds covered as GHGs and heat transfer fluids (HTF) would also be considered PFAS under this rule. Between this rule and the GHGRP, the following data elements may be duplicative for at least some GHGRP reporters:

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

Besides the limited number of PFAS covered by GHGRP, other limitations on the potential overlap between this rule and GHGRP include the exemption of GHGRP reporting for quantities imported or exported below 25 kilograms. Additionally, not all coincidentally manufactured chemicals (such as byproducts) are covered by GHGRP, though they fall under the definition of “manufacture for a commercial purpose” under this rule (40 CFR 705.3). Overall, there is a significant difference between the reporting requirements in the GHGRP and this rule, though EPA is allowing reporters to abstain from re-reporting any of the information listed previously in this unit for a PFAS that was previously reported to GHGRP, unless the GHGRP submission did not account for all quantities that are covered by this rule.

EPA also notes the potential for duplicative reporting of environmental releases of certain byproducts within this rule. Pursuant to TSCA section 8(a)(2)(D), EPA is requiring PFAS manufacturers to provide a “description of the byproducts resulting from the manufacture, processing, use, or disposal of each [PFAS].” However, EPA notes there may be occasions where a byproduct that resulted from the manufacture, processing, use, or disposal of a reported PFAS also meets this rule’s definition of PFAS. Because “manufacture for commercial

purposes” includes the coincidental manufacture of byproducts, that byproduct would also need to be reported under this rule to the extent data are known or reasonably ascertainable. As a reportable PFAS, information on that byproduct’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.

To address potentially duplicative reporting, EPA is identifying specific types of information that need not be reported if the reporting entity indicates in the reporting tool that they have previously provided such information to EPA and provides information sufficient to allow the agency to locate that information. Pursuant to TSCA section 8(a)(5)(A), EPA is limiting the requirement for reporting “duplicative” information if a PFAS manufacturer has previously submitted the requested information to EPA for that same PFAS in that same year through CDR, TRI, GHGRP, or TSCA sections 8(d) and 8(e), or is also reporting a PFAS byproduct on its own reporting form. Only the aforementioned data elements from CDR, TRI, and GHGRP; studies submitted under TSCA section 8(d) or 8(e); and certain byproduct release information may be exempt from re-reporting under this rule as potentially duplicative information. In these cases, the manufacturer would be required to indicate to which program (and in which year) that information was submitted (e.g., CDR, in 2016). Additionally, EPA notes that a manufacturer’s previous submission for the same data element under a different reporting rule (e.g., a manufacturer previously reported the production volume to CDR for a particular year) does not necessarily mean that the same quantity or information would be accurate for this rule’s purposes. Because this rule does not provide for the same exemptions as the rules discussed in Unit. III. F., the manufacturer must ensure that all quantities and other requested information for that PFAS are reported under this rule to the extent such information is

known or reasonably ascertainable. In the previous example of a CDR reporter who had previously reported a PFAS's production volume, the reporter must ensure that all manufactured quantities covered under this rule (including those that are exempt from CDR, such as impurities or imported articles) are accounted for. If a previous submission for a data element does not account for all covered volumes or activities, then the submitter may not rely on that prior submission to satisfy the reporting requirements of this rule.

EPA considered other previous information collection requests related to PFAS but did not determine those to be “duplicative” such that reporting may be exempt under TSCA section 8(a)(5)(A). For instance, EPA received many public comments asserting that information submitted through a PMN is duplicative of the information that would be collected through this rule. EPA disagrees. Information collected through a PMN (or a LVE) reflects information *before* manufacture of a substance commences.

EPA notes that the Agency has also required the submission of information on PFAS using a variety of enforcement authorities under different environmental statutes. However, most, if not all, of the information collected in the course of investigating potential non-compliance with, or liability under, TSCA or other statutes is different in numerous respects from information requested pursuant to this rule. EPA does not anticipate there to be duplicative reporting as the enforcement requests are generally narrower in scope. The enforcement requests generally focus on fewer years than this rule's reporting period, and those requests tend to focus on far fewer substances. Additionally, the requested data for enforcement authorities is both aggregated and reported in formats differently than this rule's requirements. While this rule requires data to be reported for each year over the reporting period in which the PFAS was manufactured, some enforcement requests have focused on just single years, or have requested quantities to be reported to reflect cumulative totals over multiple years. In that latter example, such a submission would not satisfy EPA's obligations under TSCA section 8(a)(7) requesting

certain information “*for each year* since January 1, 2011.” In terms of information reporting formats, EPA notes that enforcement requests may often ask for responses in a narrative format, distinct from this rule’s requests for information in quantities or within specific ranges. For these discrepancies, EPA does not believe that most information requested through previous enforcement request letters is duplicative of information requested under this rule.

The only information that may have been submitted in response to past enforcement letters that may be potentially duplicative of this rule relates to “all existing information concerning environmental and health effects.” Such information includes but is not limited to environmental monitoring, sampling, or worker exposure data. Thus, if a manufacturer has previously submitted certain information concerning environmental or health effects of a PFAS to EPA under an enforcement authority, that manufacturer does not need to resubmit that environmental or health effects information to EPA under this rule, provided that the manufacturer indicates to which program or office and in which year such information was submitted to EPA.

While the use of those enforcement authorities may be duplicative in some cases, the information is needed to ensure protection of public health and the environment in instances where the Agency feels it needs information from an entity to make that judgment call and determine if action is needed. Therefore, information duplication between previous enforcement requests and this rule is unlikely for many reasons, including various limitations on information gathered under the enforcement authorities and the fundamental differences in the type of information sought under this rule as compared with the information gathered under the other authorities. While information from PFAS manufacturers requested by EPA is, in all cases, needed to ensure the protection of public health and the environment, the information requested under the different authorities serves different purposes. EPA has determined that the information submitted in response to an enforcement letter is not duplicative of the information

requested under this rule, except for certain information concerning environmental and health effects.

Finally, some reporters may also have submitted certain information concerning environmental or health effects of a PFAS pursuant to either a TSCA section 4 action or voluntarily, in conjunction with EPA's National PFAS Testing Strategy. To the extent a reporting entity has already provided information concerning environmental or health effects (such as chemical and physical properties, hazard testing, or exposure testing), that entity need not resubmit the information to this reporting rule. Instead, the reporter should indicate that they have already submitted such information to EPA and provide the program, the specific chemical identity, the date, and an associated case number, if available, of that submission.

G. What are the requirements for submitting CBI claims?

The 2016 amendments to TSCA included new procedural requirements for the submission and Agency management of CBI claims, including new substantiation requirements, generic name requirements, a certification requirement, and a requirement for Agency review of specified CBI claims within 90 days after receipt of the claim (15 U.S.C. 2613). In accordance with the 2016 TSCA amendments, the Agency recently proposed a rule addressing the procedures for submitting CBI claims to EPA under TSCA and the procedures for EPA's review of such claims (87 FR 29078, May 6, 2022 (FRL-8223-01-OCSP)). PFAS manufacturers reporting under this rule may claim certain portions of the reporting form are CBI confidential business information, consistent with TSCA section 14, such as specific chemical identities that are not on the public Inventory, company identifier, and production volumes. Only confidentiality claims made through this rule's PFAS reporting tool will be considered properly asserted; any additional TSCA CBI claims made elsewhere will be considered improperly presented and will not be treated as having asserted a CBI claim under TSCA, and the information may be disclosed to the public without further notice. In addition to the requirement

that CBI claims be submitted through the PFAS reporting tool, TSCA requires the reporter to certify that it has: 1) Taken reasonable measures to protect the confidentiality of the information; 2) Determined the information is not required to be disclosed or made public under Federal law; 3) A reasonable basis to believe that disclosure of the information is likely to cause substantial competitive harm; and 4) A reasonable basis to believe that the information is not readily discoverable through reverse engineering; and, 5) To certify that these statements and any information provided are true and correct. Consistent with the format of other TSCA reporting forms, the statements and certification would be combined into a single certification statement.

Information under this rule that may not be asserted as CBI includes:

- Specific chemical identity if the chemical is on the public (non-confidential) Inventory or reported as non-confidential in an LVE;
- All generic chemical names;
- For any PFAS that are on the public (non-confidential) Inventory, the chemical's CASRN;
- For PFAS that are on the confidential Inventory, the Inventory Accession Number cannot be claimed as CBI (but the underlying chemical identity can be claimed as CBI);
- LVE numbers;
- The following categories of use information: industrial processing and use type, sector, and functional categories, whether a chemical is in a consumer and/or commercial product, the consumer/commercial product categories and functional categories, and its presence in products for children; or
- Any blank or NKRA designation or response.

Any entity that claims a specific chemical identity as CBI must also submit a generic name pursuant to TSCA section 14(c)(1)(C). This includes reporting a PFAS by either an Accession number or LVE number (assuming that the specific chemical identity is not on the

public Inventory), or reporting by a CAS name on a PFAS for which the CASRN, Accession number and LVE number are not known to be assigned (i.e., the CASRN and specific identifiers have not been created or generated). Entities must ensure that any such generic name is consistent with EPA's Generic Name Guidance (Ref. 19). The generic name must also "describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure that are claimed as confidential; and the disclosure of which would be likely to cause substantial harm to the competitive position of the person." 15 U.S.C. section 2613(c)(1)(C)(ii). Generic names must be sufficiently detailed to identify the reported chemical as a PFAS. Specifically, any generic name reported for a PFAS that does not contain "fluor" in the name would be rejected by EPA as insufficient under TSCA section 14(c)(1)(C). As the Agency described in the NODA published for this rule (Ref. 1), any generic name for a PFAS (including previously existing generic names from earlier TSCA section 5 submissions) that does not contain "fluor" in the name is inconsistent with this provision and will be rejected. Ultimately, if a generic name reported under the TSCA section 8(a)(7) rule lacks the structural unit "fluor," the Agency will publicly identify the chemical substance as a PFAS.

TSCA section 14 further requires that substantiation be provided for each data element claimed as CBI. The substantiation must be provided at the time of submission. However, TSCA section 14(c)(2) exempts certain information from the substantiation requirements (e.g., specific production volume). Under this rule, CBI claims for specific production or import volumes of the manufacturer need not be substantiated. Additionally, the specific chemical identity and molecular structure need not be substantiated when the substance has not been introduced into commerce (e.g., an R&D substance manufactured in small quantities meeting the new chemical reporting exemption under section 5(h)(3)). No other TSCA section 14(c)(2) exemptions apply to information requested under this rule, so CBI claims must be substantiated for all other such information. Any information which is claimed as CBI will be disclosed by EPA only in

accordance with the procedures and requirements of TSCA section 14 and 40 CFR parts 2 and 703. TSCA limits CBI protections for information in health and safety studies.

Generally, information from health and safety studies is not protected from disclosure, except to the extent such studies or information reveal information “that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture,” 15 U.S.C. section 2613(2)(B). Additional information, listed in the rule’s definition of health and safety study, are not part of a health and safety study (e.g., names of laboratory personnel). Submitters asserting a CBI claim for information under 705.15(f) are required to submit a sanitized copy, removing only the information that is claimed as CBI.

EPA expects that article importers generally do not know the Accession number or other specific identifiers (e.g., PMN or LVE number) for a confidential Inventory chemical that may be included in the article they are importing. As a result, article importers must report chemical identities to the extent that they are known to or reasonably ascertainable (generic name, trade name, or CASRN if it is a publicly known chemical substance) and use the article importer streamlined form. Public identifiers like generic names and public Inventory CASRNs may not be claimed as CBI and it is unnecessary for article importers to assert CBI claims for the specific identities of substances that are not reported by a specific identifier (i.e., Accession number or LVE number). EPA would not be able to determine an underlying confidential chemical identity from this generic identifying information, so could not disclose that specific chemical identity, regardless of whether the submitter asserted a CBI claim. It would be purposeless for the submitter to assert a CBI claim for this information or for EPA to review such claims. In this TSCA section 8(a)(7) rule, and for these reasons, EPA believes that it is appropriate to differentiate article importers from other reporters with respect to chemical identity CBI claims.

However, all other entities (i.e., other than article importers) who report a CAS name,

CASRN, or specific identifier (i.e., Accession number, LVE number) must assert and substantiate a CBI claim for the specific chemical identity if the reporter wants the chemical identity to receive confidential treatment. A person or entity (other than an article importer) who does not have knowledge of such an identifier (CAS name, CASRN, Accession number, or LVE number) must initiate a joint submission with its supplier or other entity who can provide this identifying information, if such an entity is known to or reasonably ascertainable by the manufacturer. In these cases, the secondary submitter would be responsible for providing the CAS name, CASRN, Accession number, or LVE number and for asserting and substantiating any CBI claims concerning the chemical identity (see e.g., 40 CFR 711.15(b)(3); 711.30(c)). In light of the extended timeframe (11 years) covered by this reporting rule, it is possible that the submitter's supplier is unknown or no longer exists (e.g., supplier has gone out of business without a successor entity). As applied to this reporting rule only, a submitter who lacks knowledge of the CAS name, CASRN or a specific identifier (i.e., Accession number or LVE number) and who -- after conducting due diligence and reviewing known or reasonably ascertainable existing information -- cannot identify a supplier or any other entity who could provide this information in a joint submission, the submitter would indicate that secondary submitter information is not known or reasonably ascertainable and therefore does not need to initiate a joint submission.

Generally, reporting entities will not have an opportunity to add or modify substantiations once the reporting period concludes. Therefore, reporting entities should communicate with suppliers, or any other entities with CBI concerns (e.g., non-disclosure agreements) and carefully consider the CBI implications of this rule. However, reporting entities may amend their submission to withdraw CBI claims at any time during the reporting period.

In response to comments received on CBI claims concerning the specific chemical identity, following the conclusion of the reporting period for this rule, EPA will compile a list of

reported substances it plans to move to the public Inventory because either no chemical identity CBI claim was asserted, or the claim was denied. Similar to past compilations, EPA will publish a list of Accession numbers associated with these substances on the EPA website for several months in advance of any update to the Inventory. Interested parties will have an opportunity to review the list for possible errors and contact EPA with any questions or concerns about specific candidates. In some cases, there may be assertions by a company that a mistake has been made (e.g., the wrong chemical identity was reported by a third party) or that a waiver of a CBI claim was made by a company that may not know the specific chemical identity, in which case EPA will undertake appropriate factual investigations as necessary to confirm whether EPA should reconsider whether the chemical is no longer entitled to confidential Inventory protection. Where EPA determines that a chemical identity was identified as a candidate for disclosure because there was an error or because the sole basis for the proposed move to the public portion of the Inventory was a waiver of a CBI claim by an entity that did not know the specific chemical identity, it will not move the chemical identity to the public portion of the Inventory. This investigation would take place prior to the point that the specific chemical identity would be disclosed on the public Inventory.

H. What are the electronic reporting requirements?

EPA is requiring all information to be submitted electronically, similar to the requirements established in 2013 for submitting other information under TSCA (see 40 CFR 704.20(e)). Reporters must use EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, to submit all information under this rule. EPA developed the Chemical Information Submission System (CISS) for use in submitting data electronically to the Agency for TSCA sections 4, 5, 6, 8(a), 8(b), 8(d), 8(e), and Title VI. CISS, a web-based reporting tool housed within the CDX environment, provides submitters with user-friendly applications to build and submit data packages to EPA within a secure, encrypted environment. CISS applications

provide for the capture of both fielded data as well as the attachment of additional information using a wide variety of file types. Within CDX, CISS is available under the “Submission for Chemical Safety and Pesticide Program (CSPP)” CDX flow. Users who have previously submitted under TSCA through CDX, including submitting information under sections 4 and 5, or CDR, will already have the CSPP flow linked to their account. Users reporting to EPA using other CDX housed applications, including the Toxics Release Inventory TRI-MEweb, would be able to add the CSPP flow to their existing CDX accounts.

EPA is developing a rule-specific reporting tool within CISS, which reporters must use to submit the required information. This tool will be available in CISS prior to the start of the reporting period (see the discussion in Unit III.I on reporting deadlines). EPA believes that electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft submission within their organization and more easily save a copy for their records or future use. Additionally, EPA believes that many of the anticipated reporters under this rule have experience with reporting electronically to EPA through CDX. For those reporters who do not have experience submitting information to EPA via CDX, EPA has provided guidance documents and support via a help desk to assist users with technical questions related to CDX. The resource and time requirements to review and process data by the Agency will also be reduced, and document storage and retrieval will require fewer resources.

I. What if an entity who knows the specific chemical identity will not disclose it to the PFAS manufacturer (including importer)?

In response to public comment, EPA is also enabling joint submissions for PFAS manufacturers (including importers) other than article importers who do not know the CASRN, Accession Number, and/or LVE number and whose suppliers will not disclose the identity to the PFAS reporter. Similar to the 2020 CDR cycle, this joint submission tool would allow

manufacturers (including importers) to submit all importing, processing, use, and other information to the extent it is known or reasonably ascertainable and to send a request to the appropriate supplier or other entity to create a submission to supply the PFAS identity to EPA through the reporting tool. The joint submission process does not require the supplier or other entity to disclose the specific chemical identity to their customer, thus maintaining confidentiality between the two entities.

The joint submission tool would be relevant when a manufacturer (including importer) cannot provide the CAS name, CASRN, Accession number, or LVE number of a chemical substance it manufactures, generally because it is unknown to the manufacturer (including importer) and claimed in part or in its entirety as CBI by the supplier of the chemical substance or mixture.

In a joint submission, the primary submitter (i.e., the PFAS manufacturer) may assert CBI claims over some of their supplier information, including the supplier identity and the chemical substance or mixture trade name (or other designation). Substantiation of the CBI claims for this information will not be required at the time of the primary submitter's submission. The secondary submitter of the joint submission must register with CDX if they have not previously and provide its company name and location, a technical contact, trade name, chemical identity, function, and, for PFAS in mixtures, the percentage of each PFAS in the mixture represented by the trade name. The secondary submitter is responsible for asserting all confidentiality claims for the data elements that it submits directly to EPA and for substantiating those claims not exempt under 40 CFR 705.30(a)(2). The specific chemical identity may be claimed as CBI by the secondary submitter following the provisions in 40 CFR 705.30. If the secondary submitter does not assert and substantiate a CBI claim for the identity of the chemical substance in its response to the Agency, then the chemical is not entitled to confidential treatment. Except for the percentage composition information, which is generally exempt from

substantiation pursuant to TSCA section 14(c)(2)(D), all other reported data elements are subject to substantiation at the time the information is submitted.

Similar to the CDR joint submissions, any secondary submitter in this rule will be able to request the chemical information from their own suppliers as needed, should the importer's direct supplier not have the information. There may be instances where a foreign supplier purchases a mixture, under a trade name, from another company (tertiary company) and does not know the chemical components of the mixture. The foreign supplier can ask the tertiary company manufacturing the trade secret mixture or PFAS within the mixture to directly provide EPA with the correct chemical identity in the reporting tool. In this case, the tertiary company would register with CDX and use the Unique Identifier for Joint Submissions, sent to the tertiary company by the secondary company (i.e., the foreign supplier), to complete the reporting form.

Under this scenario, the foreign supplier does not have access to any of the information submitted to EPA by the tertiary company. Likewise, the tertiary company cannot see the information the foreign supplier or the primary company (i.e., the U.S. manufacturer (including importer)) reports to EPA. This way, the confidentiality of information for all parties is protected. EPA believes this functionality addresses some concerns that have been voiced from stakeholders, including an importer's direct (or immediate) supplier may not have knowledge of the PFAS identity. By allowing a foreign supplier (secondary submitter) to request the required information from their own supplier (a tertiary submitter) as needed, EPA believes this will capture more information related to specific PFAS identities that may not be known to the importer due to confidentiality or trade secret claims, while not requiring suppliers to share any information they wish to protect from their customers.

Joint submissions are to be used only in cases when the PFAS reporter does not know the CAS name, CASRN, Accession number, or LVE number for the PFAS, but another entity (e.g., a supplier or other manufacturer) does and will not disclose it to the reporter. If a reporter

(including importer) or joint reporter (secondary or tertiary submitter) actually knows or can reasonably ascertain the CAS name, CASRN, Accession number, or LVE number of a PFAS, the reporter (including importer) must provide that information irrespective of others' confidentiality claims. If the reporter wishes to claim the specific chemical identity as confidential, the chemical substance must not be listed on the public portion of the Inventory, the submitter must check the CBI box in the reporting tool and provide the appropriate substantiation. Such a CBI claim only relates to the specific chemical identity as listed on the confidential portion of the Inventory (i.e., CAS name and/or CASRN) and does not apply to the Accession number and generic name listed on the public portion of the Inventory.

Because article importers are not required to assert or substantiate CBI claims for the chemical identity for this rule, EPA is not requiring or enabling joint submissions for article importers when they do not know the CAS name, CASRN, Accession number, or LVE number of the PFAS. Additionally, in scenarios where a secondary submitter is not known or existent (e.g., a supplier has gone out of business and does not have a successor entity), the primary submitter would indicate in the reporting tool that the secondary submitter is "not known or reasonably ascertainable." In this case, however, the PFAS manufacturer would be required to provide as much identifying detail as they have regarding the PFAS identity (e.g., trade name), but would be able to report to EPA without initiating a joint submission.

J. When are reports due?

EPA proposed a six-month information collection period following the effective date of the final rule, then a six-month reporting period. Thus, the proposed rule stipulated a reporting deadline one year following the effective date of the final rule. EPA received many public comments on the reporting timeframe, which are detailed in Unit IV.K.

In response to public comment, EPA has decided to finalize a one-year information collection period following the effective date of this rule, which will then be followed by a six-

month reporting period. Further, EPA is granting an additional six months for reporting to small manufacturers (as defined at 40 CFR 704.3) whose reporting obligations under this rule are exclusively from article import. “Small manufacturers” as defined at 40 CFR 704.3 include manufacturers who meet one of two standards: (1) a manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than \$120 million, *and* the annual production volume of a chemical substance is less than 100,000 lbs; or (2) a manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than \$12 million. EPA acknowledges that the scope of reporting for this rule is broader than for CDR, and that there may be some reporting entities who have not submitted information to EPA under a TSCA section 8(a) reporting rule before (e.g., some small manufacturers). Therefore, EPA agrees that additional time is warranted for PFAS manufacturers to familiarize themselves with the scope of the reporting rule and reporting standard, as well as begin to collect the required information and create a CDX account if necessary. The extended time period for information collection also benefits both EPA and the reporting community by providing the Agency with additional time to develop and test the CDX reporting application for this rule. Thus, reporting forms will be due 18 months following the effective date of this rule, except for small article importers (as defined at 40 CFR 704.3), whose reporting forms are due 24 months following the effective date of this rule.

K. What are the recordkeeping requirements?

EPA is finalizing the proposed recordkeeping requirements. Each person who is subject to the reporting requirements must retain records that document any information reported to EPA for five years, beginning on the last date of the information submission period. The five-year retention requirement is consistent with the CDR rule and corresponds with the statute of limitations for violations and is necessary to preserve records to support future regulatory activities that will be informed by this information collection. Further, EPA believes the burden

of retaining these records, which are likely electronic, is minimal.

L. Which proposed requirements are not being finalized as proposed?

EPA is modifying the following items from the proposed rule: the definition of “PFAS”; the reporting deadline; some of the data elements requested; enabling streamlined reporting options for article importers and manufacturers of R&D substances below 10 kilograms; enabling joint submissions; and [certain waste management/disposal facility exemptions].

As noted in Unit III.A.1, this rule defines “PFAS” as including at least one of these three structures:

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

This definition is an expansion of the proposed definition of “PFAS”, which was defined as $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons, and none of the R groups can be hydrogen. The proposed definition defined PFAS as a substance that includes the following structure: $R-(CF_2)-C(F)(R')R''$, in which both the CF_2 and CF moieties are saturated carbons and none of the R groups (R , R' or R'') can be hydrogen. The proposed definition, which existed previously in EPA’s Office of Pollution Prevention and Toxics (OPPT), was developed to focus on chemical substances in the Inventory with properties similar to PFOA, PFOS, and GenX. EPA notes that the proposed definition of “PFAS” had previously been used by OPPT, although this definition has changed over time. For instance, the polymer exemption for PMNs provided a different definition of “perfluoroalkyl” in its PFAS exception rule in 2010 (40 CFR 723.250) (Ref. 20). Over many years of research and data collection, EPA continues to learn more about these substances and may consider whether modifications to the definition are appropriate. See Unit IV.A.1 for a more detailed discussion of EPA’s reasons for modifying this definition for this rule.

EPA is also modifying the reporting deadline from the proposed rule. As noted in Unit III. J, EPA believes additional time for rule familiarization and data collection is warranted given the lookback period of this rule and that there are entities that are potentially covered by this rule which have not been previously required to respond to other TSCA section 8 reporting rules, such as CDR. Given public comments and input during the SBAR Panel, EPA is providing a one-year period following the effective date of this rule for data collection, followed by a six-month reporting period during which the reporting application will be open. EPA is further granting an additional six months for reporting to small manufacturers (as defined at 40 CFR 704.3) who would report exclusively as article importers for the purpose of this rule. Thus, reporting forms are due 18 months following the effective date of this rule, except for small article importers, which are due 24 months from the effective date of this rule.

EPA is slightly modifying the data elements requested by PFAS manufacturers. Based on public comments, EPA is not including the following proposed data elements within this rule: the maximum quantity on-site at any time, including storage; the maximum first 12 months production volume, and the maximum yearly production volume in any 3 years. EPA received public comment that it is unlikely that manufacturers have information related to the storage quantities, and other comments stated that requesting the maximum production quantities in either the first 12 months or in any three years may be duplicative of other production volume data requested. Therefore, EPA is removing these three items from the scope of the final rule. For more discussion on the comments received on the scope of data elements, see the Response to Comments document (Ref. 21).

Pursuant to public comments, EPA is also modifying the request for the molecular structure of the PFAS in all reports: submitting molecular structure of the reported PFAS is optional for any Class 1 PFAS on the Inventory. Class 1 chemical substances are those chemical substances composed of molecules with particular atoms arranged in a definite, known structure.

If a Class 1 substance is also on the Inventory, EPA knows its particular molecular structure.

However, many commercially-manufactured chemicals are not Class 1 substances (i.e., they are Class 2 substances comprised of specific molecular formula representations in variable structures, or they have unknown or indefinite molecular formulas and/or incomplete structural diagrams). Additionally, not all commercially-manufactured substances that are subject to TSCA may be on the Inventory due to various reporting exemptions. While EPA has the authority and obligation to request the molecular structure of any reported PFAS pursuant to TSCA section 8(a)(2)(A), EPA does already know the structure of Class 1 substances on the Inventory; thus, pursuant to TSCA section 8(a)(5)(A), EPA is limiting the scope of this reporting requirement in cases where the information would be duplicative of information EPA has obtained through TSCA reporting. Therefore, EPA is modifying the proposed rule by limiting the reporting requirement of molecular structures to those PFAS that are not Class 1 substances on the Inventory.

Finally, EPA is also modifying the proposed data elements for worker exposure duration. EPA proposed to request information on worker exposure for the manufacturing site, each industrial process and use, and each commercial use. For all three categories, EPA proposed to request “maximum duration of exposure for any worker” in both hours per day and days per year. However, following the publication of the proposed rule, EPA understands that the worker exposure duration information, as proposed, could lead to a manufacturer reporting unassociated variables; that is, the worker with the maximum duration of exposure in hours per day is not the same as the worker with the maximum duration of exposure in days per year. Without additional clarifying information on which worker(s) the reported durations reflect, such a request may not yield data useful for EPA’s assessments. EPA is therefore modifying the proposed request for the worker exposure duration data by clarifying the workers for whom the maximum exposure durations or frequency must be reported. EPA is requesting worker exposure duration

information (in hours per day and days per year) both for the worker with the greatest daily exposure duration (i.e., the worker with the greatest exposure in hours per day) and for the worker with the greatest annual exposure frequency (i.e., the worker exposed during the most days per year).

Additionally, EPA is modifying the scope of data elements requested for some article importers and manufacturers of R&D substances in quantities below 10 kilograms annually. Based on feedback through public comments and the SBAR Panel, EPA understands that some article importers and some manufacturers of R&D substances may not know or be able to ascertain all information being requested. Therefore, EPA is offering two streamlined reporting options for those manufacturers. (For more information on these reporting options, see additional discussions in Units III.D.2 and III.D.3.)

EPA is also modifying the proposed rule by enabling joint submissions. In the proposed rule, EPA did not propose joint submissions, but did specifically request comment on whether to enable them for this rule in cases where a supplier may not disclose the chemical identity to an importer who is covered by this reporting rule. Following public comments, EPA is finalizing this rule to include joint submissions for situations in which an importer does not know the CASRN or specific identifier (i.e., Accession number or LVE number) (see Unit III.I.). EPA further discussed requiring submitters who lack knowledge of a chemical's specific chemical identity to initiate a joint submission in the NODA.

Finally, EPA is modifying the scope of reportable activities under this rule to clarify that importing municipal solid waste streams for the purpose of disposal or destruction is not a reportable activity under this rule. As explained in Unit III.B.3., EPA learned through public comments and the SBAR Panel that entities engaged in certain municipal solid waste management activities are in the unique position of not having any knowledge of the contents of the municipal solid waste they have imported. Therefore, extending reporting requirements to

such sites would not result in any responsive information under TSCA section 8(a)(7), and EPA does not consider the import of municipal solid waste for the purpose of disposal or destruction to be a reportable activity.

IV. Summary of Comments and Other Public Input and EPA's Response

EPA received 109 unique public comments during the proposed rule's public comment period. Following publication of the proposed rule, EPA received more data related to the proposed rule's burden and cost estimates. At the time of the proposed rule's publication, EPA did not have sufficient and reliable data to inform an estimate of the scope of article importers that may be affected by the proposed rule's requirements. However, after receiving comments through the docket related to the scope of article importers (including estimates provided by companies and industry trade associations), and through the discovery of additional information and data sources related to the scope of potentially affected article importers, EPA determined the proposed rule could no longer support a certification under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, that there would be no significant economic impact on a substantial number of small entities. Specifically, the number of small businesses who may be considered importers of PFAS-containing articles and therefore potentially affected by the proposed rule was estimated to be approximately 130,000. Thus, EPA convened an SBAR Panel under the RFA to hear directly from small entities on the anticipated impact of the proposed rule on their organizations, and to hear feedback regarding recommended paths forward to finalize a rulemaking that would minimize the burden of compliance on small entities while still achieving the objectives of TSCA section 8(a)(7). This Panel convened in April 2022, with a Panel Outreach meeting conducted on April 20, 2022. The Panel (which included EPA, OMB, and SBA representatives) used feedback from the small entity representatives submitted during and after the Outreach meeting to develop its Panel Report (Ref. 22), which included recommendations for EPA to consider in its final rule.

Along with public comments on the overall cost estimates of the 2021 Proposed Rule, EPA received many public comments both in support of and against EPA's position to not exempt entities or activities that are often exempt under CDR, including small manufacturers and article importers, and the use of a structural definition for PFAS rather than a discrete list of substances.

Following this Panel, EPA published a NODA (Ref. 1) to solicit public comment on the rule's IRFA and other aspects of the proposed rule that may have been impacted by EPA actions or proposed actions since the public comment period had closed for the proposed rule in September 2021. EPA also published the SBAR Panel Report (Ref. 22) for public comment. The notice was published on November 25, 2022 (Ref.1), for a 33-day public comment period ending on December 27, 2022. EPA received 44 unique public comments during the public comment period following the publication of the NODA (Ref. 1). Comments largely focused on different regulatory alternatives presented in the Panel Report (including certain exemptions, or using a discrete list of covered PFAS) and on EPA's discussion of its approach to CBI claims of the chemical identity.

EPA considered all comments and other stakeholder input, including from the SBAR Panel, in the development of this final rule. This unit discusses many of the comments on the proposed rule received through both avenues and the Agency's responses; however, the more comprehensive response to comments related to this rule can be found in the Response to Comments document, which is available in the docket for this rulemaking (Ref. 21).

A. What is the proposed definition of covered substances?

1. Summary of public input.

Many commenters provided feedback on the specific definition of PFAS in the proposed rule. These commenters either were unsupportive of EPA's definition and requested that the Agency narrow the proposed definition of PFAS or requested that EPA broaden their definition

of PFAS, while generally supporting EPA's proposed structural definition.

Commenters who were generally unsupportive of EPA's proposed definition of PFAS noted that "the proposed rule contains a definition of 'PFAS' not recognized by any other federal agency or international organization, and which EPA itself does not use consistently." One commenter mentioned that treating PFAS as a single group or class of chemicals is "not scientifically sound or appropriate" due to it being "over- and under-inclusive." Another commenter stated that EPA's proposed definition of PFAS is overly expansive "because it includes molecules that are not obviously PFAS" such as "highly fluorinated molecules that are not PFAS by any common understanding of PFAS." This commenter suggested that the definition of PFAS in the final rule "hew much more closely to the types of PFAS molecules that motivated Section 7351 of the NDAA 2020." Commenters who suggested that EPA's proposed PFAS definition is overly broad, also suggested that an overly broad PFAS definition will "almost certainly" result in unnecessary reporting of "PFAS molecules" that are "likely unrelated to the underlying problems."

Some commenters suggested that EPA use the OECD definition of PFAS, with a few commenters recommending that EPA define PFAS "at least as broadly as the recent OECD definition." Supporters of adopting the OECD definition claimed that the OECD definition incorporates sound science based on input from the "world's leading developed countries, including scientists from EPA" and mentioned that it might make reporting compliance easier for PFAS manufacturers who have a global presence. Another commenter who supported use of the OECD definition mentioned that EPA's proposed definition excludes "many PFAS of known concern, undercutting the benefits of the Agency's actions."

A few commenters who claimed that EPA's proposed PFAS definition is overly narrow, mentioned that other regulatory agencies in some states have taken a "class-based approach" to PFAS by regulating them as a chemical class. Commenters specifically cited Vermont,

Massachusetts, and California as examples of states that are regulating PFAS in this way, “given that all PFAS, or their degradation, reaction, or metabolism products, display commonly hazardous traits.” Some commenters pointed to additional states (Colorado, Maine, Washington) that have adopted or are considering adopting a broader definition of PFAS similar to the OECD definition.

2. EPA’s response

EPA appreciates that there are differences between the definition of PFAS used for this rule, for other actions in the Agency, and by non-EPA entities. While EPA’s rule is not dictated by the definitions used by other regulatory bodies or international organizations, the Agency did consider adopting the different definitions suggested by the commenters, but ultimately determined those definitions would not satisfy EPA’s obligations under TSCA section 8(a)(7). In the development of this proposed definition, EPA intended to include substances with a strong electron withdrawing nature as this greatly effects the chemistry of the substituted, adjacent and nearby atoms, meaning they would have a minimum of two fluorine atoms on at least one carbon (e.g., -CF₂-). Additionally, EPA wanted the covered substances to be unlikely to degrade or metabolize, so an adjacent CF group was added to the requirement/definition, with the stipulations that the substitutions could not be H and both carbons must be saturated (e.g., -CF₂-CFR-). EPA also thought that branching might make a chemical less susceptible to degradation and metabolism, so EPA also removed the option for -CF₂-CF₂- when developing the proposed definition.

After reviewing public comments, EPA is modifying the proposed definition of PFAS. For the purposes of this section 8(a)(7) reporting rule, EPA is defining “PFAS” using a structural definition. PFAS is defined as including at least one of these three structures:

- R-(CF₂)-CF(R’)R’’, where both the CF₂ and CF moieties are saturated carbons;
- R-CF₂OCF₂-R’, where R and R’ can either be F, O, or saturated carbons; and

- $\text{CF}_3\text{C}(\text{CF}_3)\text{R}'\text{R}''$, where R' and R'' can either be F or saturated carbons.

For the purposes of this rule, EPA has defined PFAS to include chemical substances whose structures or sub-structures resemble, at least in part, chemicals widely known to be of concern to human health and/or the environment, i.e., PFOA, PFOS, and GenX. The definition also captures substances that may metabolize or degrade to PFAS which may present similar properties to PFOA, PFOS, or GenX. This definition is focused on substances likely to be present in the environment, thereby focusing on substances with greater potential for exposures to people and/or the environment and by extension more potential to present risks.

EPA considered adopting OECD's definition for the purpose of this rule, but for the reasons provided in this unit, determined it is not appropriate to do so. First, EPA notes that "alkyl" means an alkane missing one hydrogen, and acyclic alkyl has the general formula of $\text{C}_n\text{H}_{2(n+1)}$, while a cycloalkyl has the general formula $\text{C}_n\text{H}_{2(n-1)}$. Rather than limiting the definition of PFAS to alkyl chains, the OECD definition covers, with certain exceptions, any chemical with one or more fluorinated alkyl groups (i.e., $-\text{CF}_2-$, $-\text{CF}_3$). Many chemical substances covered by the OECD definition are unlike the structures of the PFAS of concern (i.e., PFOA, PFOS, GenX), which have more fluorinated carbons and are more likely to be present in the environment. The substances with only single fluorinated alkyl groups and no additional fluorinated moieties do not share the same environmental and/or human health impacts (including bioaccumulation, persistence, or toxicity) as substances such as PFOA, PFOS, or GenX. Further, many substances with one terminal $-\text{CF}_3$ (e.g., trifluoroacetic acid (TFA)) are well-studied. Using structures in the CompTox Chemicals Dashboard, EPA estimates that approximately 23,000 additional substances would be captured by the OECD definition, though approximately 17,000 of those would be covered only due to having one terminal $-\text{CF}_3$ and no additional fluorine. Thus, adopting the OECD definition of PFAS in this rule would mainly serve to significantly add reporting burden on many substances whose only fluorine atom is in a

terminal -CF₃ and that do not share a fluorinated substructure that is likely to result in their persistence in the environment, nor to degrade to a substance that shares toxicological or physiochemical properties with PFOA, PFOS, or GenX. Therefore, EPA is using its authority under TSCA section 8(a)(5)(A) to focus reporting on structures that contain at least one fluorinated alkyl chain rather than isolated fluorinated alkyl groups. Information on structures that would meet the OECD definition due to an isolated fluorinated alkyl group is considered “unnecessary” for the purpose of this rule and is out of scope of reporting requirements under EPA’s authority under TSCA section 8(a)(5)(A).

Further, OECD’s general definition is “based on molecular structure alone” (Ref. 8). In its 2021 terminology document, OECD notes that the current definition “serves as a starting and reference point to guide individual users to have a comprehensive understanding of the PFAS universe and to keep the big picture of the PFAS universe in mind. At the same time, individual users may define their own working scope of PFASs for specific activities according to their specific needs by combining the general definition of PFASs with additional considerations (e.g., specific properties, use areas)” (Ref. 8). Accordingly, EPA determined it is appropriate to define “PFAS” differently for this rule and to establish a definition which characterizes PFAS based on pre-defined traits. Substances which meet the OECD’s definition of PFAS but that would not be considered PFAS under this rule do not share properties with substances of concern to EPA (i.e., PFOA, PFOS, and GenX). As noted previously, EPA is defining PFAS for this rule to focus on reporting that is necessary under TSCA section 8(a)(7), while reducing unnecessary or duplicative reporting pursuant to EPA’s obligations under TSCA section 8(a)(5)(A).

Additionally, while the OECD definition of PFAS is broader than other entities’ definitions of PFAS, EPA is aware of some TSCA chemical substances which would meet this rule’s definition of PFAS but not OECD’s. In comparing the universe of PFAS that would be subject to EPA’s proposed definition and those substances captured by OECD’s definition, EPA

determined that some substances with halogens (e.g., iodine, chlorine, bromine) on the same carbon as the CF or CF₂ moiety would be in scope of EPA's proposed definition but not OECD's. Examples of substances which are considered PFAS under this rule's definition but not OECD's definition include 1-chloro-1,1,2,2-tetrafluoroethane (CASRN 354-25-6) or 1,2-dichloro-1,1,2,2-tetrafluoroethane (CASRN 76-14-2). Because all substances which were captured by the proposed definition are still captured in this final rule, EPA points out that adopting the OECD definition would still have excluded some substances that are captured by this rule's definition.

Many commenters also suggested that trifluoroacetyl fluoride (TFA; CASRN 354-34-7) should be included within the scope of this rule. Under this rule's definition of PFAS, TFA is not within scope. EPA believes TFA does not meet the threshold for reporting under TSCA section 8(a)(7), as it is a short-chain molecule (C₂) with only one terminal -CF₃, and no other fluorine atom, unlike substances such as PFOA, PFOS, and GenX. TFA is naturally occurring in some instances or is produced as an environmental degradant of many other substances, especially those with only one terminal carbon (-CF₃) (Refs. 23, 24, and 25). EPA understands that the manufacture of TFA would not always be considered "manufactured for commercial purposes" under TSCA, such as its production as an environmental degradant or its presence as a naturally-occurring substance, and therefore EPA would not receive any TSCA section 8(a)(7) reporting on those quantities. Additionally, as EPA has noted in responding to a request for testing on PFAS, TFA is "a well-studied substance" with "relatively robust toxicity information available" (Ref. 25). Therefore, EPA believes that reporting on TFA under a TSCA section 8(a) rule (i.e., one in which the scope is limited to those substances manufactured for commercial purposes and does not include environmental degradants) is not warranted as such requirements would be "unnecessary" and "duplicative" under TSCA section 8(a)(5)(A).

EPA also disagrees with commenters who expressed that the scope of substances

reportable under this rule should be a discrete list and not a structural definition. EPA points out that other TSCA requirements have relied on a structural definition when appropriate (e.g., the LCPFAC SNUR defines covered substances using a structural definition (40 CFR 721.10536) (Ref. 7), and the polymer exemption rule for new chemical pre-manufacture notices (PMNs) defines covered PFAS polymers using structural definitions (40 CFR 723.250). As some commenters pointed out, reporting exemptions for both existing chemicals (e.g., certain byproduct exemptions in the CDR rule) and new chemicals (e.g., byproducts and impurities not listed on the Inventory) mean that EPA may be unaware of some substances which meet this definition of PFAS, and which would also meet the TSCA definition of “chemical substance.” Therefore, EPA has chosen to define the scope of covered substances for the purpose of this rule using a structural definition and not inadvertently limit the scope of reporting to a discrete list.

B. What is the inclusion for articles?

1. Summary of public input.

Several commenters provided feedback on the inclusion of articles (whether imported or domestically produced) in the proposed reporting requirements.

Commenters who expressed support for the inclusion of articles in the proposed reporting requirements provided the following rationales:

- It is necessary that EPA include articles in the scope of reporting requirements to better understand where PFAS are used in products and the extent of human exposure. Additionally, EPA has recognized that PFAS in articles can be released during use and disposal, and therefore it is necessary for EPA to gather this information.

- Information on PFAS-containing articles is critical to states that are beginning to regulate PFAS-containing items.

- Even if there are data gaps related to the presence of PFAS in articles, EPA would benefit from knowing the existence of these gaps, and therefore, EPA should move forward with

requiring reporting on articles.

- Congress has authorized inclusion of articles in the reporting requirements; reporting of “known or reasonably ascertainable information” is not an excessive burden. Commenters argued that excluding articles from the scope of the final rule would be inconsistent with Congressional intent.

- The definition of “chemical substance” under TSCA is not incompatible with the inclusion of articles. Further, in other sections of TSCA, Congress specified distinct requirements for chemical substances depending on their presence in articles, though it did not do so in TSCA section 8(a)(7).

Commenters who suggested that EPA exempt articles from the proposed reporting requirements provided the following rationales:

- The proposed requirements are at odds with regulatory practices; historically, EPA has not included articles in reporting requirements. Additionally, CDR does not include reporting on imported articles, and some commenters stated that EPA should be consistent with those requirements. Some commenters suggested that the reasons EPA has provided in the past for certain CDR exemptions, including imported articles, are relevant here (i.e., the potential for exposure to chemicals contained in articles is “limited”) and encouraged EPA to incorporate an imported article exemption under this rule. Several of these comments also mentioned previous EPA actions, such as the TSCA Fees Rule and the PIP (3:1) rule, in which EPA initially aimed to include articles but eventually changed course due to “workability” issues of including articles (Refs. 26 and 27).

- EPA did not provide sufficient justification in the proposed rule for requiring article reporting, and there is no mandate in the FY 2020 NDAA for inclusion of articles. Commenters claimed that EPA underestimated or failed to account for the burden this reporting will have on article importers, and EPA is unable to accurately estimate how many importers this proposed

rule would affect.

- Under TSCA, the definition of “chemical substance” has not been interpreted to include articles which contain the chemical substance. Commenters argue that TSCA section 8 implementing regulations also distinguish “articles” from “chemical substances.”

- Requiring reporting on articles would place undue burden on industry and for manufacturers or importers to obtain the information EPA seeks is very difficult given the absence of historical PFAS reporting requirements. Commenters claimed that there will be significant data gaps if EPA requires article information, and that EPA will not be able to obtain the information it seeks. Additionally, reporting on articles going back ten years is impractical.

- EPA has acknowledged that article manufacturers and importers likely will not have the information EPA seeks, and therefore, manufacturers and importers should be exempt. These commenters also cite their foreign suppliers’ confidentiality or trade secret claims over their products and indicate that it is unlikely their suppliers will divulge the information necessary to comply with this rule.

- Supply chains are too broad and requiring articles reporting will result in duplicative information, especially for more complex articles or finished products.

Neutral comments suggested that if EPA is going to require reporting on articles, they should require reporting for domestic article manufacturers only and not article importers, and that even beyond this rule, EPA should fully consider the complexities associated with collecting data on articles under TSCA. One commenter stated that EPA should consider focusing its reporting requirements on articles with the greatest potential for human exposure. The commenter offered as an example the differences between articles containing PFAS on its surface due to the properties that PFAS would impart on the product (such as carpets or cookware) and articles containing PFAS within resins of multi-component parts. The commenter suggested that EPA exclude articles containing PFAS unless the PFAS was intentionally added

to the article due to properties imparted on the article.

2. EPA's response.

EPA appreciates the broad interest in the general topic of requiring reporting on PFAS within articles (either imported articles or articles that are domestically produced). This topic was also discussed at length during the SBAR Panel, and EPA considered all public input on the proposed inclusion of PFAS-containing articles in this rule. EPA is finalizing the requirement to include PFAS-containing articles within the scope of this rule, to the extent that the manufacturer (including importer) of PFAS within articles knows or can reasonably ascertain the requested information. EPA disagrees with commenters who stated that the Agency does not have the authority to collect information on PFAS-containing articles given the language in the FY 2020 NDAA. While the FY 2020 NDAA did not explicitly direct EPA to collect data on articles containing PFAS, the FY 2020 NDAA also did not explicitly prevent EPA from collecting information on PFAS-containing articles. Further, EPA notes that it is within the Agency's authority to collect information on chemical substances which are manufactured or imported through articles. Thus, the FY 2020 NDAA's direction to EPA to require data from PFAS manufacturers necessarily includes those PFAS manufactured (including imported) within articles. Although EPA has not typically included articles in some other TSCA section 8 reporting rules, the Agency both has the authority and has previously done so. Other TSCA rules, including other TSCA section 8 reporting rules (such as the Preliminary Assessment Information Reporting rule under TSCA section 8(a) (40 CFR 712) and the TSCA section 8(d) Health and Safety Data Reporting rule (40 CFR 716) include reporting on articles as needed for EPA to fulfill its responsibilities under TSCA. Additionally, EPA points out that the TSCA Fees and PIP 3:1 rules (Refs. 26 and 27) are authorized under separate sections of TSCA. This PFAS reporting rule was proposed and required under TSCA section 8(a), which authorizes EPA to require reporting and recordkeeping requirements of manufacturers and/or processors, to the extent such

information is known to or reasonably ascertainable by the reporter. The requirements and compliance standards of the PIP 3:1 (use in article prohibition) (Ref. 27) and Fees (self-identification of manufacture) rules were different (Ref. 26).

EPA disagrees with the commenters that under TSCA, the definition of ‘chemical substance’ “cannot be and has never been interpreted to include articles that contain the regulated chemical substance.” TSCA section 3(2) does not define “chemical substance” to exclude articles. Generally speaking, articles are manufactured goods or finished products – and the chemicals in them are subject to TSCA. The law is clear that when a chemical substance is manufactured (including imported into the United States) or is distributed or processed in the United States – whether in bulk form or in an article – it can be subject to regulation under TSCA. As such, EPA can and has imposed regulatory requirements on chemical substances in articles under TSCA. Further, no TSCA section 8 regulations exclude articles from the definition of “chemical substances.” While implementing regulations for other TSCA section 8 rules may exempt reporting for activities related to a covered chemical substance in an article (e.g., general reporting and recordkeeping provisions for TSCA section 8(a) information-gathering rules (40 CFR part 704) or the Chemical Data Reporting rule (40 CFR part 711)), there is no definitional distinction for a chemical substance depending on whether it is incorporated into an article; nothing says that an “article” is exclusive or distinct from a “chemical substance.” While the CDR rule has exempted the import of articles from reporting, the domestic manufacture of a chemical substance within an article is still subject to CDR. Further, EPA points out that the introductory paragraph of 40 CFR 704.5 for exemptions states this section is superseded by any TSCA section 8(a) rule that adds to, removes, or revises the exemptions described in this section. Thus, the commenters’ reliance on precedent under 40 CFR part 704 fails to acknowledge that EPA has long allowed for different exemptions (or lack thereof) to apply under different TSCA section 8(a) rules as appropriate.

EPA also disagrees with commenters' statements that reporting on articles would place undue burden on industry. EPA points out that the reporting standard of TSCA section 8(a) rules is limited to information which is known to or reasonably ascertainable by the manufacturer. Thus, if requested information is beyond that scope of known or reasonably ascertainable, the reporting entity would not be required to submit anything beyond indicating that such information is not known or reasonably ascertainable to them. In other words, this reporting standard is not a testing requirement; rather it asks reporters to share with EPA the information they already have (or can reasonably determine) on their manufactured and imported PFAS.

Regarding comments on the lookback period for article importers, EPA points out that the lookback period proposed is consistent with Congress's direction to EPA in TSCA section 8(a)(7). EPA is not changing the proposed requirement to provide any known or reasonably ascertainable information for the period beginning in 2011.

Regarding comments stating that requiring reporting on articles may result in duplicative information for complex articles or products that are re-imported, EPA disagrees that the information reported will result in duplicative information, especially given the reporting standard applicable to this rule. EPA acknowledges that some supply chains of manufacturers reporting under this rule are complex. However, EPA believes that information known to or reasonably ascertainable by an article manufacturer at the first instance the PFAS is imported into the United States is likely different than the scope of information known to an article importer farther down the supply chain who may re-import that PFAS later, as the article is incorporated into more complex articles or products. For instance, the person who imports a PFAS within an article in the first instance may have different worker exposure information to report than a person who may later re-import that PFAS-containing article as part of a more complex product. In another example, information related to the known industrial or consumer uses of a PFAS within an article may be clearer to the person who re-imports a PFAS within a

larger complex product than it is to the person who first manufactured the PFAS within the article. Thus, EPA does not believe that the information requested of PFAS article manufacturers would be duplicative, given the different steps of a supply chain and manufacturing processes, and is requiring all PFAS-containing article manufacturers to report the requested data to EPA to the extent it is known or reasonably ascertainable. EPA also believes that applying the reporting requirements each time a PFAS is imported into the United States is consistent with TSCA's definition of manufacturing under TSCA section 3(9) (which means "to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedules of the United States), produce, or manufacture") and the directive under TSCA section 8(a)(7). EPA also believes that if a PFAS is imported, exported, then re-imported, limiting the scope of reporting to just one instance of importation into the United States may result in certain burden on manufacturers within the supply chain who need to further communicate with each other to determine whether a PFAS within an article has already been reported and who is responsible for reporting. Further, with respect to comments claiming that the inclusion of articles will necessarily result in significant data gaps, EPA respectfully points out that there is no current database with comparable information on PFAS in commerce, including within articles, over the reporting timeframe. EPA cannot make an assessment of potential PFAS data gaps without considering all reasonably available information. Additionally, as noted by other commenters, EPA would benefit from better characterizing any data gaps after receipt of all reasonably known information.

EPA disagrees with commenters' suggestions to limit the scope of reporting on PFAS in articles by extending reporting requirements to only those articles "with the greatest exposure potential." For the purpose of a TSCA section 8 information reporting rule, there is no requirement for EPA to determine which substances or types of articles may pose greater exposure potential, unlike some other sections of TSCA (e.g., TSCA section 6 Significant New

Use Rules). This TSCA section 8(a)(7) rule in particular aims to provide EPA with a greater understanding of the scope of existing information of PFAS within the supply chain and the quantities and uses of commercially manufactured PFAS, which may include PFAS manufactured or imported within a variety of articles or products.

Finally, EPA took appropriate and necessary steps to consult with the public and consider stakeholder input on the proposed rule, including reporting on PFAS-containing articles. These steps included convening an SBAR Panel and meeting with stakeholders to discuss the proposed rule and potential reporting obligations. EPA has considered all input for this rule, including the complexity of different supply chains with respect to collecting data on articles. While EPA was not able to estimate the burden on article importers given the data limitations at the time of the proposed rule's publication, the Agency has since been able to provide such estimates, including input from public commenters, peer-reviewed journals, other government datasets, and input from the SBAR Panel. EPA has now remedied this omission in the Economic Analysis.

C. What are the exclusion of processors from rule?

1. Summary of public input.

EPA received comments both in support of and in opposition to the addition of processors to the proposed rule. Ten commenters stated that EPA should expand the rule beyond manufacturers (including importers) to cover all facilities processing PFAS. Two of these commenters expressed that processors are often in the best position to provide the information required under TSCA section 8(a). Several commenters emphasized the importance of collecting information on the full life cycle of PFAS, including from processing operations. Some commenters were concerned with a potential data gap of PFAS exposures if processors are omitted from the final rule. Another commenter highlighted the importance of tracking the PFAS solid waste stream to enhance understanding of health risks associated with PFAS and to inform other actions under environmental regulations such as the Safe Drinking Water Act (SDWA) and

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Many commenters in support of adding processors also stated that EPA has the authority to require reporting from processors, citing both the FY 2020 NDAA and TSCA section 8(a)(1).

Four commenters indicated that the Congress did not intend for the proposed rule to include processors and that EPA should not require them to report. Two of these commenters referred to the FY 2020 NDAA section 7351 language stating that the Act does not identify manufacturers that process PFAS substances as entities that would be subject to the rule. Commenters in opposition to adding processors also claimed that EPA would be creating confusion and the potential for duplicative reporting. One commenter urged EPA to clarify in the final rule that reporting is limited to only the initial importers of PFAS-containing products and not any downstream processors or users. Commenters also said that such reporting would create unnecessary burden for both EPA and processors.

2. EPA's response.

EPA appreciates commenters' perspectives on extending reporting requirements to processors for this rule under TSCA section 8(a)(7). However, the Agency's reading of the text in TSCA section 8(a)(7) and the FY 2020 NDAA's legislative history conclude that the intended scope of this rule is to only require reporting from manufacturers (including importers), distinct from processors. EPA is clarifying that entities who solely process, distribute, and/or use PFAS, and do not manufacture (including import) PFAS for a commercial purpose, are not required to report under this rule.

As some commenters noted, the Agency would have the authority to promulgate such a rule for processors under TSCA section 8(a)(1). However, this rule is being promulgated under TSCA section 8(a)(7). EPA also notes that the exclusion of processors from the scope of this rule does not preclude any potential future rulemaking under TSCA section 8(a)(1), should the Agency determine such data are needed. EPA will review the data submitted by manufacturers

under this rule and reserves the right to promulgate a rule under TSCA section 8(a)(1) to capture information from PFAS processors if appropriate. EPA disagrees with commenters who noted that including processors in the scope of this rule would lead to confusion and duplicative reporting. EPA points out that other TSCA section 8(a) rules have included processors, such as the nanoscale materials reporting rule (40 CFR 740.20).

D. What were the small business considerations.

1. Summary of public input.

Many commenters opined on the inclusion of small businesses, including small manufacturers, under the proposed rule. Several commenters stated that EPA should exempt small businesses from reporting under the proposed rule. Some of these commenters said that small businesses are not likely to provide useful information and will be disproportionately affected by the rule (including potentially being forced out of business) because fewer resources are available to them. Others expressed that they thought EPA had not evaluated whether small businesses would actually contribute meaningful data to EPA as a result of the rule.

Four commenters disagreed with EPA's position that the FY 2020 NDAA authorizes data collection from all manufacturers, including small manufacturers. Two of these commenters felt that, by not providing relief for small manufacturers, EPA did not appropriately apply TSCA section 8(a)(5) requirements. Some commenters referred to TSCA section 8(a)(1), which they state excludes small manufacturers from reporting rules. Another commenter stated that EPA needs to consider the historical lack of TSCA section 8 reporting requirements on small manufacturers or article importers, including from CDR.

Other commenters said that EPA should collect the information required under the proposed rule from all businesses regardless of size. While one commenter acknowledged that the rule could be burdensome for small entities, they also said that the health risks associated with PFAS are significant and warrant the data collection from small businesses. Another

commenter described EPA's definition of small manufacturer under TSCA section 8 as "expansive" and noted that the existing "small manufacturer" definition would result in omitting reporting from significant PFAS manufacturing and importing activities such that it would undermine this data collection effort.

One commenter stated that EPA could help small businesses comply with the proposed rule in lieu of a small manufacturer exemption by extending other reporting exemptions to them, including R&D substances, non-isolated intermediates, impurities, byproducts, and articles, as well as a minimum reporting threshold.

2. EPA's response.

EPA disagrees with commenters' positions that a broad small business or a small manufacturer exemption is appropriate for this rule. EPA appreciates that small businesses, especially those which have not previously reported under CDR or other TSCA section 8(a) rules, may not have the same resources that are available to large companies. This feedback was also voiced through the rule's SBAR Panel, and EPA is greatly appreciative of the input related to small businesses' resources and ability to respond to the rule. To that end, EPA has modified the proposed rule to include options that provide some relief to all manufacturers, including small entities. Specifically, article importers and manufacturers of R&D substances in quantities below 10 kilograms per year will have the option to submit more streamlined reporting forms than the longer, standard form for all other PFAS manufacturers. Additionally, EPA is extending the deadline for reporting forms by at least six months from what was proposed, so that all entities, including small entities, have 18 months from the effective date of this rule to submit the requested information. For small manufacturers (as defined at 40 CFR 704.3) whose reporting obligations under this rule are exclusively from article imports, EPA is further extending the deadline for reporting forms by an additional six months. Thus, small article importers have 24 months from the effective date of this rule to submit the requested information.

In response to commenters who refer to TSCA section 8(a)(1) in their support of an exemption for small manufacturers, EPA respectfully points out that this is a rule authorized under TSCA section 8(a)(7), not under TSCA section 8(a)(1). While Congress explicitly carved out potential exemptions for small manufacturers and small processors for rules implemented under TSCA section 8(a)(1) for chemicals not subject to certain TSCA actions, Congress chose not to do so in the text of TSCA section 8(a)(7). EPA considered the provisions at TSCA section 8(a)(5) to limit reporting requirements for small manufacturers and determined that reporting from small manufacturers would be appropriate under TSCA section 8(a)(5)(A) through (C). The information requested under this rule is not unnecessary nor duplicative due, in part, to exemptions in other TSCA reporting rules. Additionally, a broad exemption for all entities deemed a “small manufacturer” would not enable EPA to fulfill the express requirements of the NDAA to require “each person” to report their PFAS manufacturing activities to the extent they know or can reasonably ascertain. Regarding the provision to minimize the cost of compliance on small manufacturers, EPA has identified regulatory alternatives to the proposed rule that reduce compliance costs without a complete exemption. Finally, based on public comments and input from the SBAR Panel, EPA believes that small manufacturers are likely to have information regarding commercially manufactured PFAS, which is relevant to the effective implementation of TSCA.

E. What is the concern regarding a lack of common TSCA reporting exemptions or reporting threshold?

1. Summary of public input.

Many commenters opined on the proposed rule’s lack of common TSCA reporting exemptions and a reporting threshold. Several commenters added that incorporating exemptions and/or a reporting threshold would make the proposed rule consistent with other TSCA rules such as CDR, Fees, PAIR, and PMN reporting (Refs. 20, 26, and 27). Commenters cited

potential compliance challenges and reporting burden as the rationale for such exemptions, as they stated that the work involved in identifying, tracing, and reporting under the proposed rule is significantly increased without exemptions. Other commenters said that the lack of exemptions would significantly increase the number of substances for which reporting must occur as opposed to the 1,364 PFAS estimated in the proposed rule, as those only reflected those PFAS on the Inventory or subject to an LVE, yet those sources exempt several types of substances (e.g., impurities, byproducts, R&D substances). Another commenter said that these types of substances are not likely to result in exposure to humans or the environment, and that EPA has not articulated what the benefit of the additional data would be.

On the other hand, several commenters supported implementation of the proposed rule without any exemptions. They said that Congress intended for each person who manufactures a PFAS to be subject to the rule, without exemptions, and that incorporating exemptions would not be consistent with EPA's past approach for PFAS. Some commenters also pointed out the differences between the objectives of CDR and this PFAS reporting rule, stating that CDR's intent is to obtain initial screening information on a broad universe of chemicals, while this rule's aim is to collect information specifically on PFAS.

2. EPA's response.

EPA appreciates the input from commenters on the impacts of not incorporating certain reporting exemptions or thresholds. EPA appreciates the support from commenters who supported promulgating the final rule without exemption and, after reviewing public input, has decided to finalize that aspect of the proposed rule.

EPA disagrees with commenters' requests to include many of the reporting exemptions found in other TSCA rules such as in PMN reporting and the Fees Rule (Refs. 20 and 26). EPA points out that, unlike the Fees Rule, the scope of this rule is information which is known to or reasonably ascertainable by the manufacturer (Ref. 26).

While this rule uses the same reporting standard as CDR and other TSCA section 8(a) rules, this rule is focused on improving EPA's knowledge of commercially manufactured PFAS and their uses, which includes chemicals of concern to human health and the environment. Therefore, EPA does not believe many of the same reporting exemptions used in other TSCA rules are warranted. As directed by the statute, EPA is requesting information on PFAS manufactured for a commercial purpose to the extent such information is known or reasonably ascertainable to the manufacturer. EPA also points out that, whether types of substances (such as non-isolated intermediates, impurities, or articles) are likely to result in human or environmental exposures is not a threshold that EPA needs to satisfy for requiring reporting on those substances under TSCA section 8(a)(7). EPA aims to better understand the scope of existing knowledge of the universe of historically manufactured PFAS and implementing certain exemptions may inadvertently lead to the omission of information known to or reasonably ascertainable to some manufacturers. The information EPA receives through this rule will refine the Agency's understanding of certain exposure-related data of PFAS manufactured. If certain substances have not resulted in significant human and environmental exposures, then that would be reflected in the submitted information.

EPA appreciates the public input on the proposed rule's burden analysis, including additional information received during the proposed rule's comment period, the SBAR Panel, and the IRFA comment period. EPA has refined its economic analysis, including the estimated scope of covered substances and associated burden of determining whether reporting is required. Regarding commenters' claims that the estimated scope of covered substances may be significantly greater than estimated without certain exemptions, EPA points out that the exact challenge articulated by commenters justifies the lack of exemptions in this rule: the fact that stakeholders have questions surrounding the number of covered substances under this rule, including as impurities, intermediates, or R&D substances, reveals the lack of existing

information of the universe of PFAS in commerce. EPA aims to better understand what manufacturers know or may reasonably ascertain regarding manufactured PFAS, and exempting substances that were not previously reported under other TSCA rules would hinder that effort.

F. What is the application of the reporting standard?

1. Summary of public input.

EPA received many comments on the reporting standard proposed for this rule: information known to or reasonably ascertainable by the manufacturer. The majority of these commenters suggested that EPA revise their definition of “reasonably ascertainable” to assist businesses with compliance. Specifically, these commenters voiced concerns over the time spent to conduct compliance determination activities to satisfy the “due diligence” requirement of the reporting standard for many substances and products, and for which they do not anticipate information being readily available even after an extensive search. Commenters claimed that, for substances which have been historically exempt from other TSCA reporting requirements (especially imported articles), there is likely little if any information available, yet entities would still be required to perform due diligence and demonstrated they have examined each imported article.

However, other commenters largely supported EPA’s proposed requirements. One commenter suggested that “known and reasonably ascertainable” should be broadly interpreted and that the proposed definition of “known and reasonably ascertainable” is consistent with definitions in TSCA recordkeeping regulations and should therefore be included, as is, in the final rule. Other commenters stated that the requirement for manufacturers to assess whether they know or can reasonably ascertain PFAS’ presence in their articles is a modest cost that is outweighed by the benefits of the data to EPA and the public.

In addition, there were several comments requesting that EPA clarify or provide additional guidance on the reporting standard for this rule, including guidance tailored to article

importers and what constitutes due diligence under this standard. Some suggestions included stipulating that the scope of a manufacturer's inquiry within their supply chain is limited to just immediate suppliers (i.e., no need to inquire multiple levels of their supply chain), and that if a supplier refuses to share information with a manufacturer, then the manufacturer need not inquire further and would not face EPA enforcement action. Some commenters also requested further clarification of the proposed requirement to submit "reasonable estimates" for certain data elements where actual data are not available.

2. EPA's response.

EPA appreciates the input from commenters and the SBAR Panel related to the scope of information that may be known to or reasonably ascertainable by (KRA) PFAS manufacturers, including small article importers. EPA has incorporated the feedback into both the rule (e.g., providing an option of streamlined reporting forms for article importers and manufacturers of small quantities of R&D substances who would not know the downstream processing, use, and disposal information) and this rule's accompanying guidance and instructions on applying the KRA standard.

Regarding manufacturers who have concerns over the due diligence expected under this rule, including those who believe they ultimately will not obtain any reportable information, EPA clarifies that there is no reporting or recordkeeping requirement if an entity has no relevant information. This rule does not itself require any company to maintain information upon which a decision not to report is based. Consistent with their own business practices, companies may elect to retain documentation of their conclusion that they were not subject to reporting requirements. While manufacturers and importers are expected to exercise "due diligence" in looking for reportable PFAS and information, that effort will look different for different entities.

EPA also acknowledges that it may not be within the scope of "reasonably ascertainable" to survey all articles and products, especially for article importers. In addition to the existing

guidance on this reporting standard, EPA is providing guidance on this reporting standard with respect to article importers and other entities who may be exempt under other TSCA regulations (e.g., manufacturers of small quantities of R&D substances).

Regarding the suggestions that the rule should limit the scope of a manufacturer's inquiry of its supplier(s) to only information which the supplier does not claim as CBI or trade secret, EPA is enabling a joint submission option within the future reporting tool. Similar to one of the joint submission options in the CDR tool, a PFAS manufacturer whose supplier does not volunteer requested information, including the specific chemical identity of a PFAS imported from the supplier, would have the option to complete the PFAS reporting form to the extent information is known or reasonably ascertainable. The manufacturer would then initiate an email to its supplier via the CDX-based tool and request the supplier provide the necessary information to EPA, using a secondary reporting form, without needing to divulge to the reporting entity the specific chemical identity of the PFAS or the composition of the product. The tool will create an electronic record of the U.S.-based importer's attempts to contact the supplier and request information. Further, if the immediate supplier does not know the information, they may continue to send an email via the reporting tool to their own suppliers, in an effort to secure the requested information.

G. What are the concerns regarding potential duplicative reporting?

1. Summary of public input.

EPA received comments on potential duplicative reporting under the proposed rule and NODA public comment periods. The majority of commenters shared the sentiment that the proposed reporting requirements would result in duplicative reporting that is contrary to TSCA section 8(a)(5)(A), which requires EPA to avoid, to the extent feasible, reporting which is unnecessary or duplicative. Most of these commenters shared the opinion that some information required to be reported under the proposed rule is extremely similar to, if not the same as,

information required under the CDR rule. One commenter, however, shared a contrasting opinion that EPA should not exclude information previously reported under CDR requirements on the grounds that omitting that information would compromise EPA's ability to collect and aggregate PFAS data pursuant to TSCA section 8(a)(7).

The commenters who stated that the requirements in the proposed rule consist of duplicative reporting primarily cited reporting requirements under the CDR rule as justification for their position. Multiple commenters also cited studies submitted as unpublished health and safety studies under TSCA section 8(d) and the substantial risk notification requirements under TSCA section 8(e). One commenter claimed that EPA is likely already in possession of a considerable amount of PFAS information from studies submitted to EPA under new chemicals reporting (i.e., PMN and LVE applications) and TSCA section 8(e) reporting. A few commenters also suggested that companies should not be required to collect and repeat data for past non-principal reporting years. Other commenters specified that EPA should limit reporting of information concerning environmental or health effects by excluding information that is publicly available, such as information published in scientific journals, as requiring reporting of this information would be unnecessary and duplicative.

Multiple commenters claimed that including articles in the required reporting would substantially increase duplicative reporting due to the number of entities an article may pass through, who would then all be required to report information on that chemical. Two commenters raised the issue of articles which are exported from and then reimported into the U.S. and asserted that the reporting of reimported articles would be considered duplicative reporting. To remedy this situation, a commenter suggested that EPA require reporting at the level of manufacturing the PFAS itself, and possibly the first supplier that incorporates a PFAS, but no further.

2. EPA's response.

EPA acknowledges that some of the data elements may overlap with the data required under the 2020 CDR cycle but disagrees that the scope of such overlap is significant. There are several differences between the CDR rule and this rule which limit the scope of any potential overlaps between the datasets. First, CDR includes several reporting exemptions and a reporting threshold based on production volume, which are not included in this rule: imported articles, certain byproducts, non-isolated intermediates, small quantities of R&D chemicals, small manufacturers, and a minimum production volume reporting threshold of 25,000 lbs/year (or 2,500 lbs/year for substances subject to certain TSCA actions). Therefore, PFAS reporters with activities that are exempt in CDR or who manufacture PFAS below the CDR threshold will not have reported such information to CDR before and would not be considered “duplicative” here. Further, CDR reporters may have excluded quantities that would be reportable under this rule, based on certain CDR exemptions, and therefore the information they previously submitted to CDR would not be considered duplicative and would not be responsive to this rule. Secondly, the PFAS that have been reported to CDR are a subset of the scope of PFAS for this rule. The scope of CDR chemical substances is limited to those on the Inventory and excludes polymers. The scope of this reporting rule includes any chemical substance meeting the rule’s structural definition, which is not limited to those on the Inventory (e.g., LVEs), and includes any fluoropolymers that meet the structural definition. Finally, the years for which certain required data elements may have been reported to CDR differ. Some of the information described earlier in this unit is reported differently for the principal reporting year compared to the other three years within the four-year CDR period. For instance, the production volumes for domestic manufacture and import are combined for any non-principal reporting year. Further, prior CDR cycles had different required information. Therefore, the extent of potentially “duplicative” reporting between CDR and this rule is limited, especially when considering each year for which reporting is required under this rule.

EPA is finalizing the proposal to not require resubmission of information that has been reported to CDR, unless that information did not reflect all activities or quantities for which reporting is required under this rule. EPA disagrees with the commenter who suggested that EPA should not exclude information previously reported under CDR. Such information could be duplicative and therefore EPA is limiting that reporting under TSCA section 8(a)(5)(A).

EPA also appreciates the commenters' input regarding information previously submitted via TSCA section 8(e) reporting. EPA agrees that substantial risk notification requirements submitted to EPA under TSCA section 8(e) could be considered "information concerning the environmental or health effects" of a PFAS. To that end, EPA is finalizing the rule to acknowledge that manufacturers who have previously submitted substantial risk notifications, other unpublished health and safety studies under TSCA section 8(d), or other relevant information concerning environmental or health effects need not resubmit the information. However, to enable EPA to easily collect those prior submissions, 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. EPA also reiterates that manufacturers need not submit health and environmental effects information that is not in their possession or control, but could be found from a publicly available source.

Finally, regarding the comments related to whether reporting certain imported articles in complex products may lead to duplicative reporting: EPA disagrees that the information reported will result in duplicative information, especially given the reporting standard applicable to this rule. EPA believes that information known to or reasonably ascertainable by an article manufacturer at the first instance the PFAS is imported into the United States is likely different than the scope of information known to an article importer farther down the supply chain who may re-import that PFAS later, as the article is incorporated into more complex articles or

products. EPA also believes that applying the reporting requirements each time a PFAS is imported into the United States is consistent with TSCA's definition of manufacturing and directive under TSCA section 8(a)(7). If a PFAS is imported, exported, then re-imported, then limiting the scope of reporting to just one instance of importation into the United States may result in certain burdens on manufacturers within the supply chain who need to further communicate with each other to determine whether a PFAS within an article has already been reported and who is responsible for reporting.

H. What are the concerns regarding the lookback period?

1. Summary of public input.

Several commenters stated that attempting to obtain or develop the required information over a ten-year lookback period is not feasible and would constitute a significant burden to reporters, and they felt that EPA should eliminate or shorten the lookback period. These commenters suggested either setting the lookback period to either 3 years, or 5 years to be consistent with the CDR recordkeeping requirement. Commenters stated that it would be difficult or impossible to collect the information required due to the complexities of their supply chains, the turnover rate of foreign suppliers especially for fad markets, the lack of historical reporting requirements for PFAS in products, and the concurrent supply chain disruptions rendered by the COVID-19 pandemic. Commenters also suggested that creating or recreating data from the lookback period will result in imprecise data. In addition to the suggestions to reduce the lookback period, some commenters suggested that EPA consider implementing a "principal reporting year" approach as used in CDR, in which only production volumes are reported for each year, while the more detailed data elements are reported for only the principal reporting year. Other suggestions included exempting articles or exempting companies that have since phased out PFAS by the reporting deadline.

2. EPA's response.

EPA disagrees with the commenters who have suggested altering the lookback period from 2011 to a more recent year. The language in TSCA section 8(a)(7) directs EPA to promulgate a reporting rule for “each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011, to submit to the Administrator a report that includes, *for each year since January 1, 2011*, the information described in subparagraphs (A) through (G) of paragraph (2).” Congress’s direction to EPA is clear: the lookback period for this reporting rule must begin on January 1, 2011. EPA understands the extent of information known to or reasonably ascertainable by a manufacturer may vary for several reasons. However, EPA’s obligation under TSCA section 8(a)(7) and interest in identifying the scope of available and existing data on historically manufactured PFAS demand that PFAS manufacturers conduct their due diligence and submit requested information to the extent it is known or reasonably ascertainable.

I. What is the submission period duration and reporting deadline?

1. Summary of public input.

EPA received significant input on the duration of the proposed submission period. Many commenters and input during the SBAR Panel claimed that the proposed rule’s reporting deadline is unrealistic, and EPA should allow more time for reporting to accomplish the required data collection. Commenters provided a range of alternatives to consider for the reporting deadline, from 1.5 years from rule promulgation to 5 years from rule promulgation for article importers.

Several commenters provided detailed descriptions of the types of activities that would need to occur during the submission period as evidence of why they felt the proposed submission period to be inadequate. Some commenters raised EPA’s experiences with the PIP (3:1) rule as justification for a longer time frame for extensive PFAS data reporting (Ref. 27). Other reasons provided by commenters regarding why additional time is needed include: time to familiarize

themselves with the rule; unclear scope of requirements in the proposed rule; lack of systems in place with which to track the data leading to manual collection; and lack of ability to outsource the task to contractors due to the confidentiality concerns. In addition, one commenter noted that other jurisdictions have delayed the implementation of new rules in light of overwhelming burden, COVID, and supply chain disruptions.

EPA also received some comments urging the Agency to finalize this aspect of the proposed rule and not delay the deadline by which PFAS data are submitted. Commenters cited the pressing need for such data and the awareness within the regulated community of this rule.

2. EPA's response.

EPA appreciates the significant feedback the Agency received from the public, including through the SBAR Panel, on the duration of the reporting submission period. After considering input from the commenters and other stakeholders, EPA agrees that the proposed reporting time frame may not be sufficient for identifying, collecting, and reporting the scope of information requested by this rule. While EPA disagrees that the extent of activities necessarily requires investigations of the supply chain that would take up to five years to complete, it is modifying the proposal by adding six more months to the information collection period ahead of the reporting tool opening (for a total of one year from the effective date of this rule). This one-year information collection period will then be followed by a six-month reporting submission period. Thus, information will be due 18 months following the effective date of this rule for all PFAS manufacturers except certain small article importers. EPA has provided an additional six months for small manufacturers (as defined at 40 CFR 704.3) who would report exclusively article importers for the purposes of this rule. Therefore, small article importers have two years from the effective date of this final rule to report. Thus, information will be due 24 months following the effective date of this rule for small manufacturers (per 40 CFR 704.3) who are reporting exclusively as article importers. EPA believes this timeframe will be sufficient to allow reporters

to familiarize themselves with the rule, identify PFAS they have produced or imported, identify any suppliers or other contacts, collect information, and submit the information to EPA. The additional time will enable reporters to thoroughly review their known or reasonably ascertainable information and provide EPA with the extent of the requested information under this reporting standard.

Additionally, as this is a TSCA section 8(a) reporting rule, EPA disagrees with commenters who request additional reporting time by comparing this rule to the PIP (3:1) rule or other non-section 8 reporting rules (Ref. 27). The reporting standard under TSCA section 8(a) does not apply to those rules, which may require additional compliance activities. However, EPA agrees with commenters who pointed out the distinctions between this rule and CDR as a basis for extending the reporting period: the CDR rule requires only a four-year lookback period, includes certain exemptions and reporting thresholds, different data elements, and is regularly occurring so that companies can anticipate reporting. Due, in part, to these differences with CDR, EPA is extending the information collection period ahead of the submission period, thereby providing reporters with 18 months to submit information for this rule (or 24 months for small article importers).

EPA disagrees with commenters who have suggested the reporting deadline should be sooner than what was proposed. EPA appreciates the commenters' interest in reviewing the submitted PFAS data as soon as possible, but notes the scope of this rule and differences between this rule and CDR as factors in allowing the reporting community extra time to sufficiently review their known or reasonably ascertainable information and to submit the required data to EPA.

J. Can joint submissions be allowed?

1. Summary of public input.

Some commenters requested that EPA allow joint submissions. They suggested it might

ease the reporting burden and simplify the reporting process while still protecting CBI. However, other commenters stated that joint submissions can still be a substantial burden for companies already trying to complete their own reporting within a prescribed timeframe. Commenters urged EPA to carefully consider a workable solution to protecting CBI and reducing industry burden for compliance. In response to the NODA, one commenter asked EPA to eliminate the requirement for joint submissions in response to chemical identity CBI concerns.

2. EPA's response.

EPA agrees with the commenters' requests for joint submissions and is finalizing this requirement for reporters (other than article importers) whose suppliers do not wish to disclose chemical identity. EPA agrees that such an approach would help protect suppliers' CBI while not withholding necessary information from EPA related to PFAS identity. While this may increase burden on upstream companies, EPA believes this approach will both help downstream manufacturing and reporting entities, as well as protect CBI if the suppliers do not wish to disclose it to their customers, including reporting entities.

K. What are the economic analysis considerations?

1. Summary of public input.

Many commenters addressed the impact of the proposed rule in general: on industry, EPA, and the general public. Several commenters provided input on the industry burden estimates provided in EPA's draft Economic Analysis for the proposed rule, with many stating that EPA underestimated the cost industry would incur to comply with the proposed rule and failed to include article importer costs. Commenters provided specific feedback on EPA's burden and cost estimates for certain activities including rule familiarization, CBI substantiation, article identification, determination of chemical identity, identification of byproducts, outreach to suppliers, data collection, CDX access and training, form completion and recordkeeping. Some of these commenters provided additional data or factors to consider when estimating burden or

costs for these compliance activities, including providing results of their own industry surveys. Commenters also provided specific feedback on the proposed rule's burden on article importers and stated that EPA's draft burden assessment is significantly underestimated. Some commenters stated that article importers may face substantially more costs than domestic producers because they lack the knowledge needed for compliance yet would still incur costs under the reporting standard. Additionally, because article importers do not have experience with CDR, commenters believed their cost would be higher than EPA's draft estimates which used CDR to extrapolate burden estimates for this rule.

Some commenters also claimed that EPA's use of CDR burden to derive burden estimates under this rule was inappropriate due to the differences between the two rules. Commenters also provided feedback on the estimated number of substances subject to reporting in the draft Economic Analysis and claimed that the draft estimates were too low. Some commenters pointed out that, because the proposed rule does not have the same exemptions as CDR nor is limited to a discrete list of substances, the number of substances subject to reporting would be substantially higher than the estimates provided in the draft Economic Analysis.

EPA also received comments that the proposed rule significantly underestimated the universe of small entities that would be subject to the rule, both due to the lack of estimates related to article importers and to the extrapolation from CDR data. Some commenters described the unique difficulties or burdens small businesses face when complying with the proposed rule compared to larger businesses. Commenters stated that EPA cannot justify an RFA certification without further analysis of the small business impacts and requested that EPA convene an SBAR Panel under the RFA to obtain feedback from small businesses potentially affected by the rule.

Some commenters also stated that EPA's draft Economic Analysis underestimated burden on the Agency itself. Namely, the need to increase CDX capacity to handle the number of reporting forms and other administrative costs of reviewing the submitted data are not reflected

in the draft Economic Analysis.

Finally, other commenters claimed that EPA had not accounted for the social and health costs associated with PFAS exposure in the burden analysis. Commenters added that the public and various government entities have incurred significant health, social, and financial costs due to inadequate information related to PFAS, and that even an underestimation of industry compliance costs for this rule are minimal compared to the externalized costs that the public and governments bear related to PFAS exposure and remediation.

2. EPA's response.

EPA appreciates the feedback on the draft Economic Analysis and agrees with commenters that an SBAR Panel was appropriate given the limitations of data related to the small entity universe at the time of the proposed rule's publication. Accordingly, EPA convened an SBAR Panel for this rule in April 2022 and completed it in August 2022. Using feedback from commenters, input during the SBAR Panel, and additional data made available to EPA since the proposed rule's publication, EPA has since accounted for the burden that the rule would impose on article importers and small entities. The burden estimates include the number of article importers who will be required to report as well as the number of entities that will have to assess their product lines to determine whether they must submit reports. EPA disagrees that the article importer compliance determination activities are too low. EPA recognizes that a range of activities may be involved depending on the level of experience of the importer. Actual costs may vary based on the number of articles imported, the complexity of the articles, the number of suppliers, and the frequency of supplier changes. EPA has increased the rule familiarization costs as well as included the burden of understanding the structural definition of PFAS. Readers are referred to EPA's updated Economic Analysis for details regarding the assumptions of calculating burden and costs for article importers and small entities.

With regards to the use of CDR data, EPA acknowledges that CDR data are subject to

reporting thresholds and that the CDR universe does not reflect a perfect representation of the likely reporting universe of this rule. EPA recognizes the limitations of using CDR data in estimating the burden, including the number of PFAS for which companies may ultimately report. However, there is no comprehensive database of PFAS manufactured in the U.S. that EPA could use to develop more precise estimates. The reporting requirements of this rule will serve to fill this knowledge gap. After considering input from the proposed rule's public comments, stakeholders in the SBAR Panel, and comments received on the IRFA, EPA is continuing to rely on the CDR data to extrapolate the estimated number of PFAS to be reported per firm. EPA acknowledges that the number may vary for some manufacturers but believes that using CDR for such estimates will help provide an industry average.

EPA has updated the Agency costs to account for the volume of reports that will be submitted. EPA will incur costs in administering the final rule associated with processing submitted reports, analyzing data from the reports, maintaining the information technology systems that support these activities, reviewing CBI claim substantiations, and information technology infrastructure.

Finally, with regard to the comments that EPA has not accounted for social and health costs associated with PFAS, EPA points out that this rule is a TSCA section 8(a) reporting and recordkeeping rule and does not impose any restrictions or other chemical management requirements. While the benefits of this rule include additional information related to potential PFAS exposure, which will help inform future regulatory and research activities, EPA cannot quantify those benefits at this time, though the Agency discusses them qualitatively in the Economic Analysis.

L. What are the CBI claim submission requirements?

1. Summary of public input.

Several commenters submitted comments regarding reporting requirements in the

proposed rule and EPA's intended approach to reviewing CBI claims as stated in the NODA.

Their comments generally fell into two categories: 1) Urging EPA to protect CBI and simplify electronic reporting to allow joint submissions when needed, in addition to making substantiation procedures for CBI claims more simplified, and not allowing reporters without knowledge of a specific chemical identity to waive a CBI claim for that chemical identity; and 2) Urging EPA to require valid and well-explained rationale for any CBI exemptions, and generally asking EPA to disclose as much information to the public as possible. Some commenters also cited concerns with the proposed rule's CBI protections as being inadequate for R&D activities, including those in the defense or national security industries. Some commenters requested that the Agency allow a "blanket substantiation" for all CBI claims so that reporters would not be required to substantiate each individual CBI claim.

On the other hand, commenters who are supportive of limiting the amount of information claimed as CBI (especially regarding health and safety studies) cited the urgent need for states to address their own PFAS exposure and contamination issues and the benefit that this rule will confer on state agencies struggling with inadequate PFAS information. These commenters encouraged EPA to review claims and disclose as much information submitted under this rule as possible.

Commenters during the NODA comment period also addressed EPA's proposal to require that any PFAS generic name include "fluor," at minimum, and EPA's proposal to determine that failure to stipulate that a chemical for which the identity is being claimed as CBI is fluorinated would be an insufficient claim. Some commenters were supportive of such requirements; other commenters discouraged EPA from implementing this requirement as it may create confusion. Finally, commenters diverged on EPA's intent to move any PFAS identity to the public TSCA Inventory without prior notice if it is not claimed as CBI. While some commenters supported this approach, others described potential complications of confidential

chemical identity protection when multiple entities submit reports for the same substance, some of whom may not assert CBI for the identity, and requested that EPA notify all claimants of a potential change in CBI status for a chemical identity and allow appeal opportunities.

2. EPA's response.

EPA does not believe that an option for blanket CBI claims substantiation is appropriate for an information collection rule such as this one, in which several types of information are requested. TSCA section 14(c) requires substantiation specific to each claim. Because the type of information requested under this rule varies, a blanket substantiation is unlikely to address the specific reasons for each data element claimed as CBI. The more generic a substantiation gets, the less support it provides for any specific claim. In terms of information disclosure, EPA is committed to reviewing CBI claims and substantiations pursuant to TSCA section 14 and implementing regulations, and publicly disclosing data that are not approved as CBI to the extent possible.

As noted in the preamble of the proposed rule, TSCA limits confidentiality protections for health and safety studies, and information from health and safety studies (except to the extent such studies or information reveals “information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture”). Submitters asserting a confidentiality claim for such information in health and safety studies are also required to submit a sanitized copy of the study, removing only that information which is claimed as CBI and that discloses the process or portion of mixture information described in TSCA section 14(b). However, certain other information within study reports may be claimed as CBI, such as the names of lab personnel or the company, or other information that is not related to health or environmental effects.

In response to requests for EPA to work directly with states on disclosing CBI submitted

under this rule, EPA points out that TSCA section 14(d)(4) permits states, tribes, and political sub-divisions of states to request access to CBI in writing. Under this authority, the entity seeking CBI access must show that it can continue to protect the information as confidential. If a state or tribe requests access and that is granted per statutory conditions, EPA would have an agreement in place laying out how the requestor was going to protect the information.

In response to comments on the CBI procedures described in the NODA, EPA is not requiring article importers to assert CBI for the chemical identity and will not make public any chemical identity based on article importer submissions alone (see discussion in Unit III.G). Further, EPA acknowledges some commenters' concerns that multiple manufacturers may report the same PFAS, but not all submitters may assert a CBI claim for the PFAS identity. EPA will publish a list of Accession numbers associated with chemical identities that it plans to move to the public portion of the Inventory because either no chemical identity CBI claim was asserted or the claim was denied. Publication of these Accession numbers will provide entities an opportunity to contact EPA with questions or concerns before specific chemical identities are moved to the public Inventory (see Unit III.G for more details on this process). Finally, EPA believes that requiring "fluor" in generic name submissions is consistent with PMN reporting requirements which provide that a generic name "should reveal the chemical identity of the substance to the maximum extent possible" (40 CFR 720.85(a)(3)(i)(B)), and is finalizing this requirement as discussed in the NODA (Ref. 1).

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER**

INFORMATION CONTACT.

1. EPA. (2022). TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment (87 FR 72439, November 25, 2022 (FRL-7902-04-OCSPP)).

2. EPA (2023). Economic Analysis for the Final TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances. September 2023.

3. EPA (2023). Research on Per- and Polyfluoroalkyl Substances (PFAS). Available at <https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas>.

4. ATSDR (2021). Toxicological Profile for Perfluoroalkyls. Available at <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>. [Accessed February 10, 2023].

5. EPA (2021). PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024. October 2021. Available at https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

6. EPA. CompTox Chemicals Dashboard. Available at <https://comptox.epa.gov/dashboard/>.

7. EPA. (2020) Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule. (85 FR 45109, June 27, 2020 (FRL-10010-44)).

8. OECD (2021). Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. July 9, 2021. Series on Risk Management. No.61. Environment Directorate Chemicals and Biotechnology Committee. Available at [https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO\(2021\)25&docLanguage=En](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=En).

9. Buck, Robert C., et al. (2021). Identification and Classification of Commercially Relevant Per- and Poly-Fluoroalkyl Substances (PFAS). May 14, 2021. Integrated

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10. Gaines, Linda, et al. (2023). A Proposed Approach to Defining Per- and Polyfluoroalkyl Substances (PFAS) Based on Molecular Structure and Formula. Integrated Environmental Assessment and Management. Accepted Author Manuscript. *<https://doi.org/10.1002/ieam.4735>*.

11. UNEP (2022). Updated indicative list of substances covered by the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. March 4, 2022. Stockholm Convention on Persistent Organic Pollutants. Available at *<https://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-POPRC.17-INF-14-Rev.1.English.PDF>*.

12. EPA (2020). Advancing Sustainable Materials Management: 2018 Facts and Figures Report. December 2020. *https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf*.

13. EPA (2023). International Agreements on Transboundary Shipments of Hazardous Waste. *<https://www.epa.gov/hwgenerators/international-agreements-transboundary-shipments-hazardous-waste>*.

14. EPA (2023). Small Entity Compliance Guidance for the TSCA PFAS Data Call. September 2023.

15. EPA (2023). Data Elements included in the TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, Final Rule. September 2023.

16. OECD. OECD Harmonised Templates. Available at *<https://www.oecd.org/ehs/templates/harmonised-templates.htm>*.

17. EPA (2023). Addition of Certain PFAS to the TRI by the National Defense Authorization Act. Available at *<https://www.epa.gov/toxics-release-inventory-tri-program/>*

addition-certain-pfas-tri-national-defense-authorization-act.

18. EPA (2023). Greenhouse Gas Reporting Program (GHGRP). Available at <https://www.epa.gov/ghgreporting>.
19. EPA (2018). Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under Toxic Substances Control Act. EPA 743B18001. June 2018.
20. EPA (2010) Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to exclude Certain Perfluorinated Polymers. (75 FR 4295, January 27, 2010 (FRL-8805-5)).
21. EPA (2023). Response to Public Comments: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances. September 2023.
22. EPA (2022). TSCA Section 8(a)(7) Small Business Advocacy Review (SBAR) Panel Report. August 2022.
23. EPA (2022). Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances. November 2022.
24. EPA (2021). EPA Response to Petition on Testing for Certain PFAS. December 2021. Available at <https://www.epa.gov/system/files/documents/2021-12/pfaspetitionresponse.pdf>.
25. Frank, Harmut, et al. (2002). Trifluoroacetate in ocean waters. 2002. Environmental Science & Technology, 36(1), 12–15. Available at <https://doi.org/10.1021/es0101532>.
26. EPA. (2018). Fees for the Administration of the Toxic Substances Control Act (TSCA) (83 FR 52694, October 17, 2018 (FRL-9984-41)).
27. EPA. (2022). Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Phenol, Isopropylated Phosphate (3:1); Further Compliance Date Extension.

(87 FR 12875, March 8, 2022 (FRL-6015.6-02-OCSP)).

28. EPA (2023). Information Collection Request Supporting Statement entitled “Final Rule ICR: Reporting and Recordkeeping Requirements for PFAS (RIN 2070-AK67).” EPA ICR No. 2682.02. September 2023.

29. EPA (2023). Final Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances. September 2023.

30. EPA. Unfunded Mandates Reform Act Statement. PFAS; Reporting and Recordkeeping Requirements under the Toxic Substances Control Act (TSCA); Final. May 2023.

VI. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Orders 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review

This action is a “significant regulatory action” as defined under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, entitled “Economic Analysis for the Final TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances” (Ref. 1), is also available in the docket and is briefly summarized in Unit 1.E.

B. Paperwork Reduction Act (PRA)

The information collection requirements in this rule will be submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared has been assigned the EPA ICR No. 2682.02 (Ref. 28) and the OMB Control number. 2070-0217. You can find a copy of the ICR in the docket for this action, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The reporting requirements identified in the rule will enable EPA to meet the statutory obligations required by TSCA section 8(a)(7) and collect data related to the identities, manufacture, use, exposure, and disposal of PFAS manufactured in the United States since 2011. These one-time reporting requirements will also help the Agency to collect existing information on the health and environmental effects of PFAS. EPA intends to use information collected under the rule to assist in chemical assessments under TSCA, and to inform any additional work necessary under environmental protection mandates beyond TSCA. Respondents may claim some of the information reported to EPA under the rule as CBI under TSCA section 14. TSCA section 14(c) requires a supporting statement and certification for confidentiality claims asserted after June 22, 2016.

Respondents/affected entities: PFAS manufacturers (including importers). See Unit I.A.

Respondent obligation to respond: Mandatory. TSCA section 8(a) and 40 CFR 705.

Total estimated number of respondents: 131,410.

Frequency of response: One time.

Total estimated burden: 3,878,744 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$281 million (per year) and \$266.7 million (per year) using a 3 percent and 7 percent discount rate, respectively, which includes no annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the *Federal Register* and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to the RFA, 5 U.S.C. 601 *et seq.*, EPA prepared an IRFA for the proposed rule and convened an SBAR Panel under RFA sections 603 and 609(b) to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. Summaries of the IRFA and Panel recommendations are presented in the proposed rule's NODA (Ref. 1).

As required by RFA section 604, EPA prepared a final regulatory flexibility analysis (FRFA) for this action. The FRFA addresses the issues raised by public comments on the IRFA for the proposed rule. The complete FRFA is available for review in the docket (Ref. 29) and is summarized here.

- *Statement of need and rule objectives.* Section 7351 of the FY2020 NDAA amended TSCA by adding section 8(a)(7), which obligates EPA to promulgate a rule by January 1, 2023, that requires each person who has manufactured PFAS in any year since 2011 to report and maintain records, for each year, information described in TSCA section 8(a)(2)(A)-(G). This includes a broad range of information, such as information related to chemical identity and structure, production, use, exposure, disposal, and health and environmental effects. In addition, EPA believes that the collected data may help provide more information about PFAS manufacture, and to the extent that new information indicates the presence of negative externalities or data gaps, inform future agency actions and/or legislation governing the

manufacture, processing, use, and disposal of PFAS.

EPA developed this final rule after considering findings from information provided in public comments on the proposed rule, findings from and comments on the SBAR Panel, and public comments on the IRFA. The final rule requires all manufacturers of PFAS in any year since 2011 to report certain information to EPA related to chemical identity, categories of use, volume manufactured, byproducts, environmental and health effects, worker exposure, and disposal (i.e., the TSCA section 8(a)(2)(A)-(G) requirements). This rule also requires a five-year retention period for all relevant records following the submission period.

- *Significant comments on the IRFA.* In response to the IRFA and notice of data availability, EPA received 44 unique comments in the docket. EPA has provided a comprehensive summary of all comments received and EPA's responses in a supporting document that is included in the docket for this rulemaking (Ref. 21; see Part 2).

- *SBA Office of Advocacy comments and EPA response.* EPA received comments from SBA's Office of Advocacy on the proposed rule and the IRFA. SBA's comments and EPA's responses are in the Responses to Comments document for this rule (Ref. 21) and in the FRFA (Ref. 29). SBA comments that led to changes to the proposed rule, and EPA's responses to those comments, are also summarized in this unit.

Comments: EPA has improperly certified the rule under the RFA. EPA should convene a SBREFA Panel and consider burden-reducing compliance flexibilities for small businesses. Additionally, EPA underestimated the impact of compliance costs associated with the proposed reporting requirements.

Response: EPA initially certified the proposed rule under the RFA based on all information available to it at the time of proposal. However, after receiving additional information related to the scope of small entities (including article importers) potentially impacted by the proposed rule, EPA updated its estimated scope of the universe of small entities

potentially affected (including article importers) and the small entity compliance costs. Thus, EPA convened an SBAR Panel in April 2022. The Panel concluded in August 2022, and EPA subsequently published the Panel Report, updated Economic Analysis, and IRFA for public comment in November 2022. Input received through the Panel and during the subsequent comment period for the IRFA were considered in the development of this final rule, including comments related to EPA's small entity analysis. As a result of public input, EPA identified certain regulatory alternatives to the proposed rule, which EPA is implementing in the final rule: streamlined reporting forms for article importers and for manufacturers of low quantities of R&D substances; extending the reporting deadline; providing additional guidance on the TSCA section 8(a) reporting standard for article importers. These modifications to the proposed rule reduce compliance costs without a complete exemption of small entities. EPA has not made a determination that a complete exemption of small entities is not legally viable in this rulemaking. EPA believes such an exemption would result in diminished collection of reasonably known or ascertainable information about PFAS manufacturing and import since 2011 and therefore is exercising its discretion to not implement this alternative. EPA estimates that each manufacturer would incur \$2,240 in costs to complete the streamlined R&D form and \$41,850 in costs to complete the general reporting form. Thus, incurring a total of \$44,089 in costs per firm for form completion, compared to \$52,739 without the streamlined form. For the streamlined form for article importers, EPA estimates that each article importer will incur an average of approximately 91.7 burden hours and \$7,531 in costs per firm. Without a streamlined reporting form, EPA estimates that each article importer would incur an average of approximately 168 burden hours and \$13,818 in costs for form completion. Additionally, extending the reporting deadline may reduce the opportunity costs if firms are diverting resources from other business activities to report information under the rule. This may be particularly true for small entities. See Table 24 for more information on the costs associated with the finalized option and alternatives identified

in the IRFA.

- *Estimate of the number of small entities to which the final rule applies.* This final rule will impact PFAS manufacturers, including article importers, across a broad number of industries, including the following: utilities; construction; manufacturing; wholesale and retail trade; and some waste management. Entities who solely process, distribute, and/or use PFAS, and do not manufacture (including import) PFAS, are not covered. EPA estimates that approximately 97% of all firms potentially affected by this rule would meet the SBA standard of “small business,” for a total of 128,051 affected small entities. It is expected that all 128,051 firms will undertake structural definition familiarization, some rule familiarization activity, and compliance determination, including article importers that do not report under this rule. However, EPA does not assume that all potentially affected firms will ultimately have known or reasonably ascertainable information to report, so 13,021 small entities are estimated to report under this rule.

- *Reporting, recordkeeping, and other compliance requirements of the final rule.*

- i. *Compliance requirements.* Pursuant to TSCA section 8(a)(7), EPA is finalizing this reporting and recordkeeping rule for entities who have manufactured a PFAS in any year since January 1, 2011. For each year since January 1, 2011, PFAS manufacturers (including importers) are required to report the following types of information for each PFAS to the extent it is known or reasonably ascertainable: chemical identity, production volume, categories of use, byproducts, worker exposure, disposal practices, and existing information concerning environmental or health effects. In instances where reporters have already submitted the requested information to EPA under certain reporting programs, they will not be required to re-report. The reporters will simply indicate they have already submitted such information to EPA. The reporting deadline is 18 months following the effective date of this rule, except for small manufacturers (defined at 40 CFR 704.3) whose reporting obligations exclusively arise from article imports; the latter’s

reporting deadline is 24 months following the effective date of this rule. The reporting deadline is then followed by a five-year recordkeeping period.

ii. Classes of small entities subject to the compliance requirements. The small entities that are potentially affected by this rule are manufacturers (including importers) who have manufactured (including imported) PFAS in any year since January 1, 2011. This includes entities who have imported articles containing PFAS in any year since January 1, 2011.

iii. Professional skills needed to comply. Understanding some of the reporting requirements may involve special skills or expertise, though hiring or contracting such skills specifically for this rule are not required to comply, given the TSCA section 8(a) reporting standard of “known or reasonably ascertainable.” For example, understanding the rule’s structural definition of PFAS and other reporting requirements may involve special expertise of chemistry. EPA assumes that chemical manufacturing and importing firms and large article importers will have staff with the technical knowledge to understand a structural definition more easily than small article importers. Based on input from the Small Entity Representatives, EPA estimated the cost of small article importer firms contracting outside help to understand the chemical structural definition, despite it not being a necessary step for compliance. Small article importers that contract outside help (which is not required for this rule’s compliance) would incur \$1,212 in structural definition compliance costs, while small article importers that do not contract outside help would incur approximately \$831. Additionally, environmental and health effects data may require some technical knowledge to report.

• *Steps taken to reduce economic impact to small entities.*

i. Small Business Advocacy Review Panel. As required by RFA section 609(b), EPA convened an SBAR Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. A copy of the full SBAR Panel Report (Ref. 22) is available in the docket. The comments received on the proposed

rule, the IRFA and EPA's responses to those comments are summarized in Unit IV and in further detail in the Response to Comments document in the docket (Ref. 21).

ii. Alternatives considered. EPA considered a wide variety of alternatives to the proposed rule. EPA considered the impact (both cost and in anticipated reporting) of providing exemptions for all small businesses, or a portion of small businesses (e.g., small article importers, small manufacturers using the TSCA section 8 definition, or entities below various sales thresholds). EPA also evaluated the impact of exemptions for certain substances, including imported articles, byproducts, impurities, non-isolated intermediates, and R&D substances. EPA also evaluated the impact of implementing a production volume-based reporting threshold in this rule. For each of these alternatives, EPA found that it would reduce the amount of PFAS reporting of reasonably known or ascertainable information from PFAS manufacturers (including importers) under TSCA section 8(a)(7). The amount of reporting that certain alternatives would reduce varied, ranging from exempting approximately 91% of all potentially covered firms from reporting under a small manufacturer exemption for any firm with under \$12 million in sales (which would have resulted in a final rule costing small businesses approximately \$48.8 million under a 7 percent discount rate), to exempting 69% of firms (all article importers) under an exemption for just article importers with sales below \$2 million (which would have resulted in a final rule costing small businesses approximately \$229.5 million under a 7 percent discount rate). EPA also considered applying a production volume reporting threshold of both 2,500 lbs per year and 25,000 lbs per year, to align with CDR reporting thresholds. Because the amount of reporting and burden under a reporting threshold was difficult to estimate with existing data, EPA conducted sensitivity analyses for this alternative, based on the estimated number of PFAS article importers who would be able to determine whether they are below the reporting threshold. On the low-end estimate for this alternative (i.e., 5% of affected article importers import PFAS-containing articles above threshold), EPA estimates that total number of PFAS reports submitted

would decrease by 49 percent, and total small business costs would be approximately \$736.6 million under a 7 percent discount rate. On the high-end (i.e., 9.5% of affected article importers import PFAS-containing articles above threshold), EPA estimates the total number of PFAS reports submitted to decrease by 5%, with total small business costs of \$785.2 million under a 7 percent discount rate. Given the reduced reporting expected under alternatives including various exemptions and reporting thresholds, EPA determined that implementing such alternatives contradicted EPA's mandate under section 8(a)(7) to collect information from "each person" who had manufactured a PFAS. Further, while EPA recognizes there is a tradeoff between rule compliance costs and information collection, PFAS exposure presents significant human health and environmental concerns that it is critical for EPA to collect as much existing information on PFAS presence in commerce (including through disposal) as possible.

In addition to alternatives related to reporting exemptions and reporting thresholds, EPA considered limiting the scope of PFAS subject to this rule to a finite list, rather than a structural definition. This alternative simplifies rule familiarization for affected entities and removes the cost and burden of understanding the structural definition of PFAS. Additionally, it reduces compliance determination costs for affected firms. However, this also significantly limits the number of PFAS subject to the rule and excludes many PFAS that cannot be listed due to CBI claims but are active in U.S. commerce. If EPA limited the scope to a discrete list of PFAS on the TSCA Inventory and LVEs that could be specifically named under the final definition, 602 PFAS would be subject to the rule. This alternative would result in an estimated 50% decrease in reporting forms submitted, along with an estimated small business cost of approximately \$626.4 million under a 7 percent discount rate.

However, EPA also considered alternatives to the proposed rule that the Agency is finalizing to reduce burden on small entities. EPA considered providing streamlined reporting form options for both imported articles and R&D substances manufactured in low quantities (i.e.,

no more than 10 kg/year). Based on EPA's knowledge of manufacturers of those substances, and public input from commenters and small entity representatives, EPA believes such manufacturers have less information that is known or reasonably ascertainable to them. Therefore, the streamlined reporting form reduces the burden of reporting on the standard form while still enabling EPA to collect all known or reasonably ascertainable historical PFAS data.

Additionally, EPA considered and is finalizing a longer compliance timeframe for all reporting entities. Providing an additional six months for a data collection period ahead of the reporting period will reduce the opportunity costs on affected firms, particularly small entities, without sacrificing any PFAS manufacturing data. In addition, EPA is granting small manufacturers (as defined at 40 CFR 704.3) who would report exclusively as article importers an additional six months to collect data. Therefore, those small entities would have 24 months from the effective date of this rule to submit information on their imported articles. EPA is finalizing such alternatives to meet the Agency's obligations under TSCA sections 8(a)(5)(A) through (C), as this rule is requesting information that is neither duplicative nor unnecessary and will not exclude manufacturers who are likely to have relevant information, while minimizing costs on small manufacturers to the extent feasible.

- *Small entity compliance guide.* EPA prepared a Small Entity Compliance Guide to help small entities comply with the rule. This guide is available in the docket for this rulemaking and will be available on EPA's website prior to the effective date of this final rule (Ref. 14).

D. Unfunded Mandates Reform Act (UMRA)

This action contains a Federal mandate under UMRA, 2 U.S.C. 1531-1538, that may result in expenditures of \$100 million or more for state, local, and tribal governments, in the aggregate, or for private sector in any one year. Accordingly, the EPA has prepared a written statement (Ref. 30) as required under UMRA section 202 that is include in the docket for this action and is briefly summarized here.

1. *Authorizing legislation.* This rule is issued under the authority of TSCA section 8(a)(7) 15 U.S.C. 2607 (a)(7).

2. *Benefit-cost analysis.* EPA has prepared an Economic Analysis (Ref. 2) and a Final Regulatory Flexibility Analysis (Ref. 29) to evaluate, among other things, the benefits and costs of this rule as well as various regulatory options. The rule is calculated to result in a total one-time cost to the private sector of approximately \$843 million using a 3 percent discount rate and \$800 million using a 7 percent discount rate. When adjusted for inflation, the \$100 million UMRA threshold is equivalent to approximately \$184 million. Thus, the cost of the rule to the private sector in the aggregate exceeds the inflation-adjusted UMRA threshold.

Because this is an information-collecting rule, EPA is not able to quantitatively measure the associated benefits. However, the rule may supply information on PFAS to which Federal agencies (and the public) do not currently have access. By enhancing the data supplied to risk-screening and risk-management programs, EPA expects to more effectively and expeditiously evaluate and manage any potential unreasonable risk posed by PFAS. The more EPA can base its decisions on actual data rather than on assumptions, the better EPA is able to tailor its risk management decisions to the level of actual risk, whether higher or lower than it would be if based on assumptions alone. Ultimately, enhancing the risk evaluation process will have positive consequences for human health and the environment and may enable a more efficient allocation of EPA's and society's resources. Additionally, this rule fulfills EPA's obligations under TSCA section 8(a)(7).

3. *Impacts on state, local, and tribal governments.* This rule does not contain a significant Federal intergovernmental mandate because it neither imposes enforceable duties on State, local, or Tribal governments nor reduces an authorized amount of Federal financial assistance provided to State, local, or Tribal governments. This rule contains no regulatory requirements that might significantly or uniquely affect small governments. The rule would require reporting from certain

persons who manufactured (including imported) PFAS for commercial purposes, including in articles. Governments do not typically engage in these activities, so State, local, and Tribal government entities are not expected to be subject to the rule's requirements. This action is not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. The requirements of this action would primarily affect manufacturers (including importers) of PFAS.

E. Executive Order 13132: Federalism

This action does not have federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999) because it will not have substantial direct effects on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes. It does not have substantial direct effects on tribal government because EPA does not anticipate that PFAS was manufactured (including imported) for commercial purposes by Tribes so this rulemaking is not expected to impose substantial direct compliance costs on Tribal governments.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of Executive Order 13045. This action is not subject to Executive Order 13045,

because it does not concern an environmental health or safety risk. Since this action does not concern human health, EPA's Policy on Children's Health also does not apply.

Although this action does not concern an environmental health or safety risk, this one-time data collection will aid in collecting all existing and reasonably ascertainable information related to the manufacturing (including importing) of PFAS since 2011. This rule will be of use in identifying current data gaps surrounding the knowledge of commercially manufactured PFAS. Understanding the extent of existing data gaps related to manufactured PFAS will also help inform and tailor future EPA actions to address PFAS as needed. This regulatory action establishes one-time reporting requirements for PFAS that will result in information on the quantity of PFAS to which children may be exposed. EPA believes that the information obtained as a result of this one-time data collection could also be used by the public, government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential human health or environmental risks.

H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution in Commerce, or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. Further, we have concluded that this action is not likely to have any adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards. As such, NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that it is not practicable to assess whether the human health or environmental conditions that exist prior to this action result in disproportionate and adverse effects on communities with environmental justice concerns. The purpose of this action is to require reporting activity. EPA was unable to perform an environmental justice analysis because it lacks data on every exposure source.

However, this regulatory action makes changes to the reporting requirements for PFAS that will result in more information being collected and provided to better evaluate exposures and the risks posed by such exposures as explained in Unit II.A., certain PFAS exposure may be a hazard to human health. This action establishes one-time reporting requirements for companies to submit to EPA certain known or reasonably ascertainable information on manufactured PFAS by those entities as discussed in detailed in Unit III.D. The determination of potential risk to human health and/or the environment depends upon many factors, including the toxicity of the chemical, the fate of the chemical in the environment, and the amount and duration of human or other exposure to the chemical. This action does not directly address human health or environmental risks. However, the action will increase the level of information available to assess environmental protection for all affected populations without having any disproportionate and adverse human health or environmental effects on any population, including any community with environmental justice concerns. The information obtained as a result of this action may be used to collect all existing and reasonably ascertainable information related to PFAS-containing articles will be of use in identifying current data gaps surrounding the knowledge of commercially manufactured PFAS, and reporting of PFAS within imported articles will enable EPA to meet its obligations under the FY 2020 NDAA. Understanding the extent of existing data gaps related to manufactured PFAS will also help inform and tailor future EPA actions to address PFAS as needed. EPA also believes that the information obtained as a result of this action potentially could be used by the public (including communities with environmental justice

concerns) with access to data which they may use to seek lower exposures and consequently reductions in chemical risks for themselves and their children. Technical assistance may be provided to communities with environmental justice concerns and efforts will be made to ensure meaningful access for individuals with limited English proficiency and individuals with disabilities. This information can also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Therefore, informational benefits, of the action, including behavioral changes such as consumers avoiding specific products, may have positive impact on the human health and environmental impacts on all communities, including communities with environmental justice concerns.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR part 705

Chemicals, Environmental protection, Hazardous Materials, Recordkeeping, and Reporting Requirements.

Dated: September 28, 2023.

Michal Freedhoff

Assistant Administrator Office of Chemical Safety and Pollution Prevention

Therefore, for the reasons set forth in the preamble, 40 CFR chapter I, subchapter R, is amended by adding a new part 705 to read as follows:

PART 705 – REPORTING AND RECORDKEEPING REQUIREMENTS FOR CERTAIN PER- AND POLYFLUOROALKYL SUBSTANCES

Sec.

- 705.1. Scope, compliance, and enforcement.
- 705.3. Definitions.
- 705.5. Substances for which reports must be submitted.
- 705.10. Persons who must report.
- 705.12. Persons not subject to this part.
- 705.15. What information to report.
- 705.18. Article importer and R&D substance reporting options.
- 705.20. When to report.
- 705.22. Duplicative reporting.
- 705.25. Recordkeeping requirements.
- 705.30. Confidentiality claims.
- 705.35. Electronic reporting.

Authority: 15 U.S.C. 2607(a)(7).

§ 705.1. Scope, compliance, and enforcement.

(a) This part specifies reporting and recordkeeping procedures for manufacturers (including importers) of per- and polyfluoroalkyl substances (hereafter referred to as PFAS) under section 8(a)(7) of the Toxic Substances Control Act (TSCA).

(b) TSCA section 15(3) makes it unlawful for any person to fail or refuse to submit information required under this part. In addition, TSCA section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by this part. TSCA section 16 provides that any person who violates a provision of TSCA section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to TSCA section 17, the Federal Government may seek judicial relief to compel submission of TSCA section 8(a) information and to otherwise restrain any violation of TSCA section 15. TSCA section 11 allows for inspections to assure compliance, and the Administrator may by subpoena require the

attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary.

(c) Each person who reports under this part must maintain records that document information reported under this part and, in accordance with TSCA, permit access to, and the copying of, such records by EPA officials.

§ 705.3. Definitions.

The definitions in this section and the definitions in TSCA section 3 apply to this part. In addition, the definitions in 40 CFR 704.3 also apply to this part, except the definition for “*small quantities solely for research and development.*”

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.

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

Chemical Information Submission System or *CISS* means EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information, or its successors.

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.

Consumer use 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.

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 that 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; dermatotoxicity; 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.

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 chemicals substance or mixture containing a chemical substance, and any test performed under TSCA. The following information is not part of a health and safety study:

(1) The name, address, or other identifying information for the submitting company, including identification of the laboratory that conducted the study in cases where the laboratory is part of or closely affiliated with the submitting company;

(2) Internal product codes (*i.e.*, code names for the test substance used internally by the submitting company or to identify the test substance to the test laboratory);

(3) Names and contact details for testing laboratory personnel and names and other private information for health and safety study participants or persons involved in chemical incidents such as would typically be withheld under 5 USC 552(b)(6) or under other privacy laws; and

(4) Information pertaining to test substance product development, advertising, or marketing plans, or to cost and other financial data.

Highest-level U.S. parent company means the highest-level company of the site's ownership hierarchy as of the start of the submission period during which data are being reported according to the following instructions. The highest-level U.S. parent company is located within

the United States. The following rules govern how to identify the highest-level U.S. parent company:

(1) If the site is entirely owned by a single U.S. company that is not owned by another company, that single company is the U.S. parent company.

(2) If the site is entirely owned by a single U.S. company that is, itself, owned by another U.S.-based company (e.g., it is a division or subsidiary of a higher-level company), the highest-level domestic company in the ownership hierarchy is the U.S. parent company.

(3) If the site is owned by more than one company (e.g., company A owns 40 percent, company B owns 35 percent, and company C owns 25 percent), the company with the largest ownership interest in the site is the U.S. parent company. If a higher-level company in the ownership hierarchy owns more than one ownership company, then determine the entity with the largest ownership by considering the lower-level ownerships in combination (e.g., corporation X owns companies B and C, for a total ownership of 60 percent for the site).

(4) If the site is owned by a 50:50 joint venture or a cooperative, the joint venture or cooperative is its own parent company. If the site is owned by a U.S. joint venture or cooperative, the highest level of the joint venture or cooperative is the U.S. parent company.

(5) If the site is federally owned, the highest-level federal agency or department is the U.S. parent company.

(6) If the site is owned by a non-federal public entity, that entity (such as a municipality, State, or tribe) is the U.S. parent company.

Industrial function 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 means use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed.

Intended for use by children means the chemical substance or mixture is used in or on a product that is specifically intended for use by children aged 14 or younger. A chemical substance or mixture containing a chemical substance is intended for use by children when the submitter answers “yes” to at least one of the following questions for the product into which the submitter's chemical substance or mixture containing a chemical substance is incorporated:

(1) Is the product commonly recognized (*i.e.*, by a reasonable person) as being intended for children aged 14 or younger?

(2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children aged 14 or younger?

(3) Is the advertising, promotion, or marketing of the product aimed at children aged 14 or younger?

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.

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.

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 containing a chemical substance:

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

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

(2) Manufacture for commercial purposes also applies to substances that are produced

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

Per- and polyfluoroalkyl substances or *PFAS* 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:

- (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.

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.

Research and development (R&D) means activities intended solely as scientific experimentation, research, or analysis. R&D focuses on the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance, a mixture containing the substance, or an article. R&D encompasses a wide range of activities which may occur in a laboratory, pilot plant, commercial plant outside the research facility, or at other sites appropriate for R&D. General distribution of chemical substances to consumers does not constitute R&D.

Site-limited means a chemical substance is manufactured and processed only within a site and is not distributed as a chemical substance or as part of a mixture or article containing a chemical substance outside the site. Imported chemical substances are never site-limited.

Worker means someone at a site of manufacture, import, or processing who performs work activities near sources of a chemical substance or mixture or directly handles the chemical substance or mixture during the performance of work activities.

§ 705.5 Substances for which reports must be submitted.

The requirements of this part apply to all chemical substances and mixtures containing a chemical substance (including articles) that are a PFAS, consistent with the definition of PFAS at § 705.3.

§ 705.10 Persons who must report.

Persons who have manufactured for commercial purposes a chemical substance identified in § 705.5 at any period from January 1, 2011, through the end of the last calendar year prior to the effective date of this rule, except as described in § 705.12, is subject to the requirements of this part.

§ 705.12 Activities for which reporting is not required.

Reporting under this part is not required for the import of municipal solid waste streams for the purpose of disposal or destruction of the waste. Additionally, reporting is not required for a federal agency which imports PFAS when it is not for any immediate or eventual commercial advantage.

§ 705.15 What information to report.

For the one-time submission, persons identified in § 705.10 of this part must report to EPA, for each site of each of the chemical substances identified in § 705.5, the following information to the extent known to or reasonably ascertainable by them, except as allowed under § 705.18. In the event that actual data is not known to or reasonably ascertainable by the submitter, then reasonable estimates may be submitted:

(a) *Company and plant site information.* The following currently correct company and plant site information must be reported for each site at which a reportable chemical substance is manufactured (see § 711.3 for the “site” for importers):

(1) The highest-level U.S. parent company name, address, and Dun and Bradstreet D-U-N-S® (D&B) number, if one exists.

(2) The name of a person who will serve as Authorized Official for the submitter company, and who will be able to sign the certification statement as described in paragraph (i) of this section, the Authorized Official’s full mailing address, telephone number, and e-mail address.

(3) The name of a person who will serve as technical contact for the submitter company, and who will be able to answer questions about the information submitted by the company to EPA, the contact person's full mailing address, telephone number, and e-mail address.

(4) The name, full street address, and six-digit North American Industry Classification System (NAICS) code(s) of the site. A submitter under this part must include the appropriate

D&B number for each plant site reported, and the county or parish (or other jurisdictional indicator) in which the plant site is located. A submitter under this part must obtain a D&B number for the site reported if none exists. A submitter under this part must also provide other site identification numbers, including the Facility Registry Service (FRS) identification number, if they exist.

(b) *Chemical-specific information.* The following chemical-specific information must be reported for each chemical substance that is a PFAS manufactured for each year since January 1, 2011, except as allowed under § 705.18. This includes each chemical substance that is a PFAS and incorporated into mixtures:

(1) The common or trade name, the chemical identity, and, except for chemical substances that are Class 1 substances on the TSCA Inventory, the representative molecular structure of each PFAS for which such a report is required.

(i) The specific, currently correct Chemical Abstracts (CA) Index name as used to list the chemical substance on the TSCA Inventory and the correct corresponding CASRN for each reportable PFAS at each site. Submitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory will need to report the chemical substance using a TSCA Accession Number. If a submitter has a low-volume exemption (LVE) case number for the chemical substance, that number may also be used if a CASRN is not known to or reasonably ascertainable by the submitter.

(ii) In addition to reporting the number itself, submitters must specify the type of number they are reporting by selecting from among the codes in Table 1 of this paragraph.

Table 1—Codes to Specify Type of Chemical Identifying Number

Code	Number Type
A	TSCA Accession Number.
C	Chemical Abstracts Service Registry Number (CASRN).
L	Low-volume exemption (LVE) Case Number.

(iii) If the CASRN or specific identifier (i.e., Accession number or LVE number) of the PFAS is not known to or reasonably ascertainable (NKRA) to the submitter (e.g., if the chemical identity is claimed as confidential business information by the submitter's supplier, or if the submitter knows they have a PFAS but are unable to ascertain its specific identifier and/or specific chemical identity), the submitter may provide a generic name or description of the PFAS and also initiate a joint submission if the secondary submitter is known. The submitter may only initiate a joint submission if the CASRN or the specific identifier (i.e., Accession number or LVE number) is not known or reasonably ascertainable, and a secondary submitter (who would provide such information) is known. The manufacturer (including importer) must use the reporting tool described under § 705.35 to ask the supplier or other entity to provide the chemical identity directly to EPA in a joint submission. Such request must include instructions for submitting chemical identity information electronically, using e-CDRweb and CDX (see 40 CFR 711.35), and for clearly referencing the manufacturer's (including importer) submission. Contact information for the supplier or other entity, a trade name or other designation for the chemical substance, and a copy of the request to the supplier or other entity must be included with the manufacturer's (including importer) submission. If, after conducting due diligence and reviewing known or reasonably ascertainable information, a secondary submitter to complete the joint submission is not known, the reporter may indicate that the secondary submitter is NKRA. However, the PFAS manufacturer would be required to provide as much identifying detail as they have regarding the PFAS identity, and would be able to report to EPA without initiating a joint submission even if they do not know the underlying identity of the chemical substance.

(2) The physical form(s) of the PFAS as it is sent off-site from each site. If the PFAS is site-limited, you must report the physical form(s) of the PFAS at the time it is reacted on-site to produce a different chemical substance. For each PFAS at each site, the submitter must report as many physical forms as applicable from among the physical forms listed in this unit:

- (i) Dry powder.
- (ii) Pellets or large crystals.
- (iii) Water- or solvent-wet solid.
- (iv) Other solid.
- (v) Gas or vapor.
- (vi) Liquid.

(c) *Categories of use.* For each year since January 1, 2011, report the following information on categories of use of each chemical substance that is a PFAS manufactured for commercial purposes.

(1) *Industrial processing and use information.* A designation indicating the type of industrial processing or use operation(s) at each site that receives a PFAS from the submitter site directly or indirectly (whether the recipient site(s) are controlled by the submitter site or not). For each PFAS, report the letters which correspond to the appropriate processing or use operation(s) listed in Table 2 of this paragraph. A particular designation may need to be reported more than once, to the extent that a submitter reports more than one sector that applies to a given designation under this paragraph.

Table 2—Codes for Reporting Type of Industrial Processing or Use Operation

Designation	Operation
PC	Processing as a reactant.
PF	Processing—incorporation into formulation, mixture, or reaction product.
PA	Processing—incorporation into article.
PK	Processing—repackaging.
U	Use—non-incorporative activities.

(2) *Corresponding sector code.* A code indicating the sector(s) that best describes the industrial activities associated with each industrial processing or use operation reported under this section. For each chemical substance, report the code that corresponds to the appropriate sector(s) listed in Table 3 of this paragraph. A particular sector code may need to be reported

more than once, to the extent that a submitter reports more than one function code that applies to a given sector code under this paragraph.

Table 3—Codes for Reporting Industrial Sectors

Code	Sector Description
IS1	Agriculture, forestry, fishing, and hunting.
IS2	Oil and gas drilling, extraction, and support activities.
IS3	Mining (except oil and gas) and support activities.
IS4	Utilities.
IS5	Construction.
IS6	Food, beverage, and tobacco product manufacturing.
IS7	Textiles, apparel, and leather manufacturing.
IS8	Wood product manufacturing.
IS9	Paper manufacturing.
IS10	Printing and related support activities.
IS11	Petroleum refineries.
IS12	Asphalt paving, roofing, and coating materials manufacturing.
IS13	Petroleum lubricating oil and grease manufacturing.
IS14	All other petroleum and coal products manufacturing.
IS15	Petrochemical manufacturing.
IS16	Industrial gas manufacturing.
IS17	Synthetic dye and pigment manufacturing.
IS18	Carbon black manufacturing.
IS19	All other basic inorganic chemical manufacturing.
IS20	Cyclic crude and intermediate manufacturing.
IS21	All other basic organic chemical manufacturing.
IS22	Plastics material and resin manufacturing.
IS23	Synthetic rubber manufacturing.
IS24	Organic fiber manufacturing.
IS25	Pesticide, fertilizer, and other agricultural chemical manufacturing.
IS26	Pharmaceutical and medicine manufacturing.
IS27	Paint and coating manufacturing.
IS28	Adhesive manufacturing.
IS29	Soap, cleaning compound, and toilet preparation manufacturing.
IS30	Printing ink manufacturing.
IS31	Explosives manufacturing.
IS32	Custom compounding of purchased resins.
IS33	Photographic film, paper, plate, and chemical manufacturing.
IS34	All other chemical product and preparation manufacturing.
IS35	Plastics product manufacturing.
IS36	Rubber product manufacturing.
IS37	Non-metallic mineral product manufacturing (includes cement, clay, concrete, glass, gypsum, lime, and other non-metallic mineral product manufacturing).
IS38	Primary metal manufacturing.
IS39	Fabricated metal product manufacturing.
IS40	Machinery manufacturing.

IS41	Computer and electronic product manufacturing.
IS42	Electrical equipment, appliance, and component manufacturing.
IS43	Transportation equipment manufacturing.
IS44	Furniture and related product manufacturing.
IS45	Miscellaneous manufacturing.
IS46	Wholesale and retail trade.
IS47	Services.
IS48	Other (requires additional information).

(3) *Corresponding function category.* For each sector reported under paragraph (c)(2) of this section, the applicable code(s) from Table 4 must be selected to designate the function category(ies) that best represents the specific manner in which the PFAS is used.

Table 4—Codes for Reporting Function Categories

Code	Category
F001	Abrasives
F002	Etching agent
F003	Adhesion/cohesion promoter
F004	Binder
F005	Flux agent
F006	Sealant (barrier)
F007	Absorbent
F008	Adsorbent
F009	Dehydrating agent (desiccant)
F010	Drier
F011	Humectant
F012	Soil amendments (fertilizers)
F013	Anti-adhesive/cohesive
F014	Dusting agent
F015	Bleaching agent
F016	Brightener
F017	Anti-scaling agent
F018	Corrosion inhibitor
F019	Dye
F020	Fixing agent (mordant)
F021	Hardener
F022	Filler
F023	Anti-static agent
F024	Softener and conditioner
F025	Swelling agent
F026	Tanning agents not otherwise specified
F027	Waterproofing agent
F028	Wrinkle resisting agent
F029	Flame retardant
F030	Fuel agents

F031	Fuel
F032	Heat transferring agent
F033	Hydraulic fluids
F034	Insulators
F035	Refrigerants
F036	Anti-freeze agent
F037	Intermediate
F038	Monomers
F039	Ion exchange agent
F040	Anti-slip agent
F041	Lubricating agent
F042	Deodorizer
F043	Fragrance
F044	Oxidizing agent
F045	Reducing agent
F046	Photosensitive agent
F047	Photosensitizers
F048	Semiconductor and photovoltaic agent
F049	UV stabilizer
F050	Opacifer
F051	Pigment
F052	Plasticizer
F053	Plating agent
F054	Catalyst
F055	Chain transfer agent
F056	Chemical reaction regulator
F057	Crystal growth modifiers (nucleating agents)
F058	Polymerization promoter
F059	Terminator/Blocker
F060	Processing aids, specific to petroleum production
F061	Antioxidant
F062	Chelating agent
F063	Defoamer
F064	pH regulating agent
F065	Processing aids not otherwise specified
F066	Energy Releasers (explosives, motive propellant)
F067	Foamant
F068	Propellants, non-motive (blowing agents)
F069	Cloud-point depressant
F070	Flocculating agent
F071	Flotation agent
F072	Solids separation (precipitating) agent, not otherwise specified
F073	Cleaning agent
F074	Diluent
F075	Solvent
F076	Surfactant (surface active agent)
F077	Emulsifier

F078	Thickening agent
F079	Viscosity modifiers
F080	Laboratory chemicals
F081	Dispersing agent
F082	Freeze-thaw additive
F083	Surface modifier
F084	Wetting agent (non-aqueous)
F085	Aerating and deaerating agents
F086	Explosion inhibitor
F087	Fire extinguishing agent
F088	Flavoring and nutrient
F089	Anti-redeposition agent
F090	Anti-stain agent
F091	Anti-streaking agent
F092	Conductive agent
F093	Incandescent agent
F094	Magnetic element
F095	Anti-condensation agent
F096	Coalescing agent
F097	Film former
F098	Demulsifier
F099	Stabilizing agent
F100	Alloys
F101	Density modifier
F102	Elasticizer
F103	Flow promoter
F104	Sizing agent
F105	Solubility enhancer
F106	Vapor pressure modifiers
F107	Embalming agent
F108	Heat stabilizer
F109	Preservative
F110	Anti-caking agent
F111	Deflocculant
F112	Dust suppressant
F113	Impregnation agent
F114	Leaching agent
F115	Tracer
F116	X-ray absorber
F999	Other

(4) *Consumer and commercial use information.* Using the applicable codes listed in Table 5 to paragraph (c)(4), submitters must designate the consumer and commercial product category(ies) that best describe the consumer and commercial products in which each PFAS is used (whether the recipient site(s) are controlled by the submitter site or not). If more than 10

codes apply to a PFAS, submitters need only report the 10 codes for PFAS that cumulatively represent the largest percentage of the submitter's production volume for that chemical, measured by weight. If none of the listed consumer and commercial product categories accurately describes the consumer and commercial products in which each PFAS is used, the category “Other” may be used, and must include a description of the use.

Table 5—Codes for Reporting Consumer and Commercial Product Categories

Code	Category
Chemical Substances in Furnishing, Cleaning, Treatment Care Products	
CC101	Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
CC102	Furniture & furnishings including plastic articles (soft); leather articles
CC103	Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles
CC104	Leather conditioner
CC105	Leather tanning, dye, finishing, impregnation and care products
CC106	Textile (fabric) dyes
CC107	Textile finishing and impregnating/surface treatment products
CC108	All-purpose foam spray cleaner
CC109	All-purpose liquid cleaner/polish
CC110	All-purpose liquid spray cleaner
CC111	All-purpose waxes and polishes
CC112	Appliance cleaners
CC113	Drain and toilet cleaners (liquid)
CC114	Powder cleaners (floors)
CC115	Powder cleaners (porcelain)
CC116	Dishwashing detergent (liquid/gel)
CC117	Dishwashing detergent (unit dose/granule)
CC118	Dishwashing detergent liquid (hand-wash)
CC119	Dry cleaning and associated products
CC120	Fabric enhancers
CC121	Laundry detergent (unit-dose/granule)
CC122	Laundry detergent (liquid)
CC123	Stain removers
CC124	Ion exchangers
CC125	Liquid water treatment products
CC126	Solid/Powder water treatment products
CC127	Liquid body soap
CC128	Liquid hand soap
CC129	Solid bar soap
CC130	Air fresheners for motor vehicles
CC131	Continuous action air fresheners
CC132	Instant action air fresheners

CC133	Anti-static spray
CC134	Apparel finishing, and impregnating/surface treatment products
CC135	Insect repellent treatment
CC136	Pre-market waxes, stains, and polishes applied to footwear
CC137	Post-market waxes, and polishes applied to footwear (shoe polish)
CC138	Waterproofing and water-resistant sprays
Chemical Substances in Construction, Paint, Electrical, and Metal Products	
CC201	Fillers and putties
CC202	Hot-melt adhesives
CC203	One-component caulks
CC204	Solder
CC205	Single-component glues and adhesives
CC206	Two-component caulks
CC207	Two-component glues and adhesives
CC208	Adhesive/Caulk removers
CC209	Aerosol spray paints
CC210	Lacquers, stains, varnishes and floor finishes
CC211	Paint strippers/removers
CC212	Powder coatings
CC213	Radiation curable coatings
CC214	Solvent-based paint
CC215	Thinners
CC216	Water-based paint
CC217	Construction and building materials covering large surface areas, including wood articles
CC218	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
CC219	Machinery, mechanical appliances, electrical/electronic articles
CC220	Other machinery, mechanical appliances, electronic/electronic articles
CC221	Construction and building materials covering large surface areas, including metal articles
CC222	Electrical batteries and accumulators
Chemical Substances in Packaging, Paper, Plastic, Toys, Hobby Products	
CC990	Non-TSCA use
CC301	Packaging (excluding food packaging), including paper articles
CC302	Other articles with routine direct contact during normal use, including paper articles
CC303	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)
CC304	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)
CC305	Toys intended for children's use (and child dedicated articles), including fabrics, textiles, and apparel; or plastic articles (hard)
CC306	Adhesives applied at elevated temperatures
CC307	Cement/concrete
CC308	Crafting glue
CC309	Crafting paint (applied to body)
CC310	Crafting paint (applied to craft)

CC311	Fixatives and finishing spray coatings
CC312	Modelling clay
CC313	Correction fluid/tape
CC314	Inks in writing equipment (liquid)
CC315	Inks used for stamps
CC316	Toner/Printer cartridge
CC317	Liquid photographic processing solutions
Chemical Substances in Automotive, Fuel, Agriculture, Outdoor Use Products	
CC401	Exterior car washes and soaps
CC402	Exterior car waxes, polishes, and coatings
CC403	Interior car care
CC404	Touch up auto paint
CC405	Degreasers
CC406	Liquid lubricants and greases
CC407	Paste lubricants and greases
CC408	Spray lubricants and greases
CC409	Anti-freeze liquids
CC410	De-icing liquids
CC411	De-icing solids
CC412	Lock de-icers/releasers
CC413	Cooking and heating fuels
CC414	Fuel additives
CC415	Vehicular or appliance fuels
CC416	Explosive materials
CC417	Agricultural non-pesticidal products
CC418	Lawn and garden care products
Chemical Substances in Products not Described by Other Codes	
CC980	Other (specify)
CC990	Non-TSCA use

(5) *Applicable codes for each commercial and consumer products.* For each consumer and commercial product category reported under paragraph (c)(4) of this section, the applicable code(s) described in Table 4 under paragraph (c)(3) of this section must be selected to designate the function category(ies) that best represents the specific manner in which the PFAS is used.

(6) *Commercial and consumer products.* Submitters must indicate, for each consumer and commercial product category reported under paragraph (c)(4) of this section, whether the use is a consumer or a commercial use, or both.

(7) *Consumer product category.* Submitters must determine, within each consumer and commercial product category reported under paragraph (c)(4) of this section, whether any

amount of each reportable chemical substance manufactured (including imported) by the submitter is present in (for example, a plasticizer chemical substance used to make pacifiers) or on (for example, as a component in the paint on a toy) any consumer products intended for use by children age 14 or younger, regardless of the concentration of the chemical substance remaining in or on the product. Submitters must select from the following options: The chemical substance is used in or on any consumer products intended for use by children; the chemical substance is not used in or on any consumer products intended for use by children; or information as to whether the chemical substance is used in or on any consumer products intended for use by children is not known to or reasonably ascertainable by the submitter.

(8) *Concentrations of PFAS*. For each year where the PFAS is used in consumer or commercial products, the estimated typical maximum concentration, measured by weight, of the chemical substance in each consumer and commercial product category reported under paragraph (c)(4) of this section. For each PFAS in each commercial and consumer product category reported under paragraph (c)(4) of this section, submitters must select from among the ranges of concentrations listed in Table 6 of this paragraph and report the corresponding code (i.e., M1 through M5):

Table 6—Codes for Reporting Maximum Concentration of Chemical Substance

Code	Concentration Range (% weight)
M1	Less than 1% by weight.
M2	At least 1 but less than 30% by weight.
M3	At least 30 but less than 60% by weight.
M4	At least 60 but less than 90% by weight.
M5	At least 90% by weight.

(d) *Manufactured amounts*. For each year since January 1, 2011, the total amounts manufactured of each PFAS, including the amounts manufactured in each calendar year for each category of use as described in paragraph (c) of this section.

(1) *Total volume*. For each year the PFAS was manufactured, the total annual volume (in

pounds) of each PFAS domestically manufactured or imported at each site. The total annual domestically manufactured volume (not including imported volume) and the total annual imported volume must be separately reported. These amounts must be reported to two significant figures of accuracy.

(2) *Site designation.* A designation indicating, for each PFAS at each site, whether the imported PFAS is physically present at the reporting site.

(3) *Volume imported.* The volume directly exported of each PFAS domestically manufactured or imported at each site. These amounts must be reported to two significant figures of accuracy.

(4) *Production volume.* The estimated percentage, rounded off to the closest 10 percent, of total production volume of the reportable chemical substance associated with each combination of industrial processing or use operation, sector, and function category as reported in paragraph (c) of this section. Where a particular combination of industrial processing or use operation, sector, and function category accounts for less than 5 percent of the submitter's site's total production volume of a reportable chemical substance, the percentage must not be rounded off to 0 percent. Instead, in such a case, submitters must report the percentage, rounded off to the closest 1 percent, of the submitter's site's total production volume of the reportable chemical substance associated with the particular combination of industrial processing or use operation, sector, and function category.

(5) *Site production volume.* The estimated percentage, rounded off to the closest 10 percent, of the submitter's site's total production volume of the PFAS associated with each consumer and commercial product category as reported in paragraph (c)(4) of this section. Where a particular consumer and commercial product category accounts for less than 5 percent of the total production volume of a reportable chemical substance, the percentage must not be rounded off to 0 percent. Instead, in such a case, submitters must report the percentage, rounded

off to the closest 1 percent, of the submitter's site's total production volume of the reportable chemical substance associated with the particular consumer and commercial product category.

(6) *Site-limited*. An indication of whether the PFAS was site-limited.

(7) *Volume recycled*. The total volume (in pounds) of each PFAS recycled on-site.

(e) *Byproduct reporting*. A description of the byproducts resulting from the manufacture, processing, use, or disposal of each PFAS.

(1) *Byproduct identification*. For each byproduct produced from the manufacture, processing, use, or disposal of a PFAS, the submitter will identify the byproduct by its specific, currently correct CA Index name as used to list the chemical substance on the TSCA Inventory and the correct corresponding CASRN. A submitter under this part may use a known EPA-designated TSCA Accession Number for a chemical substance in lieu of a CASRN when a CASRN is not known to or reasonably ascertainable by the submitter. Submitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory will need to report the chemical substance using a TSCA Accession Number.

(i) In addition to reporting the number itself, submitters must specify the type of number they are reporting by selecting from among the codes in Table 1 of paragraph (b)(1)(i).

(ii) If the specific chemical identity of the byproduct is unknown to the submitter, the submitter may provide a description of the chemical substance.

(iii) An indication of which specific PFAS activity(ies) (i.e., manufacture, process, use, or disposal) manufactured the byproduct.

(2) *Releases*. An indication of whether the byproduct is released to the environment, and if so, the environmental medium (a) to which it is released (i.e., air, water, land).

(3) *Volume*. For each year, the byproduct volume (in pounds) released to the environment.

(f) *Environmental and health effects*. All existing information concerning the

environmental and health effects of such substance or mixture containing a chemical substance in the manufacturer's possession or control. The scope of this information shall not be limited to studies conducted or published since 2011.

(1) *Organization for Economic Cooperation and Development (OECD) Harmonized Templates.* For each published study report, the submitter shall complete an OECD Harmonized Templates for Reporting Chemical Test Summaries and submit the accompanying study reports and supporting information. This can be accomplished by using the freely available IUCLID software.

(2) *Human health data – preliminary studies.* Submitters shall also provide any additional human health data not in study reports, including but not limited to any preliminary studies, informal test results in workers, or inhalation studies.

(3) *Analytical tests.* Submitters shall also provide the names of any analytical or test methods used to detect or otherwise test for the PFAS.

(g) *Worker exposure data.* The number of individuals exposed to PFAS in their places of employment and the duration of such exposure.

(1) *Employment activities.* A narrative description of worker activities involving the PFAS at the manufacturing site, such as bag dumping, sampling, cleaning, or unloading drums.

(2) *Number of workers.* For each worker activity in this paragraph, indicate the number of workers reasonably likely to be exposed. The submitter must select from among the worker ranges listed in Table 7 of this section and report the corresponding code (i.e., W1 through W8).

Table 7—Codes for Reporting Number of Workers Reasonably Likely to be Exposed

Code	Range
W1	Fewer than 10 workers.
W2	At least 10 but fewer than 25 workers.
W3	At least 25 but fewer than 50 workers.
W4	At least 50 but fewer than 100 workers.
W5	At least 100 but fewer than 500 workers.
W6	At least 500 but fewer than 1,000 workers.

W7	At least 1,000 but fewer than 10,000 workers.
W8	At least 10,000 workers.

(3) *Exposure scenarios.* For each worker activity in this paragraph, the maximum duration of exposure for any worker at the manufacturing site, for each of the following scenarios:

(i) The daily exposure duration (in hours per day) in the case of the worker with greatest annual exposure frequency (i.e., the worker exposed the most days per year), and

(ii) The annual exposure frequency (in days per year) in the case of the worker with greatest daily exposure duration (i.e., the worker exposed for the most hours per day during the year).

(4) *Exposure by category.* For each combination of industrial processing or use operation, sector, and function category identified in paragraph (c) of this section, the submitter must estimate the number of workers reasonably likely to be exposed to each PFAS. For each combination associated with each chemical substance, the submitter must select from among the worker ranges listed in Table 7 of this section and report the corresponding code (i.e., W1 through W8).

(5) *Duration of exposure industrial use.* For each PFAS, the maximum duration of exposure for any worker for each combination of industrial processing or use operation, sector, and function category, for each of the following scenarios:

(i) The daily exposure duration (in hours per day) in the case of the worker with the greatest annual exposure frequency (i.e., the worker exposed the most days per year), and

(ii) The annual exposure frequency (in days per year) in the case of the worker with the greatest daily exposure duration (i.e., the worker exposed for the most hours per day during the year).

(6) *Commercial workers.* Where the PFAS is used in a commercial product, the submitter

must estimate the number of commercial workers reasonably likely to be exposed to each reportable chemical substance. For each commercial use associated with each substance, the submitter must select from among the worker ranges listed in Table 7 of this section and report the corresponding code (i.e., W1 through W8).

(7) *Duration of exposure commercial use.* For each PFAS, the maximum duration of exposure for any worker for each commercial use, for each of the following scenarios:

(i) The daily exposure duration (in hours per day) in the case of the worker with greatest annual exposure frequency (i.e., the worker exposed the most days per year), and

(ii) The annual exposure frequency (in days per year) in the case of the worker with greatest daily exposure duration (i.e., the worker exposed for the most hours per day during the year).

(h) *Disposal data.* During the years in which the PFAS was manufactured, the manners or methods of its disposal, and any changes to the disposal methods or processes.

(1) *Categories of disposal methods.* Description of disposal processes or methods, using the appropriate codes in Table 8 of this section, and additional descriptions as needed.

Table 8—Codes for Reporting Disposal Methods

Code	Disposal Method
D1	On-site land disposal: RCRA Class C landfill (hazardous)
D2	On-site land disposal: other landfill
D3	Other on-site land disposal
D4	On-site underground injection (UIC)
D5	Off-site land disposal: RCRA Class C landfill (hazardous)
D6	Off-site land disposal: other landfill
D7	On-site incineration
D8	Off-site incineration
D9	Publicly owned treatment works (POTW)
D10	Other off-site waste transfer
D11	Release to surface water
D12	Release to air (stack emissions)
D13	Release to air (fugitive emissions)
D99	Other

(2) *Disposal processes.* Describe any changes to the disposal process(es) or method(s)

indicated in paragraph (h)(1) for any PFAS manufactured since 2011.

(3) *Disposal volume*. Indicate total volume of the PFAS that was released to each environmental medium in each year since 2011: land, water, and air.

(4) *Incineration volume*. Indicate total volume of the PFAS that was incinerated on-site in each year since 2011. If incineration occurred, indicate the temperature (in degrees Celsius) at which the PFAS was incinerated. If incineration occurred at multiple temperatures, indicate the minimum temperature (in degrees Celsius) at which the PFAS was incinerated.

§ 705.18 Article importer and R&D substance reporting options.

For the one-time submission, certain manufacturers have the option to use a streamlined reporting form if they do not know nor can reasonably ascertain information requested under § 705.15, beyond what is listed in this subpart. Paragraph (a) lists the information which a manufacturer who has imported a PFAS within an article must report to the extent they know or can reasonably ascertain. Paragraph (b) lists the information that manufacturers of PFAS that are solely R&D substances manufactured in volumes no greater than 10 kilograms per year must report to the extent they know or can reasonably ascertain.

(a) *Article reporting*. Any importer of an article which contains a chemical substance that is a PFAS and who meets the reporting requirements described in § 705.10 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. The information requested on the streamlined reporting form for article importers includes:

(1) *Company and plant site information*. All company and plant site information requested under § 705.15(a) shall be reported.

(2) *Chemical-specific information.* The following chemical-specific information must be reported for each chemical substance that is a PFAS imported in an article, for each year since January 1, 2011, in which that PFAS was imported within an article.

(i) The common or trade name, the chemical identity, and, except for chemical substances that are Class 1 substances on the Inventory, the representative molecular structure of each PFAS for which such a report is required. Submitters who wish to report chemical substances listed on the confidential portion of the Inventory will need to report the chemical substance using a TSCA Accession Number. If a submitter has a low-volume exemption (LVE) case number for the chemical substance, that number may also be used if a CASRN is not known to or reasonably ascertainable by the submitter. In addition to reporting the number itself, submitters must specify the type of number they are reporting by selecting from among the codes in Table 1 of § 705.15(b)(1)(ii).

(ii) If the specific chemical identity of the PFAS imported in an article is not known to or reasonably ascertainable to the submitter (e.g., if the chemical identity is claimed as confidential business information by the submitter's supplier, or if the submitter knows they have a PFAS but is unable to ascertain its specific chemical identity), the submitter may provide a generic name or description of the PFAS.

(3) *Categories of use.* For each year since January 1, 2011, report the following information on categories of use of each PFAS imported in an article.

(i) *Industrial processing and use information.* A designation indicating the type of industrial processing or use operation(s) at each site that receives a PFAS from the submitter site directly or indirectly (whether the recipient site(s) are controlled by the submitter site or not). For each PFAS that was imported in an article, report the letters which correspond to the appropriate processing or use operation(s) listed in Table 2 of § 705.15(c)(1). A particular designation may need to be reported more than once, to the extent that a submitter reports more than one sector

that applies to a given designation under this paragraph.

(ii) *Industrial activities sector.* A code indicating the sector(s) that best describe the industrial activities associated with each industrial processing or use operation reported under this section. For each PFAS that was imported in an article, report the code that corresponds to the appropriate sector(s) listed in Table 3 of § 705.15(c)(2). A particular sector code may need to be reported more than once, to the extent that a submitter reports more than one function code that applies to a given sector code under this paragraph.

(iii) *Sector specific function categories.* For each sector reported under subparagraph (3)(ii) of this section, the applicable code(s) from Table 4 of § 705.15(c)(3) must be selected to designate the function category(ies) that best represents the specific manner in which the PFAS in the imported article is used.

(iv) *Consumer and commercial use information.* Using the applicable codes listed in Table 5 to § 705.15(c)(4), submitters must designate the consumer and commercial product category(ies) that best describe the consumer and commercial products in which each PFAS that is in an imported article is used (whether the recipient site(s) are controlled by the submitter site or not). If more than 10 codes apply to a PFAS in an imported article, submitters need only report the 10 codes for PFAS that cumulatively represent the largest percentage of the submitter's production volume for that chemical, measured by weight. If none of the listed consumer and commercial product categories accurately describe the consumer and commercial products in which each PFAS is used, the category "Other" may be used, and must include a description of the use.

(v) *Product specific function categories.* For each consumer and commercial product category reported under subparagraph (3)(iv) of this section, the applicable code(s) described in Table 4 under § 705.15(c)(3) must be selected to designate the function category(ies) that best represents the specific manner in which the PFAS in an imported article is used.

(vi) *Consumer or commercial use designation.* Submitters must indicate, for each consumer and commercial product category reported under subparagraph (3)(v) of this section, whether the use is a consumer or a commercial use, or both.

(vii) *In or on consumer products intended for children.* Submitters must determine, within each consumer and commercial product category reported under subparagraph (3)(v) of this section, whether any amount of each reportable chemical substance manufactured (including imported) by the submitter is present in (for example, a plasticizer chemical substance used to make pacifiers) or on (for example, as a component in the paint on a toy) any consumer products intended for use by children age 14 or younger, regardless of the concentration of the chemical substance remaining in or on the product. Submitters must select from the following options: The chemical substance is used in or on any consumer products intended for use by children; the chemical substance is not used in or on any consumer products intended for use by children; or information as to whether the chemical substance is used in or on any consumer products intended for use by children is not known to or reasonably ascertainable by the submitter.

(viii) *Estimated maximum concentration.* For each year where the PFAS in an imported article is used in consumer or commercial products, the submitter must report the estimated typical maximum concentration, measured by weight, of the chemical substance in each consumer and commercial product category reported under subparagraph (3)(v) of this section. For each PFAS in an imported article in each commercial and consumer product category reported under subparagraph (3)(v) of this section, submitters must select from among the ranges of concentrations listed in Table 9 of this paragraph and report the corresponding code (i.e., AM1 through AM5):

Table 9—Codes for Reporting Maximum Concentration of PFAS in an Imported Article

Code	Concentration Range (% weight)
AM1	Less than 0.1% by weight.
AM2	At least 0.1% but less than 1% by weight.

AM3	At least 1% but less than 10% by weight.
AM4	At least 10% but less than 30% by weight.
AM5	At least 30% by weight.

(4) *Imported article production volume.* For each calendar year since January 1, 2011, in which the PFAS was imported in an article, the production volume of the imported article. The imported production volume must be reported to two significant figures of accuracy. The submitter must also provide the unit of measurement of the imported production volume by selecting among the Table 10 of this paragraph. The submitter must also designate, for each PFAS imported in an article, whether the imported PFAS was ever physically present at the reporting site.

Table 10—Codes to Specify Unit of Measurement for the Imported Article Production Volume

Code	Unit of Measurement
LB	Pounds
TN	Tons
QT	Quantity of imported article
O	Other (must specify)

(5) *Additional article data.* The submitter has the option to provide any additional information to EPA that is requested under § 705.15 on the PFAS imported in an article, including supplemental attachments.

(b) *Research and development (R&D).* Any manufacturer of a PFAS R&D substance that was manufactured in volumes no greater than 10 kilograms per year and who meets the reporting requirements described in § 705.10 has the option to submit information to EPA using a streamlined reporting form for each such PFAS, for each year since January 1, 2011, in which the PFAS was manufactured for R&D purposes in volumes no greater than 10 kilograms per year. 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. The information requested on the

streamlined reporting form for R&D manufacturers includes:

(1) *Company and plant site information.* All company and plant site information requested under § 705.15(a) shall be reported.

(2) *Chemical-specific information.* The following chemical-specific information must be reported for each R&D chemical substance that is a PFAS and each mixture containing a chemical substance that is a PFAS and meets the requirements for the reporting option under this paragraph. The information must be reported for each year since January 1, 2011, in which that PFAS was manufactured for R&D purposes in quantities no greater than 10 kilograms per year.

(i) The common or trade name, the chemical identity, and, except for chemical substances that are Class 1 substances on the TSCA Inventory, the representative molecular structure of each PFAS for which such a report is required. Submitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory will need to report the chemical substance using a TSCA Accession Number. If a submitter has a low-volume exemption (LVE) case number for the chemical substance, that number may also be used if a CASRN is not known to or reasonably ascertainable by the submitter. In addition to reporting the number itself, submitters must specify the type of number they are reporting by selecting from among the codes in Table 1 of § 705.15(b)(1)(ii).

(ii) If the specific chemical identity of the PFAS is not known to or reasonably ascertainable to the submitter (e.g., if the chemical identity is claimed as confidential business information by the submitter's supplier, or if the submitter knows they have a PFAS but are unable to ascertain its specific chemical identity), the submitter may provide a generic name or description of the PFAS.

(3) *Production volume.* The submitter must report for each year since January 1, 2011, in which the PFAS was manufactured, the total annual volume (in pounds) of each PFAS domestically manufactured or imported at each site. The total annual domestically manufactured

volume (not including imported volume) and the total annual imported volume must be separately reported. These amounts must be reported to two significant figures of accuracy.

(i) A designation indicating, for each PFAS at each site, whether any imported PFAS is ever physically present at the reporting site.

(ii) [Reserved]

(4) *Additional R&D data*. The submitter has the option to provide any additional information to EPA that is requested under § 705.15 on the PFAS, including supplemental attachments.

§ 705.20 When to report.

All information reported to EPA in response to the requirements of this part must be submitted during the applicable submission period. For all reporters submitting information pursuant to § 705.15 and § 705.18(b) (research and development), the submission period shall begin one year following the effective date of this rule and last for six months: **[INSERT DATE 395 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** through **[INSERT DATE 548 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. For any reporter who is reporting under this part exclusively pursuant to § 705.18(a) (article importers), and is also considered a small manufacturer under the definition at 40 CFR 704.3, the submission period shall begin one year following the effective date of this rule and last for 12 months: **[INSERT DATE 365 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** through **[INSERT DATE 730 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

§ 705.22 Duplicative reporting.

Any person covered in this part may notify EPA through the electronic reporting system in § 705.35 that certain information has already been submitted to EPA, and any such person does not need to re-submit the information. The notification must include the statutory and

regulatory provision under which the information was submitted and in which year it was submitted. This ability is limited to the type of information listed in this section. If the previous submission did not account for all information required to be submitted pursuant to this rule (e.g., due to exemptions inapplicable to this rule), then the person may not rely on that prior submission to satisfy the reporting requirements of this rule.

(a) *Chemical Data Reporting rule.* If a person identified in § 705.10 has already reported certain information in § 705.15 to EPA pursuant to the Chemical Data Reporting rule at 40 CFR Part 711, then duplicative reporting of that information is not required of the years for which the information has already been reported. Such information that may potentially be duplicative under this part is limited to:

(1) *Chemical description.* Physical state of the chemical or mixture containing a chemical substance, pursuant to § 711.15(b)(3)(C)(ix).

(2) *Sector description.* 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).

(3) *Product category.* 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).

(4) *Workers.* 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).

(5) *Volume.* Production volume, both domestically manufactured and imported, an indicator for the imported chemical never physically at site, and the volume directly exported,

pursuant to § 711.15(b)(3)(iii) through (v).

(b) *Greenhouse Gas Reporting rule.* If a person identified in § 705.10 has already reported certain information in § 705.15 to EPA pursuant to the Greenhouse Gas Reporting rule at 40 CFR part 98, then duplicative reporting of that information is not required of the years for which the information has already been reported. Such information that may potentially be duplicative under this part is limited to:

(1) *Imported.* Production volume (imported), pursuant to § 98.416(c)(1) and (2).

(2) *Exported.* Volume directly exported, pursuant to § 98.416(d)(1).

(3) *Incinerated.* Total volume incinerated on-site, pursuant to 40 CFR part 98.

(c) *Toxics Release Inventory reporting rule.* If a person identified in § 705.10 has already reported certain information in § 705.15 to EPA pursuant to the Toxics Release Inventory reporting rule at 40 CFR part 372, then duplicative reporting of that information is not required of the years for which the information has already been reported. Such information that may potentially be duplicative under this part is limited to:

(1) *Recycled.* Total volume recycled on-site, pursuant to § 372.85(b)(16).

(2) *Disposal.* Description of disposal process(es), pursuant to § 372.85(b)(14) and (15).

(3) *Release to land.* Total volume released to land, pursuant to § 372.85(b)(14)(i)(D) and (E).

(4) *Release to water.* Total volume released to water, pursuant to § 372.85(b)(14)(i)(C).

(5) *Release to air.* Total volume released to air, pursuant to § 372.85(b)(14)(i)(A) and (B).

(6) *Incinerated.* Total volume incinerated on-site, pursuant to § 372.85(b)(16).

(d) *TSCA sections 8(d) and 8(e) reporting.* If a person identified in § 705.10 has already reported certain information in § 705.15(f) to EPA, then duplicative reporting of that information is not required of the years for which the information has already been reported. Such

information that may potentially be duplicative under this part is limited to health and safety studies submitted pursuant to TSCA section 8(d), notification of substantial risks pursuant to TSCA section 8(e), or other information concerning environmental and health effects of the PFAS.

(e) *Byproduct reporting.* If a person identified in § 705.10 must report byproducts information pursuant to § 705.15(e), and those byproducts are also PFAS that are reported independently pursuant to this part, then duplicative reporting of the environmental releases as byproducts is not required. Such information that may potentially be duplicative is limited to:

(1) *Incineration.* An indication of whether the byproduct is released to the environment, and if so, the environmental medium (a) to which it is released (i.e., air, water, land), pursuant to § 705.15(e)(2).

(2) *Byproduct volume.* For each year, the byproduct volume (in pounds) released to the environment, pursuant to § 705.15(e)(3).

(f) *Environmental and health effects information.* If a person identified in § 705.10 has already reported the information in § 705.15(f) to EPA, then duplicative reporting of that information is not required, except to the extent required by to § 705.30. The notification required by this provision must also include the EPA office (e.g., EPA region or Headquarters Office) and case number or other identifier for the prior submission.

(g) *Reporting timeframe.* Any person covered in this part must report all information to EPA in § 705.15 for each year since January 1, 2011, in which that person manufactured a chemical substance that is a PFAS or a mixture containing a PFAS. If a person has already reported any of the data elements identified in paragraph (a) of this section, but not for all years since 2011, then that person must submit the required information for the intervening years. If a person has already reported any of the data elements identified in paragraphs (a), (b), or (c) of this section, and the previous submissions did not account for all activities that are reportable

under this rule due to exemptions or thresholds that do not apply to this rule, then that information is not considered duplicative reporting, and the person must submit information for that data element responsive to this rule.

§ 705.25 Recordkeeping requirements.

Each person who is subject to the reporting requirements of this part must retain records that document any information reported to EPA. Relevant records must be retained for a period of 5 years beginning on the last day of the submission period.

§ 705.30 Confidentiality claims.

(a) *Making confidentiality claims.* (1) *Generally.* Any person submitting information under this part may assert a confidentiality claim for that information, except for information described in paragraph (a)(2). All such confidentiality claims must be asserted at the time the information is submitted. Instructions for asserting confidentiality claims are provided in the document identified in § 705.35. Information claimed as confidential business information in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 703 and TSCA section 14.

(2) *Exceptions.* Confidentiality claims cannot be asserted for the following:

(i) Specific chemical identity if the chemical is on the public (non-confidential) TSCA Inventory or reported as non-confidential in an LVE;

(ii) For processing and use data elements required by § 705.15(c)(1) through (7) and § 705.18(a)(3)(i) through (vii);

(iii) When a response is left blank or designated as “not known or reasonably ascertainable;”

(iv) For specific chemical identity by submitters of article importer forms described in § 705.18(a);

(v) For all generic chemical names;

(vi) For any PFAS that are on the public (non-confidential) TSCA Inventory, the chemical's CASRN;

(vii) For the Inventory Accession Numbers for PFAS that are on the confidential TSCA Inventory; or,

(viii) For LVE numbers.

(3) *All existing information concerning environmental and health effects.* (i) Any person submitting a health and safety study, or information from a health and safety study, under this part may only assert a confidentiality claim for information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

(ii) If any information submitted under 705.15(f) is claimed as confidential business information, a person who submits the information must provide EPA, at the time of submission, a sanitized copy for public release, removing only that information that is claimed as confidential business information.

(iii) Any person who has previously submitted information under 705.15(f) and claimed it as confidential business information is required to reassert and re-substantiate the confidential business information claim if they seek to maintain the claim of confidential business information. Such persons are required to submit a revised sanitized copy.

(b) *Unless exempted, all confidentiality claims require substantiation at the time of submission and must be signed and dated by an authorized official.* Confidentiality claims for the following data elements are exempt from this substantiation requirement:

(1) *Volume.* Production volume information required pursuant to § 705.15(d)(1), (5), and (6); § 705.18(a)(4), and § 705.18(b)(3)(i).

(2) *Primary submitter.* Joint submission information from the primary submitter,

consisting of trade name and supplier identification required pursuant to § 705.15(b)(1)(i) and (ii).

(3) *Secondary submitter.* Joint submission information from the secondary submitter, consisting of the percentage of formulation required pursuant to § 705.15(b)(1)(i) and (ii).

(c) *Marking information claimed as confidential business information in confidentiality substantiation documentation.* If any of the information contained in the answers to the questions listed in paragraph (e) of this section is asserted to contain information that itself is considered to be confidential, you must clearly identify the information that is claimed confidential.

(d) *Certification statement for claims.* An authorized official representing a person asserting a claim of confidentiality must certify that the submission complies with the requirements of this part by signing and dating the following certification statement:

“I certify that all claims for confidentiality asserted with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001. I further certify that: (1) I have taken reasonable measures to protect the confidentiality of the information; (2) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law; (3) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and (4) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.”

(e) *Substantiation requirements for all types of confidentiality claims.* For each data element that is claimed as confidential business information, you must submit with your report detailed written answers to the following questions:

(1) *Substantial harm due to release.* Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential business information. How would that harm be *substantial*? Why is the substantial harm to your competitive position *likely* (i.e., probable) to be caused by release of the information rather than just *possible*? If you claimed multiple types of information

to be confidential (e.g., site information, exposure information, environmental release information, etc.), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business. (40 CFR 703.5(b)(3)).

(2) *Precautions to protect confidentiality.* Has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential business information. If the same or similar information was previously reported to EPA as non-confidential (such as in an earlier version of this submission), please explain the circumstances of that prior submission and reasons for believing the information is nonetheless still confidential.

(3) *Disclosure under Federal law or publicly available information.*

(i) Is any of the information claimed as confidential business information required to be publicly disclosed under any other Federal law? If yes, please explain.

(ii) Does any of the information claimed as confidential business information otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; state, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential. If this chemical is patented and the patent reveals the information you are claiming to be confidential business information, please explain your reasons for believing the information is nonetheless still confidential.

(4) *Duration of claims.* Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If yes, please indicate the number of years (between 1-10 years) or the specific date after which the claim is withdrawn.

(5) *Previously disclosed information.* Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance?

If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(f) *Additional requirements for specific chemical identity.* A person may assert a claim of confidentiality for the specific chemical identity of a chemical substance as described in § 705.15(b)(1)(i) and § 705.18(b)(2)(i) of this part only if the identity of that chemical substance is treated as confidential in the Master Inventory File (or as a confidential LVE) as of the time the report is submitted for that chemical substance, if that substance is currently on the Inventory or is an LVE. Any person who asserts a claim of confidentiality for the specific chemical identity under this paragraph must provide a generic chemical name. To assert a claim of confidentiality for the identity of a reportable chemical substance, you must submit with the report detailed written answers to the questions from paragraph (b) of this section and to the following questions.

(1) *Chemical substance in U.S. commerce.* Is this chemical substance publicly known (including by your competitors) to be in U.S. commerce? If yes, please explain why the specific chemical identity should still be afforded confidential status (*e.g.*, the chemical substance is publicly known only as being distributed in commerce for research and development purposes, but no other information about the current commercial distribution of the chemical substance in the United States is publicly available) (40 CFR 703.5(b)(4)). If no, please complete the certification statement:

“I certify that on the date referenced, I searched the Internet for the chemical substance identity (*i.e.*, by both chemical substance name and CASRN). I did not find a reference to this chemical substance and have no knowledge of public information that would indicate that the chemical is being manufactured or imported by anyone for a commercial purpose in the United States. [provide date].”

(2) *Leave manufacturing site.* Does this particular chemical substance leave the site of manufacture (including import) in any form, *e.g.*, as a product, effluent, emission? If yes, please

explain what measures have been taken to guard against the discovery of its identity.

(3) *Chemical identity*. If the chemical substance leaves the site in a form that is available to the public or your competitors, can the chemical identity be readily discovered by analysis of the substance (e.g., product, effluent, emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies? Please explain why or why not.

(4) *Chemical name*. Would disclosure of the specific chemical name release confidential process information? If yes, please explain.

(g) *Joint submissions*. If a primary submitter asks a secondary submitter to provide information directly to EPA in a joint submission under § 705.15(b)(1)(i) and § 705.18(b)(2)(i), only the primary submitter may assert a confidentiality claim for the data elements that it directly submits to EPA. The primary submitter must substantiate those claims that are not exempt under paragraph (b)(2) of this section. The secondary submitter is responsible for asserting all confidentiality claims for the data elements that it submits directly to EPA and for substantiating those claims that are not exempt under paragraph (b)(3) of this section.

(h) *No claim of confidentiality*. Except for the chemical identity on article importer forms submitted under § 705.18(a), information not claimed as confidential business information in accordance with the requirements of this section may be made public (e.g., by publication of specific chemical name and CASRN on the public portion of the TSCA Inventory). EPA will provide advance public notice of specific chemical identities to be added to the public portion of the TSCA Inventory.

§ 705.35 Electronic reporting.

You must use CDX to complete and submit the reporting form required under this part. Submissions may only be made as set forth in this paragraph. Submissions must be sent electronically to EPA via CDX. The information submitted and all attachments (unless the attachment appears in scientific literature) must be in English. All information must be true and

correct. Access the PFAS 8(a)(7) reporting tool and instructions, as follows:

(1) *By website.* Access the PFAS 8(a)(7) reporting tool via the CDX homepage at <https://cdx.epa.gov/> and follow the appropriate links.

(2) *By phone or e-mail.* Contact the EPA TSCA Hotline at (202) 554-1404 or TSCA-Hotline@epa.gov.

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